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Improved Scoring System to Assess Adult Donors For Cadaver Renal Transplantation

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We previously proposed a quantitative approach to assess donor organs for cadaver renal transplantation. To improve on our original scoring system, we studied 34 324 patients who received cadaver renal transplants from adult donors between 1994 and 1999 and were reported to the UNOS Scientific Renal Transplant Registry. A scoring system was developed from five donor variables (age, 0–25 points; history of hypertension, 0–4; creatinine clearance before procurement, 0–4; cause of death, 0–3; HLA mismatch, 0–3) that showed a significant correlation with renal function and long-term graft survival. Cadaver kidneys were stratified by cumulative donor score: grade A, 0–9 points; grade B, 10–19; grade C, 20–29; and grade D, 30–39. The influence of donor score on renal function and graft survival was most severe above 20 points, designated 'marginal' kidneys. In summary, a donor scoring system developed from a large population database was useful in predicting outcome after cadaver renal transplantation. The improved system provides a quantitative approach to evaluation of marginal kidneys and may improve allocation of these organs in cadaver renal transplantation.

Key words: Graft survival, marginal donor, organ allocation, renal function

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Introduction

The number of patients with end-stage renal disease waiting for a cadaver kidney transplant continues to grow (1). To address this critical shortage of donor kidneys, the use of cadaver kidneys from suboptimal donors, referred to as expanded criteria donors or 'marginal' donors (2,3), has been adopted at some transplant centers. The current study is an attempt to develop a quantitative approach to better assess the quality of kidneys from adult marginal donors at the time of procurement.

In a preliminary study using data from two centers, we showed that a scoring system of seven risk factors for delayed graft function provided a better estimation of early renal function and need for hemodialysis after cadaver renal transplantation than any single variable (4). In the current study, we extend that analysis to a large population database with long-term follow up. The primary goal of this study was to devise an improved scoring system based on donor information available at the time of procurement with predictive ability to estimate graft function and graft survival after cadaver renal transplantation. A second goal of the new study was to simplify the scoring system (i.e. reduce the number of donor variables) without adversely affecting its predictive ability. The improved scoring system was developed from data collected 6 months after cadaver transplantation and was then applied to renal function data obtained 12 months after transplantation. A direct correlation was observed between donor score and long-term graft survival data, suggesting that the improved scoring system may better assist transplant physicians and their patients in the allocation of cadaver kidneys, including those from adult marginal donors.

Methods

Study populations

We studied the records of 34 324 patients who received cadaver renal transplants from adult (18 years or older) donors between April 1, 1994, and December 31, 1999. All cases were reported to the United Network for Organ Sharing (UNOS) Scientific Renal Transplant Registry. Donor and recipient information used in the analysis is summarized in Table 1. Small recipients (younger than 12 years, less than 30 kg) were excluded because estimation of creatinine clearance (CrCl) was not considered to be reliable in these individuals.

Determination of renal function (donor and recipient)

CrCl, estimated by the Cockcroft-Gault method (5), was used as the measure of renal function in all donors and recipients. On the basis of findings from our preliminary study (4), we used terminal serum creatinine (final value obtained before procurement) in the calculation of donor CrCl. Recipient CrCl was determined from serum creatinine and recipient weight values obtained 6 months (all patients) and 12 months (32 901 patients) after cadaver renal transplantation.

Development of the scoring system

A scoring system was developed from combined univariate and multivariate analyses of donor and recipient variables. Donor variables included age,

Table 1: Variables used for analysis

Donor variables
Age
Cause of death
CMV antibody status
History of diabetes mellitus
History of hypertension
HLA type
Duration of cold ischemia
Ethnicity
Creatinine clearance[1]
Recipient variables
CMV antibody status
Graft survival
HLA type
Creatinine clearance[2]

CMV = cytomegalovirus.
[1]By Cockcroft-Gault equation from age, sex, weight, and final serum creatinine before procurement.
[2]By Cockcroft-Gault equation from age, sex, weight, and serum creatinine 6 and 12 months after transplantation.

cause of death, cold ischemia, cytomegalovirus antibody status (CMV status, positive or negative), history of diabetes, history of hypertension, HLA tissue typing (HLA type), ethnicity, serum creatinine, sex, and weight. Cause of donor death was stratified into four categories: ischemic or hemorrhagic cerebrovascular accident, traumatic brain injury, anoxic brain death, and all other causes. Donor history of hypertension was classified into five categories: none, 0–5 years of duration, 6–10 years of duration, more than 10 years of duration, and unknown duration. For each transplant, the HLA types of the donor and recipient were compared on the basis of six antigens at A, B, Dr loci to identify donor-recipient mismatches.

The primary end point used to develop the scoring system was renal recipient CrCl at 6 months after transplantation. Five variables that showed the strongest correlation with CrCl at 6 months by univariate analysis and multivariate analysis were used to develop the scoring system. The scoring system was then applied to two new sets of data: recipient CrCl at 12 months and long-term graft survival.

Statistical analysis

Univariate and multivariate assessment of variables was performed in a fashion similar to the analysis used to develop our original scoring system (4). Variables that provided a substantial incremental improvement (delta R^2 value >0.0010) in the ability of the multivariate model to predict CrCl at 6 months were used in the scoring system. Graft survival was determined by the Kaplan–Meier method and significance was assessed by the log-rank test. *P*-values ≤ 0.05 were considered statistically significant for all comparisons.

Results

Univariate analysis

By univariate analysis, a highly significant association ($p < 0.001$) was observed between all nine donor variables considered for analysis and recipient CrCl 6 months after transplantation (Table 2). Of these nine variables, the influence of donor age on recipient renal function was most significant. The steady decline in renal function averaged more than 6 mL/min per decade of donor age (Figure 1). Average recipient CrCl fell below 60 mL/min in the 30- to 35-year-old group and below 40 mL/min in the 60- to 65-year-old group. As expected, recipient CrCl was lowest from donors older than 70 years, averaging less than 35 mL/min.

More than 21% of cadaver donors had a history of hypertension, which correlated negatively with renal function 6 months after transplantation (Figure 2). A positive correlation was observed between CrCl of the donor before procurement and CrCl of the recipient 6 months after transplantation (Figure 3).

A beneficial effect was observed between HLA matching and recipient CrCl at 6 months (Figure 4). Cadaver kidneys with no antigen mismatches (more than 14% of total) had the highest CrCl 6 months after transplantation, exceeding the CrCl of cadaver kidneys with six antigen mismatches by more than 5 mL/min (0.08 mL/s) on average.

Cerebrovascular and traumatic causes of death accounted for nearly 90% of donor deaths in this study population. Six months after transplantation, CrCl was significantly ($p < 0.001$) lower in recipients of kidneys from donors with a cerebrovascular cause of death than in kidneys from donors with other causes of death (Figure 5).

Duration of cold ischemia had a detrimental effect on CrCl 6 months after transplantation. When compared with

Table 2: Association between donor variables and recipient creatinine clearance at 6 months

Donor variable	p-value by univariate analysis	p-value by multivariate analysis	Delta R^2 [1]
Age	<0.001	<0.001	0.0950
Creatinine clearance	<0.001	<0.001	0.0044
History of hypertension	<0.001	<0.001	0.0027
HLA mismatch	<0.001	<0.001	0.0019
Cause of death	<0.001	<0.001	0.0013
Duration of cold ischemia	<0.001	<0.001	0.0009
Ethnicity	<0.001	<0.001	0.0003
CMV antibody status	<0.001	0.019	0.0002
History of diabetes mellitus	<0.001	0.022	0.0001

CMV = cytomegalovirus.
[1]Improvement in R^2 by adding donor variable to linear regression model.

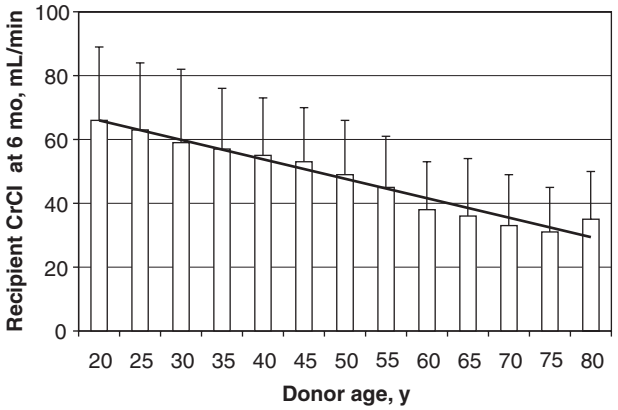

Figure 1: Influence of donor age on recipient creatinine clearance (CrCl) 6 months after cadaver renal transplantation. Mean values (± standard deviation) are provided at 5-year intervals. Numbers on *x*-axis represent lower limit of age range. The linear regression curve-fit of mean values intercepts the *y*-axis at 69.0 mL/min, corresponding to the expected CrCl in a recipient of a kidney from an ideal cadaver donor. To convert values for creatinine clearance to milliliters per second, multiply by 0.01667.

kidneys with less than 12 h of cold ischemia, in which CrCl was 56.6 ± 25.8 mL/min (0.94 ± 0.43 mL/s) (n = 3538), kidneys with longer cold ischemia had progressively lower CrCl: 12–24 h of cold ischemia, 55.2 ± 26.0 mL/min (0.92 ± 0.43 mL/s) (n = 20 195; $p < 0.0055$); 24–36 h, 53.2 ± 25.9 mL/min (0.89 ± 0.43 mL/s) (n = 9370; $p < 0.001$); and more than 36 h, 50.4 ± 25.8 mL/min (0.84 ± 0.43 mL/s) (n = 1221; $p < 0.001$).

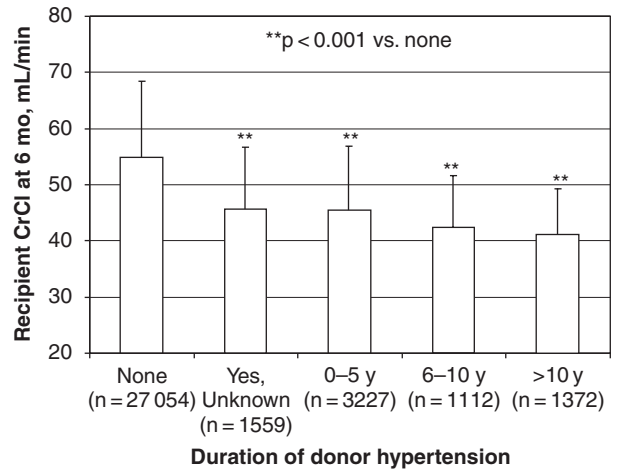

Figure 2: Duration of donor hypertension adversely affects recipient creatinine clearance (CrCl) 6 months after cadaver renal transplantation. The difference in renal function between kidneys from nonhypertensive donors and those with any history of hypertension was significant in all cases ($p < 0.05$). To convert values for creatinine clearance to milliliters per second, multiply by 0.01667.

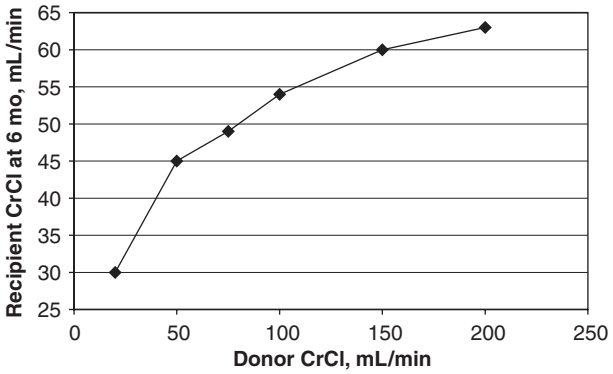

Figure 3: Direct correlation exists between donor renal function and recipient creatinine clearance (CrCl) 6 months after cadaver renal transplantation. Donor CrCl was estimated from terminal Cr before procurement. Average recipient CrCl per interval of donor CrCl (◆).

History of donor diabetes mellitus also adversely influenced CrCl at 6 months: no history of diabetes, 54.9 mL/min (0.92 mL/s) (n = 31 900); positive history of diabetes, 48.7 mL/min (0.81 mL/s) (n = 1107; $p < 0.001$); and unknown history of diabetes, 54.8 mL/min (0.91 mL/s) (n = 1317).

Positive CMV antibody status of the donor adversely influenced CrCl at 6 months (54.7 mL/min [0.91 mL/s] vs. 53.3 mL/min [0.89 mL/s]; $p < 0.001$). Approximately 62% of donors were CMV-positive. Recipient CMV antibody status did not significantly influence graft function at 6 months.

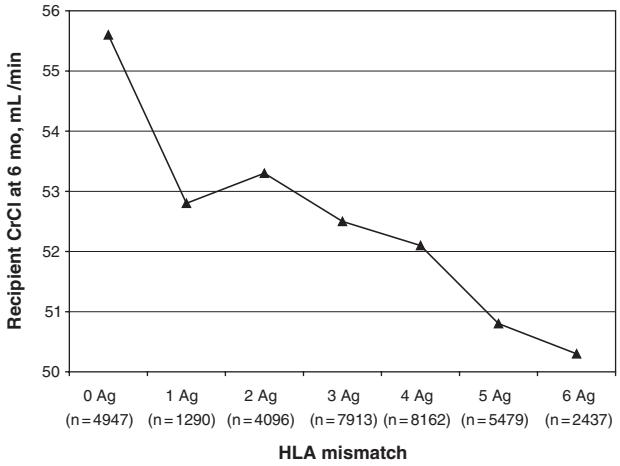

Figure 4: HLA matching improves renal function after cadaver renal transplantation. Average recipient creatinine clearance (CrCl) at 6 months after transplantation for each HLA mismatch group (▲). The number of transplantations performed in each group is indicated along the *x*-axis.

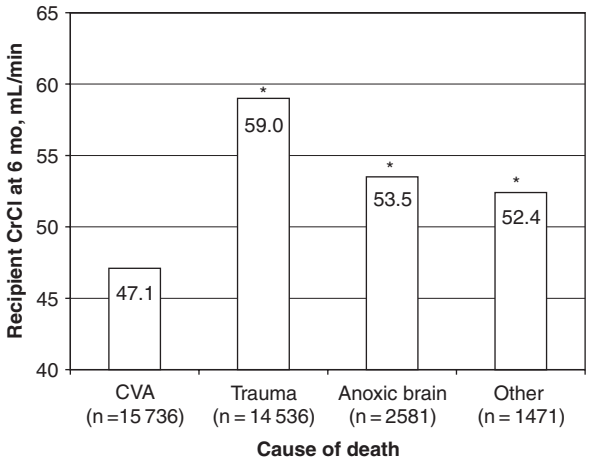

Figure 5: Cause of death influences renal function after cadaver renal transplantation. Values indicate the recipient creatinine clearance (CrCl) at 6 months after cadaver renal transplantation from donors; cause of death is specified along the *x*-axis. *$p < 0.001$ in comparison with donors in the cerebrovascular accident (CVA) group.

The influence of donor ethnicity on CrCl 6 months after transplantation was also significant ($p < 0.001$). Average CrCl at 6 months was significantly higher if donors were Hispanic (55.8 mL/min [0.93 mL/s]; n = 3105) or white (54.8 mL/min [0.91 mL/s]; n = 27 295) compared with donors who were African American (53.1 mL/min [0.89 mL/s]; n = 3316) or Asian (49.2 mL/min [0.82 mL/s]; n = 608).

Multivariate analysis

Results of the multivariate analysis of donor variables on recipient CrCl at 6 months are summarized in Table 2. Nine donor values demonstrated a significant influence on recipient CrCl at 6 months ($p < 0.05$). Seven donor variables (age, CrCl, history of hypertension, HLA mismatch, cause of death, cold ischemia, ethnicity) were highly significant ($p < 0.001$). The relative importance of each donor variable on recipient CrCl at 6 months was estimated from the R^2 value of the stepwise linear regression (Table 2). According to this method, donor age had the strongest independent influence on recipient CrCl at 6 months (delta $R^2 = 0.0950$). Four other donor variables provided substantial improvement (delta R^2 values > 0.0010) in the ability of the model to predict CrCl at 6 months.

Donor scorecard

A donor scoring system summarized in Table 3 was developed from the results of the univariate and multivariate analyses of 6-month CrCl data. The five donor variables utilized in this scoring system were highly significant by both univariate and multivariate analysis ($p < 0.001$) and achieved delta R^2 values > 0.0010 by stepwise linear regression analysis. Although duration of cold ischemia and ethnicity were also highly significant by univariate and multivariate analysis, these variables contributed little to the ability of the multivariate model to predict CrCl 6 months after transplantation (delta $R^2 < 0.0010$). Donor CMV status and donor diabetes were omitted from the donor scoring system for similar reasons. The decision to drop cold ischemia from the scoring system was reinforced by the fact that this information would not be available at the time of donor procurement.

Table 3: System for scoring adult donors in cadaver renal transplantation

Variable	Score
Age, y	
< 30	0
30–39	5
40–49	10
50–59	15
60–69	20
≥ 70	25
History of hypertension	
None	0
Yes; duration unknown	2
≤ 5 y	2
6–10 y	3
> 10 y	4
Creatinine clearance, mL/min[1]	
≥ 100	0
75–99	2
50–74	3
< 50	4
HLA mismatch, no. of antigens	
0	0
1–2	1
3–4	2
5–6	3
Cause of death	
Non-CVA	0
CVA	3
Total points, range	0–39

CVA = cerebrovascular accident, including ischemic and hemorrhagic types.
[1]To convert values to mL/s, multiply by 0.01667.

A total of 39 points were distributed among the five variables based on the results of the univariate and multivariate analyses (Table 3). The maximum number of points allocated to each variable (donor age, 25 points; history of hypertension, 4 points; donor CrCl, 4 points; HLA mismatch, 3 points; cause of death, 3 points) was proportional to its contribution (i.e. coefficient) in the linear regression equation of the multivariate analysis. Points were then portioned within each variable based on results of the univariate analysis. In the case of donor age, points were distributed uniformly (5 points to each decade of donor age beginning at age 30 to a maximum of 25 points at age 70) based on the linear decline in recipient CrCl at 6 months observed in Figure 1. Donors with 0–5 years of hypertension and donors with hypertension of unknown

duration provided kidneys with similar CrCl 6 months after transplantation (Figure 2) and therefore were both allocated 2 points in the scoring system. Donors with a longer duration of hypertension received a greater number of points (6–10 years, 3 points; > 10 years, 4 points). The allocation of points for donor CrCl was based on the results shown in Figure 3. Four points were given to donors with a CrCl less than 50 mL/min (0.83 mL/s) at procurement. Point allocation decreased uniformly as donor CrCl increased at intervals of 25 mL/min (0.42 mL/s) above 50 mL/min (0.83 mL/s). Donors with CrCl greater than 100 mL/min received no points in the scoring system. HLA match was divided into three groups based on data in Figure 4, with no points allocated to zero antigen-mismatched kidneys. Kidneys from donors with a cerebrovascular cause of death were allotted the maximum of 3 points because this group was significantly lower than all other causes of death (Figure 5).

Renal function at 12 months

The scoring system was applied to renal function data obtained 12 months after cadaveric transplantation ($n = 32\,901$) (Table 4). On the basis of total score, a grade was assigned to each kidney (A, 0–9 points; B, 10–19 points; C, 20–29 points; D, 30–39 points). Donor score and grade of kidney showed an inverse correlation with renal function 12 months after cadaver renal transplantation. Twelve months after cadaver renal transplantation, renal function was poor (CrCl < 20 mL/min [0.33 mL/s]) in only 9% of grade A kidneys but in 27% of grade D kidneys. In contrast, renal function was excellent (CrCl > 60 mL/min [1.00 mL/s]) in 53% of grade A kidneys but in only 8% of grade D kidneys. The negative influence of donor score on renal function was most apparent above 20 points and included both grade C and grade D kidneys. These data suggested a cutoff of 20 points between marginal and nonmarginal kidneys.

The adverse effect of increasing donor score was balanced by a beneficial effect of short cold ischemia in group C marginal kidneys. For example, average CrCl of grade C kidneys 12 months after transplantation was highest if cold ischemia was < 12 h (44.1 mL/min) compared with 12–24 h (42.7 mL/min; $p = 0.07$) and > 24 h (41.7 mL/min; $p < 0.001$). No benefit of shortened cold ischemia was observed with grade D kidneys based on CrCl at 12 months: < 12 h, 34.3 mL/min; 12–24 h, 33.7 mL/min ($p = 0.79$); > 24 h, 33.5 mL/min ($p = 0.72$).

Graft survival

Graft survival after cadaver renal transplantation was determined for all recipients of grade A to D kidneys (Figure 6). Donor score had a significant ($p < 0.001$) influence on graft survival during 6 years following cadaver renal transplantation. The survival of grade A and grade B kidneys was slightly greater than and slightly less than 80%, respectively. In contrast, 6-year graft survival was less than 70% for both grade C and grade D kidneys. These data support a cutoff of ≥ 20 points for the definition of marginal organs.

Subgroup analysis of 6-year graft survival in younger (< 60 years) and older (≥ 60 years) recipients also supported a cutoff of ≥ 20 points for the definition of marginal organs. The following comparisons were highly significant ($p < 0.001$): 80.2% (< 20 points, < 60 years) vs. 68.8% (≥ 20 points, < 60 years); 81.5% (< 20 points, ≥ 60 years) vs. 69.5% (≥ 20 points, ≥ 60 years). The difference in graft survival between younger and older recipients of nonmarginal kidneys was significant (80.2% vs. 81.5%; $p = 0.047$) and favored the older recipient group. No difference existed in the comparison of graft survival between younger and older recipients of marginal kidneys.

Discussion

We report a scoring system based on five donor variables available at the time of organ procurement that demonstrated a close correlation with both CrCl at 12 months and graft survival at 6 years after cadaver renal transplantation. The five variables were selected from a list of nine established risk factors for poor outcome after transplantation. The findings of the current analysis are similar to the findings of an earlier pilot study (4). However, we believe

Table 4: Renal function in 32 901 patients 12 months after cadaver renal transplantation

Kidney grade	Points	Patients, no.	Mean CrCl, mL/min[1]	Patients with renal function[2], no. (%)			
				Excellent	Good	Fair	Poor
A	0–9	12 683	61.0	6 575 (52)	3 734 (29)	1 258 (10)	1 116 (9)
B	10–19	11 005	51.8	3 931 (36)	3 950 (36)	1 691 (15)	1 433 (13)
C	20–29	8 065	42.6	1 605 (20)	2 925 (36)	2 041 (25)	1 494 (19)
D	30–39	1 148	33.7	95 (8)	337 (29)	404 (35)	312 (27)

CrCl = creatinine clearance.
[1]To convert values to mL/s, multiply by 0.01667.
[2]Based on CrCl, mL/min; excellent, > 60; good, 40–60; fair, 20–40; poor, < 20.

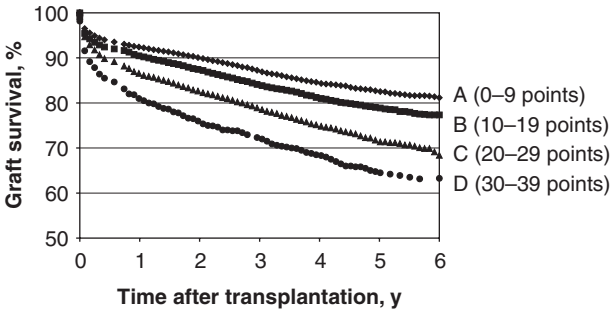

Figure 6: Grade of cadaver kidney determined by donor score (value in parentheses) significantly influenced graft survival after transplantation ($p < 0.001$). The greatest difference in graft survival at 6 years was observed between grade B (10–19 points) and grade C (20–29 points), suggesting a cutoff for 'marginal' kidneys of approximately 20 points according to this scoring system.

that the new scoring system is a significant improvement on our previously reported system for multiple reasons. First, the new analysis is more reliable because it was conducted on a large population database encompassing all cadaver kidney transplants in the United States over a 5-year interval, whereas the pilot study included 250 transplants at two centers. Second, the new system is based on end points of long-term graft survival and recipient CrCl 12 months after transplantation compared with 30-day end points in the pilot study. Third, the new scoring system is based on a 39-point scoring system compared with only 32 points in the pilot study. By doing so, the definition of a marginal kidney has been expanded to differentiate moderate (grade C, 20–29 points) from severe (grade D, 30–39 points). This differentiation has significance. For example, the new scoring system showed that grade C kidneys benefited from short cold ischemia, but the average grade D kidney did not. The new scoring system also has been simplified by decreasing the number of variables from seven to five.

An important difference between the original scoring system and the new improved scoring system is that HLA mismatch has been included as one of the five variables of the improved scoring system. HLA mismatch was not a significant predictor of outcome in our preliminary study. The difference in HLA findings between our two studies may be explained by longer follow up in the current study. This explanation suggests a time-dependent process, such as chronic rejection, that may be accounted for by including HLA matching in the new scoring system (6,7).

Our analysis of UNOS renal function and graft survival data suggests a cutoff for marginal donors of 20 points, the division between grade B and grade C kidneys. On the basis of this cutoff, approximately 25% of cadaver kidneys studied were procured from marginal donors. It follows that marginal donors would include all donors $\geq$ 60 years old, those donors 50–59 years old with at least 5 points from other categories, and those 40–49 years old with at least 10 points from other categories. Adult donors younger than 40 years would always be nonmarginal (grade A or grade B) according to our definition.

We believe that a donor scoring system could assist in expediting the allocation of marginal organs. Such a policy was recently proposed at a consensus meeting sponsored by the American Society of Transplantation and American Society of Transplant Surgeons on March 28 and 29, 2001, in Crystal City, Virginia (8). That group recommended that kidneys from expanded criteria donors be allocated to a separate local list. A similar policy is already in place in New England.

On the basis of these recommendations, a definition of expanded criteria (i.e. marginal) kidney donor and a targeted allocation policy for kidneys from these donors were approved by the UNOS board as of November 2001. The UNOS definition includes donors $\geq$ 60 years old and 50–59-year-old donors with at least two of the following risk factors: cerebrovascular accident as cause of death, any history of hypertension, and procurement serum creatinine $>$ 1.5 mg/dL. These risk factors were identified by an independent analysis (i.e. Cox regression model) of UNOS data prepared by the Scientific Registry of Transplant Recipients. Time to graft failure was the dependent variable in their model, and a relative risk of graft failure greater than 1.7 was used to identify expanded criteria donors.

When our improved donor scoring system is applied to donors meeting the UNOS definition, all categories of expanded criteria kidney donors receive a score of 19 points or greater. Therefore, our definition of marginal kidney donor is highly compatible with the definition of expanded criteria kidney donor recently approved by UNOS. Along with being closely compatible with the new UNOS definition, our new scoring system has the advantage of being able to quantify the risk of expanded criteria donors: grade C (20–29 points) vs. grade D (30–39 points). This differentiation has significance. For example, the new scoring system showed that grade C kidneys benefited from short cold ischemia although the average grade D kidney did not. We support the recent decision by the UNOS board to adopt a proactive approach to the allocation of kidneys from expanded criteria donors. In addition, we suggest that a quantitative assessment, such as our improved donor scoring system, be considered in this approach.

In summary, we have developed a scoring system that can be used to grade kidneys based on the likelihood of success following cadaver renal transplantation. We believe that this system is reliable and practical because it was developed from a national database and uses information available at the time of organ retrieval. We hope

that our scoring system is used along with the new UNOS guidelines to improve allocation of kidneys from expanded criteria donors. Although the use of kidneys from these donors will always incur some increased risk of graft dysfunction and failure, we believe that a quantitative approach to assessing these kidneys is justified.

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