Deceased-Donor Characteristics and the Survival Benefit of Kidney Transplantation

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Kidney transplantation is the preferred therapy for most patients with end-stage renal disease (ESRD) and is superior to dialysis in terms of long-term mortality risk.1,2 As posttransplantation results have improved and the number of patients with ESRD has increased, the pool of deceased donor renal transplant candidates has increased dramatically.3,4 Living-donor transplantation has increased, but the number of deceased donors has increased only modestly.5 Recent increases in kidneys from deceased donors have been principally from older donors or those with other attributes associated with an increased risk of graft failure.6

In 2002, the term expanded criteria donor (ECD) was codified to be deceased donors aged 60 years or older and those aged 50 to 59 years with at least 2 of the following characteristics: history of hypertension, serum creatinine level >1.5 mg/dL [132.6 µmol/L], and cerebrovascular cause of death.5 The risk of graft failure after an ECD kidney transplant is 70% higher than after a non-ECD transplant.6 About 17% of deceased-donor transplants in the United States now use ECD kidneys.4

Definition of the ECD kidney led to changes in allocation policy for deceased-donor kidneys in the United States starting in November 2002.7 On entering the waiting list, candidates must now state whether they will accept offers of ECD kidneys. Such organs are offered only to these candidates.

Context Transplantation using kidneys from deceased donors who meet the expanded criteria donor (ECD) definition (age ≥60 years or 50 to 59 years with at least 2 of the following: history of hypertension, serum creatinine level >1.5 mg/dL [132.6 µmol/L], and cerebrovascular cause of death) is associated with 70% higher risk of graft failure compared with non-ECD transplants. However, if ECD transplants offer improved overall patient survival, inferior graft outcome may represent an acceptable trade-off.

Objective To compare mortality after ECD kidney transplantation vs that in a combined standard-therapy group of non-ECD recipients and those still receiving dialysis.


Main Outcome Measure Long-term (3-year) relative risk of mortality for ECD kidney recipients vs those receiving standard therapy, estimated using time-dependent Cox regression models.

Results By end of follow-up, 7,790 ECD kidney transplants were performed. Because of excess ECD recipient mortality in the perioperative period, cumulative survival did not equal that of standard-therapy patients until 3.5 years posttransplantation. Long-term relative mortality risk was 17% lower for ECD recipients (relative risk, 0.83; 95% confidence interval, 0.77-0.90; P<.001). Subgroups with significant ECD survival benefit included patients older than 40 years, both sexes, non-Hispanics, all races, unsensitized patients, and those with diabetes or hypertension. In organ procurement organizations (OPOs) with long median waiting times (>1,350 days), ECD recipients had a 27% lower risk of death (relative risk, 0.73; 95% confidence interval, 0.64-0.83; P<.001). In areas with shorter waiting times, only recipients with diabetes demonstrated an ECD survival benefit.

Conclusions ECD kidney transplants should be offered principally to candidates older than 40 years in OPOs with long waiting times. In OPOs with shorter waiting times, in which non-ECD kidney transplant availability is higher, candidates should be counseled that ECD survival benefit is observed only for patients with diabetes.

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METHODS
Sources of Data

The study used Scientific Registry of Transplant Recipients data for all wait-listed candidates and transplant recipients in the United States, supplemented with vital status information from the Social Security Death Master File and information on patients receiving dialysis available from the Centers for Medicare and Medicaid Services. From January 1, 1995, through December 31, 2002, 144,049 patients with ESRD were placed on the waiting list for deceased-donor kidneys. Candidates were excluded if they previously received a kidney transplant (n = 18,816), were wait-listed for another organ (n = 5057), had not begun dialysis by December 31, 2002 (n = 3828), or underwent transplantation prior to initiation of dialysis (n = 7221). The resulting cohort included 109,127 patients. Among these candidates, 7790 received an ECD transplant, 41,052 received a non-ECD deceased-donor transplant, 15,203 received a living-donor transplant, and 45,082 received no transplant by July 31, 2004. The study was approved by the Health Resources and Services Administration, US Department of Health and Human Services, which has determined that it satisfies the criteria for the institutional review board exemption described in the “Public Benefit and Service Program” provisions of 45 CFR 46.101(b)(5) and Health Resources and Services Administration Circular 03. Race and ethnicity data were reported by the individual transplant centers to the Organ Procurement and Transplantation Network, using classifications determined by the network. Race and ethnicity were assessed in this study as part of an ongoing effort to ensure equitable access to transplantation for all patients, regardless of background.

Analytical Methods

Time to death was modeled using time-dependent nonproportional Cox regression models. Candidates entered the study on the date of kidney waiting-list registration or the date of first dialysis therapy, whichever came later. A preliminary model compared mortality for non-ECD and ECD recipients separately with wait-listed candidates (ie, those not receiving transplants). The main survival benefit model compared the mortality risk associated with ECD transplants with that of wait-listed candidates who did not receive ECD kidney transplants (ie, standard therapy). Follow-up survival time at risk was censored at the time of living-donor transplantation, wait-listing for another organ, or end of study (July 31, 2004). Since non-ECD kidneys may be received by wait-listed candidates, the effect of non-ECD transplantation on mortality of wait-listed candidates was accounted for in the calculation of mortality risk in the standard-therapy group by not censoring follow-up time at risk in the event of non-ECD kidney transplantation. This time-dependent model is the most clinically relevant construct for the calculation of the survival benefit of an ECD transplant. In other words, all patients contributed data for time at risk (and death, if it occurred) to the standard-therapy group starting at study entry and to the ECD transplant group starting at the time of ECD transplantation. This “switch” constituted the time-dependent ECD transplant covariate in the model. Patients who received a non-ECD transplant remained in the standard-therapy group.

Covariates used for model adjustment included candidate age, sex, race, ethnicity, blood type, ESRD cause, panel reactive antibody values, dialysis modality, comorbid conditions present at wait-listing, wait-listing year, donation service area for the organ procurement organization (OPO) of candidate registration, and time from first dialysis to wait-listing. Time to equal death rates and time to equal cumulative survival probabilities were calculated as in Mauger et al, accounting for time since wait-listing. At the time of transplantation, mortality risk increases (due to the effects of surgery and other factors related to the transplant), remains elevated for a period of time, and then decreases. Time to equal death rates is the number of days between wait-listing and the point at which mortality risks become equal in the ECD and standard-therapy groups. Time to equal mortality is the number of days between wait-listing and the point at which cumulative mortality in the 2 groups becomes equal. Patient mortality after removal from the waiting list and after graft failure in these intention-to-treat analyses was ascertained by linking to data from the Social Security Death Master File.

As an index of the relative availability of non-ECD kidneys, we examined the time to transplantation for each OPO. The tertile of waiting time to transplantation for the OPO of each candidate’s registration (<700 days; 700-1350 days; >1350 days) was assigned as a baseline patient-level covariate in subgroup analyses. These tertiles are consistent with OPO median waiting times reported in the Scientific Registry of Transplant Recipients OPO-Specific Reports.

All statistical analyses were performed using SAS version 9.1 (SAS Institute Inc, Cary, NC).
RESULTS

Patient and Donor Characteristics

Wait-listed candidate and transplant recipient characteristics are shown in Table 1. The percentages of transplant recipients 60 years and older, male, non-Hispanic, those with diabetes or hypertension as cause of ESRD, and those wait-listed at an OPO with a medium or long waiting time were higher in the ECD transplant group than in the non-ECD group. Characteristics of donors of non-ECD and ECD transplants are shown in Table 2. Differences in age and cause of death distributions between ECD and non-ECD donors are consequences of the ECD donor definition.

Unadjusted Death and Graft Failure Rates

There were 28,322 deaths among the 109,127 patients (26%) (458,042 overall patient-years) in the study. Among 45,082 patients who never received a transplant, 19,715 (44%) died before study end (239,976 patient-years). There were 5585 deaths among 41,052 non-ECD deceased-donor transplant recipients (14%) (141,839 patient-years), 1779 among 7790 ECD transplant recipients (23%) (23,534 patient-years), and 1243 among 15,203 living-donor transplant recipients (8%) (52,693 patient-years).

Unadjusted annual death rates for patients on the waiting list, non-ECD transplant recipients, ECD transplant recipients, and living-donor transplant recipients were 8.2%, 3.9%, 7.6%, and 2.4%, respectively.

Unadjusted death-censored graft survival at 1 and 5 years posttransplantation was 93.7% and 79.4%, respectively, for non-ECD transplants and 87.4% and 66.4%, respectively, for ECD transplants.

Adjusted Risk of Death for Transplant Recipients vs Candidates Without Transplant

The adjusted long-term relative mortality risk at 3 years was 60% lower for
ECD transplant recipients than for patients on the waiting list (relative risk [RR], 0.40; 95% confidence interval [CI], 0.37-0.44; P<.001). Recipients of non-ECD kidney transplants had a 72% lower long-term mortality risk when compared with wait-listed candidates (RR, 0.28; 95% CI, 0.27-0.30; P<.001).

**Adjusted Risk of Death for ECD Transplantation vs Standard Therapy**

The adjusted long-term relative mortality risk (beyond 3 years posttransplantation) was 17% lower for recipients of ECD transplants compared with patients receiving standard therapy, ie, wait-listed patients including those who subsequently received non-ECD transplants (RR, 0.83; 95% CI, 0.77-0.90; P<.001). We also tested whether the effect of ECD transplants on mortality risk varied with the magnitude of graft failure risk (graft failure risk, 1.7-2.0 vs >2.0 based on Port et al9). This sub-analysis showed no significant effect on long-term mortality risk reduction associated with ECD transplantation by graft failure risk level (P=.79).

Perioperative mortality risk for ECD recipients was 5.2-fold higher during the first 2 posttransplant weeks than for the standard-therapy group. Mortality risk declined thereafter, became equal to that in the standard-therapy group at 33 weeks posttransplantation, and was lower thereafter (Figure 1). However, due to the excess deaths accumulated among ECD recipients during the period of higher risk, overall cumulative mortality did not become equal in the 2 groups until 3.5 years posttransplantation (Figure 1). Thereafter, cumulative survival for the ECD recipients was higher. Adjusted patient survival at 5 years was 76.2% among all ECD recipients and 75.1% in the standard-therapy group.

Most, but not all, subgroups of ECD recipients had significantly lower long-term mortality risk compared with those receiving standard therapy (Table 3). Important findings from the subgroup analyses warrant further exploration. Patients aged 40 years and older had a significant survival benefit from an ECD kidney transplantation by 19% to 22% lower relative mortality risk. On the other hand, children and adults aged 18 to 39 years did not show a statistically significant ECD survival benefit. For the pediatric subgroup, the wide CI is related to a very small number of ECD transplants (n=50). All racial subgroups had significantly lower long-term mortality risk with ECD kidney transplants compared with standard therapy: 10%
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for whites, 21% for African Americans, and 56% and 60% for Asians and other races, respectively. Non-Hispanic ECD recipients had a 16% lower mortality risk (P < .001); for Hispanics, the survival benefit was similar but not statistically significant. Long-term mortality risk was 23% and 18% lower after ECD transplantation in patients with diabetes (P < .001) or hypertension (P = .02) as cause of ESRD, respectively, while risk reduction for ECD recipients with glomerulonephritis and other diagnoses was more modest and not statistically significant.

The impact of OPO waiting time on relative mortality risk of ECD transplantation was striking (Table 3). Candidates registered in OPOs with waiting time in the longest tertile (> 1350 days; 54% of all candidates) had a 27% lower risk of death with an ECD transplant compared with standard therapy (RR, 0.73; 95% CI, 0.64-0.83; P < .001). Those wait-listed with OPOs in the middle and lower waiting-time tertiles did not have a demonstrable survival benefit from ECD kidney transplantation (middle tertile: RR, 0.89; 95% CI, 0.78-1.03; P = .11; lower tertile: RR, 0.97; 95% CI, 0.82-1.16; P = .76).

We separately examined candidates aged 40 years and older by OPO waiting-time tertile. For this analysis, candidates listed with OPOs in the long-waiting-time tertile were contrasted with those in the short- and medium-waiting-time tertiles combined (46% of candidates) (TABLE 4). Among those aged 40 years and older and wait-listed at OPOs with short or medium waiting times, ECD transplantation was not associated with significantly lower long-term mortality risk for the group as a whole or for any subgroup, with the exception of those with diabetes (RR, 0.77; 95% CI, 0.64-0.94; P = .01). Among 2016 diabetic candidates younger than 40 years in OPOs with short or medium waiting times, a 41% risk reduction was observed (RR, 0.59; 95% CI, 0.30-1.16; P = .13).

Among candidates aged 40 years and older wait-listed at OPOs with long waiting times, 3 additional subgroups showed significant benefit. These included sensitized candidates and candidates with ESRD diagnoses of glomerulonephritis or other conditions (Table 4).

FIGURE 2 illustrates a decision algorithm based on the significant observations of the study.

### Table 4. Long-term (3-Year) Relative Risk of Mortality for ECD Transplantation vs Standard Therapy (Waiting-List Candidates and Non-ECD Transplant Recipients) for Candidates Aged 40 Years and Older, by OPO Waiting Time*

<table>
<thead>
<tr>
<th>Group</th>
<th>≤1350 d</th>
<th>&gt;1350 d</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>RR (95% CI)</td>
<td>P Value</td>
</tr>
<tr>
<td>All</td>
<td>0.91 (0.81-1.02)</td>
<td>.10</td>
</tr>
<tr>
<td>Age, y</td>
<td></td>
<td></td>
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<tr>
<td>≥60</td>
<td>0.90 (0.77-1.05)</td>
<td>.19</td>
</tr>
<tr>
<td>40-59</td>
<td>0.92 (0.77-1.09)</td>
<td>.33</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>0.87 (0.75-1.00)</td>
<td>.06</td>
</tr>
<tr>
<td>Male</td>
<td>1.02 (0.85-1.23)</td>
<td>.85</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>0.98 (0.86-1.12)</td>
<td>.76</td>
</tr>
<tr>
<td>Other</td>
<td>0.90 (0.71-1.15)</td>
<td>.42</td>
</tr>
<tr>
<td>African American</td>
<td>0.90 (0.71-1.15)</td>
<td>.42</td>
</tr>
<tr>
<td>Asian</td>
<td>0.90 (0.71-1.15)</td>
<td>.42</td>
</tr>
<tr>
<td>Other</td>
<td>0.90 (0.71-1.15)</td>
<td>.42</td>
</tr>
<tr>
<td>Ethnicity</td>
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<td></td>
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<tr>
<td>Hispanic</td>
<td>0.75 (0.44-1.29)</td>
<td>.30</td>
</tr>
<tr>
<td>Non-Hispanic</td>
<td>0.93 (0.82-1.04)</td>
<td>.20</td>
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<tr>
<td>ESRD cause</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glomerulonephritis</td>
<td>0.95 (0.71-1.28)</td>
<td>.75</td>
</tr>
<tr>
<td>Diabetes</td>
<td>0.77 (0.64-0.94)</td>
<td>.01</td>
</tr>
<tr>
<td>Hypertension</td>
<td>0.96 (0.76-1.21)</td>
<td>.73</td>
</tr>
<tr>
<td>Other</td>
<td>0.97 (0.77-1.24)</td>
<td>.83</td>
</tr>
<tr>
<td>Panel reactive antibody, %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-9</td>
<td>0.93 (0.83-1.05)</td>
<td>.26</td>
</tr>
<tr>
<td>≥10</td>
<td>0.98 (0.66-1.47)</td>
<td>.93</td>
</tr>
</tbody>
</table>

**Abbreviations:** CI, confidence interval; ECD, expanded criteria donor; ESRD, end-stage renal disease; NA, not available; OPO, organ procurement organization; RR, relative risk.

*Data not shown for waiting-list candidates and recipients missing information on ESRD cause and panel reactive antibody.

+Relative risks for subgroups with fewer than 2000 patients in an OPO category are not shown.

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Figure 2 were followed (TABLE 5). Overall, 41.9% of all kidney transplant candidates were listed for an ECD kidney. Using the proposed algorithm, 46.5% would be listed for an ECD kidney, and the proportions of ECD-listed candidates by subgroup would be quite different in some cases. For example, there was a monotonic relationship between candidate age and actual ECD kidney listing, whereas no candidates younger than 40 years would be listed in the optimized scenario. Nearly twice as many candidates with diabetes would be listed for ECD transplantation. The highest proportion of any subgroup of candidates on the ECD list was found among patients listed with OPOs with the shortest waiting times (58%). The proportion would be 17% using the proposed algorithm.

COMMENT

Kidney transplantation is lifesaving for most patients receiving dialysis. In 1999, Wolfe et al reported that long-term mortality (beyond 18 months) among recipients of deceased-donor renal transplants was reduced by 68% when compared with that among patients receiving dialysis who remained on the waiting list. These findings, along with significant growth in the pool of patients receiving dialysis, have led to up to 8% annual growth in the number of registrants joining the waiting list. Increasing demand has led to use of deceased-donor kidneys that were previously deemed unsuitable. Thus, use of ECD kidneys has nearly tripled in the past 10 years.

Ojo et al reported on the survival of recipients of marginal kidneys. Transplantation using such kidneys was associated with a 25% reduction in long-term mortality risk when compared with the risk for patients receiving dialysis who remained on the waiting list, whereas recipients of ideal kidneys from donors without adverse characteristics had a 48% reduction in long-term relative mortality risk.

However, comparison of the survival of ECD kidney recipients with that of candidates who remain on the waiting list represents only part of the picture needed to understand mortality risk and counsel transplant candidates. The analyses reported by Ojo et al did not consider the survival experience of waiting-list candidates once they received a non-ECD kidney transplant, since follow-up was censored at that point. From a clinical standpoint, a decision to decline an offer of an ECD kidney does not preclude a subsequent non-ECD transplant. A composite comparison group, which we have referred to as the standard-therapy group, includes wait-listed candidates as well as those who subsequently receive non-ECD kidney transplants. Outcome for the standard-therapy group reflects the total survival experience of patients on the waiting list who do not receive an ECD transplant, since it includes the salutary effect of non-ECD kidney transplants in a proportion of candidates.

Not surprisingly, the standard-therapy model showed a smaller overall survival benefit for ECD transplants (17% lower mortality) than when the comparison was with the waiting list alone (60% lower mortality). Candidates older than 40 years had a significant 19% to 22% lower long-term mortality risk with an ECD kidney. Those younger than 40 years did not have a statistically significant ECD survival benefit. Clinical practice during the years of the study was reflective of this observation, in that patients younger than 40 years made up only 15% of all ECD transplant recipients. However, under the current allocation system, 5287 (31%) of 16,823 candidates younger than 40 years are listed for ECD kidneys. Candidate counseling and listing practices such as these warrant review in light of the findings of our study.

We posit that differences in the relative benefit of an ECD transplant among the members of various subgroups are attributable to underlying disparities in access to non-ECD kidneys. Since non-
ECD transplants reduce the mortality risk for patients receiving dialysis who remain on the waiting list, there should be less of a survival advantage from an ECD kidney transplant in such cases. Our findings are consistent with this explanation. For example, we found that white patients, who have better access than nonwhites to non-ECD kidneys, had a smaller ECD benefit than African Americans and Asians. The results of our direct approach to this question were supportive; the average candidate listed in an OPO with a waiting time longer than 44 months benefited significantly from ECD kidney transplantation (27% lower mortality), whereas those listed in OPOs with shorter waiting times did not. Candidates older than 40 years in OPOs with long waiting times benefited even more (31% mortality reduction). As waiting times continue to increase, ECD transplantation will produce even more survival benefit.

Wait-listed patients with poor survival rates while receiving dialysis also derived notable survival advantage from ECD transplants. Patients with diabetes, those with hypertensive nephrosclerosis, and older candidates had large and significant survival benefit. One might imagine that African Americans would have manifested the opposite pattern, since their survival while receiving dialysis has been reported to be better than that of non–African Americans. However, the large deficit in access to transplantation for wait-listed African Americans appeared to outweigh this factor.

In the early posttransplantation period, mortality is higher for ECD transplant recipients than for candidates. This reflects risk associated with the operative procedure itself and with postoperative complications. It takes more than 7 months for the elevated risk of death to return to that of the standard-therapy group. After this point, the risk is lower for ECD recipients, but because of the accumulated excess deaths, cumulative survival in the ECD transplant group did not equal that in the standard-therapy group until 3.5 years posttransplantation. Beyond 3.5 years, cumulative survival favors the ECD recipient. These observations have important ramifications for candidates who must decide whether to accept an ECD kidney.

A reported decision model suggested that for an average candidate who receives an ECD transplant at an average time after placement on the waiting list, the survival break-even point would be 3.2 years. The authors suggested that ECD kidney transplantation is less desirable for African American candidates because the break-even point was longer. In contrast, our analyses showed that candidates of all races derive a significant survival benefit from ECD transplantation. The benefit appears to be greater for minority candidates than for white candidates, the latter having been repeatedly shown to have better access to non-ECD kidneys.

The break-even method requires one to know when non-ECD kidneys will become available in order to decide whether to accept an ECD kidney. Given the current allocation system in the United States, which assigns points for degree of HLA mismatch and waiting time, predictions about the timing of non-ECD kidney offers are difficult. We assessed this issue from the candidate’s standpoint when an ECD kidney is offered and integrated the subsequent experience of all comparable patients then on the waiting list. In addition to minority ethnicity, our results showed that ECD kidneys had the greatest effect on survival among older candidates and those whose underlying disease is associated with shorter survival while on the waiting list (eg,
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Thorough understanding of the advantages and disadvantages of ECD kidney transplantation is important, and patients generally express the desire to be informed about and participate in discussions about these issues. Improvements in quality of life that have been documented after successful kidney transplantation, while not necessarily applicable to ECD kidney transplantation, could contribute to decision-making regarding this procedure and warrant further study. The results of our study provide useful information for decision-makers and offer information for dialogue between potential kidney transplant candidates and their transplant teams.

Author Contributions: Dr Merion had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Merion, Ashby, Distant, Hulbert-Shearon, Metzger, Ojo, Port.

Acquisition of data: Port.

Analysis and interpretation of data: Merion, Ashby, Wolfe, Distant, Hulbert-Shearon, Metzger, Ojo, Port.

Drafting of the manuscript: Merion, Ashby, Ojo.

Critical revision of the manuscript for important intellectual content: Merion, Ashby, Wolfe, Distant, Hulbert-Shearon, Metzger, Ojo, Port.

Statistical analysis: Ashby, Wolfe, Hulbert-Shearon, Ojo.

Obtained funding: Port.

Administrative, technical, or material support: Merion, Metzger, Port.

Study supervision: Merion, Port.

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