

## COMPARISON OF MORTALITY IN ALL PATIENTS ON DIALYSIS, PATIENTS ON DIALYSIS AWAITING TRANSPLANTATION, AND RECIPIENTS OF A FIRST CADAVERIC TRANSPLANT

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## ABSTRACT

**Background** The extent to which renal allotransplantation — as compared with long-term dialysis — improves survival among patients with end-stage renal disease is controversial, because those selected for transplantation may have a lower base-line risk of death.

**Methods** In an attempt to distinguish the effects of patient selection from those of transplantation itself, we conducted a longitudinal study of mortality in 228,552 patients who were receiving long-term dialysis for end-stage renal disease. Of these patients, 46,164 were placed on a waiting list for transplantation, 23,275 of whom received a first cadaveric transplant between 1991 and 1997. The relative risk of death and survival were assessed with time-dependent non-proportional-hazards analysis, with adjustment for age, race, sex, cause of end-stage renal disease, geographic region, time from first treatment for end-stage renal disease to placement on the waiting list, and year of initial placement on the list.

**Results** Among the various subgroups, the standardized mortality ratio for the patients on dialysis who were awaiting transplantation (annual death rate, 6.3 per 100 patient-years) was 38 to 58 percent lower than that for all patients on dialysis (annual death rate, 16.1 per 100 patient-years). The relative risk of death during the first 2 weeks after transplantation was 2.8 times as high as that for patients on dialysis who had equal lengths of follow-up since placement on the waiting list, but at 18 months the risk was much lower (relative risk, 0.32; 95 percent confidence interval, 0.30 to 0.35;  $P < 0.001$ ). The likelihood of survival became equal in the two groups within 5 to 673 days after transplantation in all the subgroups of patients we examined. The long-term mortality rate was 48 to 82 percent lower among transplant recipients (annual death rate, 3.8 per 100 patient-years) than patients on the waiting list, with relatively larger benefits among patients who were 20 to 39 years old, white patients, and younger patients with diabetes.

**Conclusions** Among patients with end-stage renal disease, healthier patients are placed on the waiting list for transplantation, and long-term survival is better among those on the waiting list who eventually undergo transplantation. (N Engl J Med 1999; 341:1725-30.)

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IN patients with end-stage renal disease, successful renal allotransplantation improves the quality of life and increases survival, as compared with long-term dialysis treatment.<sup>1-3</sup> The survival advantage of renal transplantation varies among patients,<sup>4-7</sup> but this variability has not been well characterized. Most studies have not considered the fact that transplant recipients are derived from a highly selected subgroup of patients on dialysis who are deemed suitable candidates for transplantation. Patients on dialysis who are placed on the waiting list for cadaveric renal transplantation are on average younger and healthier and of higher socioeconomic status than those who are not selected.<sup>8-10</sup> Because of these selection factors, the survival of patients on dialysis who are awaiting transplantation is better than that of other patients on dialysis, even before renal transplantation.

The number of cadaveric organs available has not kept up with the increasing number of patients awaiting transplantation.<sup>11</sup> The rapid expansion of the recipient pool, particularly of high-risk patients, has increased the pressure on transplantation programs to devise appropriate selection criteria (e.g., age) to optimize the use of scarce organs. The present study was designed to compare survival of patients undergoing transplantation with survival of those awaiting transplantation.

## METHODS

We used data from the U.S. Renal Data System for this study. From 1991 through 1996, 252,358 patients under the age of 70 years began treatment for end-stage renal disease in the United States. We excluded patients who were 70 years of age or older, because only about 1 percent of them received a cadaveric renal transplant; those whose race was listed as other than Asian, Native American, black, or white; and those for whom the cause of end-stage renal disease or the region they were from was not reported. Patients who received transplants without first undergoing dialysis were also excluded. The resulting study population included

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**TABLE 1.** CHARACTERISTICS OF PATIENTS WITH END-STAGE RENAL DISEASE, 1991–1997.

CHARACTERISTIC	ALL PATIENTS ON DIALYSIS (N=228,552)	PATIENTS ON THE WAITING LIST (N=46,164)	RECIPIENTS OF CADAVERIC TRANSPLANTS (N=23,275)
			percent
Age*			
0–19 yr	1.7	2.8	3.7
20–39 yr	17.0	31.2	33.6
40–59 yr	42.5	50.9	49.7
≥60 yr	38.8	15.0	13.0
Female sex	45.6	39.5	37.2
Race			
White	60.3	65.4	71.3
Black	34.7	28.6	23.6
Asian	3.1	4.4	3.9
Native American	1.9	1.7	1.2
Cause of end-stage renal disease			
Diabetes	44.7	32.9	31.2
Glomerulonephritis	12.5	22.0	23.0
Other	42.8	45.1	45.8

\*The ages shown are the age at the time of the first treatment for end-stage renal disease in the group of all patients on dialysis (age limit, 69 years), the age at the time of initial placement on the waiting list for patients on the waiting list, and the age at transplantation for transplant recipients.

228,552 patients, of whom 46,164 had been placed on the waiting list for transplantation for the first time. Among these patients on the waiting list, 23,275 received a first cadaveric transplant by December 31, 1997.

Survival was analyzed as the time from initial placement on the waiting list to death, with data censored at the time of receipt of

a first transplant from a living donor or on December 31, 1997. A time-dependent, nonproportional-hazards analysis was used to account for the fact that patients switched from the dialysis group to the transplantation group during follow-up. The analysis showed that mortality was higher in the transplantation group immediately after transplantation and then dropped below the rate in the dialysis group over the long term. We calculated the number of days between placement on the waiting list and the time at which the death rates became equal in the two groups as well as cumulative survival probabilities and the projected years of life, with adjustment for the time spent on the waiting list.<sup>12</sup> The analyses were adjusted for age, race, sex, cause of end-stage renal disease (glomerulonephritis, diabetes, or other causes), year of placement on the waiting list, time from first treatment for end-stage renal disease to placement on the waiting list, and geographic region. The analysis was conducted according to the intention to treat; therefore, patients were not dropped from the analysis if they were removed from the waiting list or if transplantation failed. Although some patients were on the waiting list at multiple centers and received more than one transplant, we only considered the time of the initial placement on the waiting list and the first transplantation. We analyzed subgroups of patients separately. In addition, we calculated standardized mortality ratios, adjusted for age, sex, race, and diabetes as the cause of end-stage renal disease,<sup>13</sup> to compare the death rates among the 46,164 patients on dialysis who were placed on the waiting list and the 23,275 recipients of cadaveric transplants with those among the entire group of 228,552 patients on dialysis; we used the death-rate tables of the U.S. Renal Data System for all U.S. patients on dialysis in 1997 as a reference.<sup>11</sup>

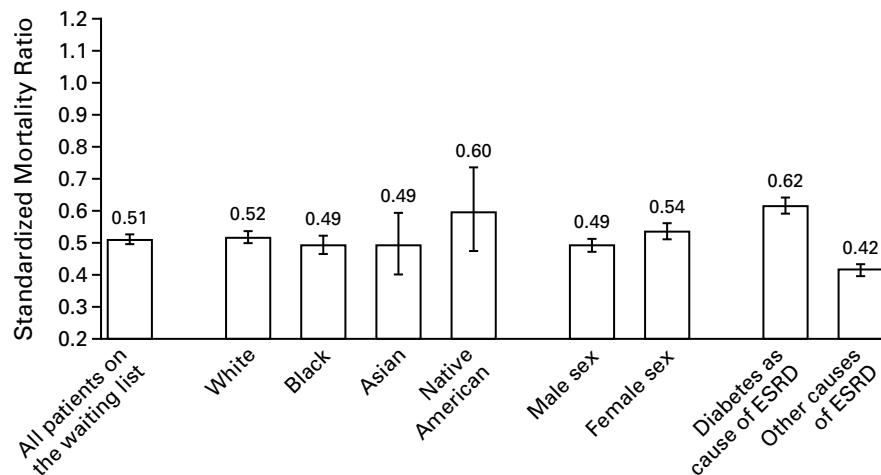
## RESULTS

The percentages of blacks, Native Americans, women, and patients with diabetes were lower among patients who had been placed on the waiting list and recipients of cadaveric transplants than among the group of patients on dialysis as a whole (Table 1). The unadjusted annual death rates per 100 patient-

**TABLE 2.** ANNUAL DEATH RATES AND TOTAL NUMBERS OF DEATHS, 1991–1997.

VARIABLE	ALL PATIENTS ON DIALYSIS (N=228,552)		PATIENTS ON THE WAITING LIST (N=46,164)		RECIPIENTS OF CADAVERIC TRANSPLANTS (N=23,275)	
	RATE/100 PATIENT-YR	NO. OF DEATHS	RATE/100 PATIENT-YR	NO. OF DEATHS	RATE/100 PATIENT-YR	NO. OF DEATHS
All patients	16.1	84,713	6.3	4353	3.8	2436
Age*						
0–19 yr	3.6	257	2.2	31	0.9	21
20–39 yr	8.6	7,499	4.3	897	2.3	500
40–59 yr	13.3	30,935	6.5	2372	4.1	1293
≥60 yr	23.2	46,022	10.0	1053	7.4	622
Sex						
Male	16.2	45,366	6.3	2556	3.9	1590
Female	16.1	39,347	6.3	1797	3.5	846
Race						
White	19.3	55,786	7.5	2993	3.9	1859
Black	12.4	25,733	4.8	1168	3.4	478
Asian	9.9	1,783	3.0	108	2.6	64
Native American	13.3	1,411	6.5	84	4.7	35
Cause of end-stage renal disease						
Diabetes	19.9	44,916	10.8	2312	5.6	1091
Other	13.3	39,797	4.3	2041	3.0	1345

\*The ages shown are the age at the time of the first treatment for end-stage renal disease in the group of all patients on dialysis (age limit, 69 years), the age at the time of initial placement on the waiting list for patients on the waiting list, and the age at transplantation for transplant recipients.



**Figure 1.** Standardized Mortality Ratios for Patients on the Waiting List for Renal Transplants, According to Race, Sex, and Diabetes as the Cause of End-Stage Renal Disease (ESRD), 1991–1997.

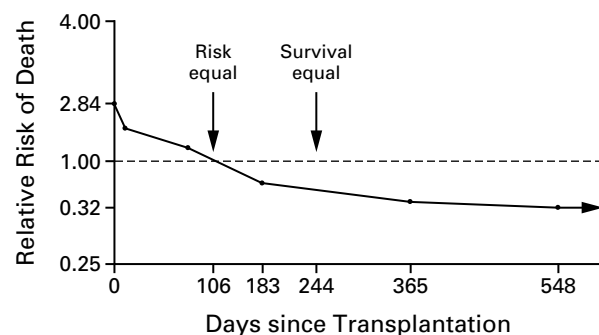
The reference groups were all patients on dialysis who were less than 70 years of age at the onset of end-stage renal disease and the corresponding subgroups classified according to race, sex, and diabetes as the cause of end-stage renal disease (relative risk of death, 1.0). The ratios were adjusted for age, race, sex, and diabetes as the cause of end-stage renal disease. I bars indicate 95 percent confidence intervals.  $P < 0.001$  for all comparisons.

years at risk for all patients on dialysis, patients on the waiting list, and transplant recipients were 16.1, 6.3, and 3.8, respectively (Table 2). The annual death rate for all patients on dialysis was 2.6 times as high as that for patients on the waiting list, and the annual death rate for patients on the waiting list was 1.7 times as high as that for transplant recipients. The total deaths in each group are also shown in Table 2.

The standardized mortality ratios, adjusted for age, race, sex, and diabetes as the cause of end-stage renal disease, for patients on the waiting list as compared with the corresponding group of all patients on dialysis who were younger than 70 years at the onset of end-stage renal disease (relative risk, 1.0) are shown in Figure 1.<sup>13</sup> The standardized mortality ratio was 49 percent lower (relative risk, 0.51; 95 percent confidence interval, 0.49 to 0.53;  $P < 0.001$ ) among patients on the waiting list and 69 percent lower (data not shown) among the recipients of cadaveric transplants. Thus, much of the large reduction in risk among the recipients of cadaveric transplants was most likely due to the selection of healthier patients for placement on the waiting list. The standardized mortality ratio was also significantly lower among each subgroup of patients on the waiting list (whites, blacks, Asians, Native Americans, female patients, male patients, those with diabetes, and those without diabetes) than among the corresponding subgroup of all patients on dialysis ( $P < 0.001$  for each comparison).

The relative risk of death among transplant recipients, as compared with patients on the waiting list, adjusted for age, sex, race, cause of end-stage renal

disease, year of placement on the waiting list, and time from first treatment for end-stage renal disease to placement on the waiting list, is shown in Figure 2. Transplant recipients, including patients in whom transplantation was unsuccessful, were compared with patients on the waiting list who had equal lengths of follow-up since placement on the waiting list but who had not yet received a cadaveric transplant. The



**Figure 2.** Adjusted Relative Risk of Death among 23,275 Recipients of a First Cadaveric Transplant.

The reference group was the 46,164 patients on dialysis who were on the waiting list (relative risk, 1.0). Patients in both groups had equal lengths of follow-up since placement on the waiting list. Values were adjusted for age, sex, race, cause of end-stage renal disease, year of placement on the waiting list, geographic region, and time from first treatment for end-stage renal disease to placement on the waiting list. The points at which the risk of death and the likelihood of survival were equal in the two groups are indicated. A log scale was used.

**TABLE 3.** OUTCOME AMONG RECIPIENTS OF FIRST CADAVERIC TRANSPLANTS, ACCORDING TO CHARACTERISTICS AT THE TIME OF INITIAL PLACEMENT ON THE WAITING LIST, 1991–1997.\*

GROUP	RELATIVE RISK 18 Mo AFTER TRANSPLANTATION (95% CI)†	P VALUE	TIME AT WHICH RISK OF DEATH EQUALS THAT IN REFERENCE GROUP days after transplantation	TIME AT WHICH LIKELIHOOD OF SURVIVAL EQUALS THAT IN REFERENCE GROUP	PROJECTED YEARS OF LIFE (IN REFERENCE GROUP) WITHOUT TRANSPLANTATION‡	PROJECTED YEARS OF LIFE WITH TRANSPLANTATION‡
All recipients of first cadaveric transplants	0.32 (0.30–0.35)	<0.001	106	244	10	20
Age						
0–19 yr	0.33 (0.12–0.87)	0.03	3	5	26	39
20–39 yr	0.24 (0.20–0.29)	<0.001	11	57	14	31
40–59 yr	0.33 (0.29–0.37)	<0.001	95	251	11	22
60–74 yr	0.39 (0.33–0.47)	<0.001	148	369	6	10
Sex						
Male	0.34 (0.30–0.38)	<0.001	110	255	10	19
Female	0.30 (0.26–0.34)	<0.001	94	220	11	23
Race						
Native American	0.50 (0.27–0.96)	0.04	123	304	9	14
Asian	0.43 (0.25–0.75)	0.003	161	673	15	23
Black	0.52 (0.44–0.62)	<0.001	109	305	13	19
White	0.28 (0.25–0.30)	<0.001	100	220	9	19
Cause of end-stage renal disease						
Diabetes	0.27 (0.24–0.30)	<0.001	57	146	8	19
Glomerulonephritis	0.39 (0.31–0.48)	<0.001	130	360	11	18
Other	0.38 (0.33–0.43)	<0.001	137	353	12	20
Age and diabetes status						
20–39 yr, no diabetes	0.38 (0.28–0.50)	<0.001	14	220	20	31
20–39 yr, diabetes	0.18 (0.14–0.23)	<0.001	10	35	8	25
40–59 yr, no diabetes	0.38 (0.33–0.43)	<0.001	126	356	12	19
40–59 yr, diabetes	0.27 (0.23–0.32)	<0.001	66	181	8	22
60–74 yr, no diabetes	0.37 (0.30–0.46)	<0.001	159	442	7	12
60–74 yr, diabetes	0.46 (0.34–0.61)	<0.001	89	247	5	8

\*All analyses were adjusted for age, sex, race, cause of end-stage renal disease, year of placement on the waiting list, geographic region, and time from first treatment for end-stage renal disease to placement on the waiting list. CI denotes confidence interval.

†The reference group was the 46,164 patients on dialysis who were on the waiting list.

‡The starting point for the calculation was the time of initial placement on the waiting list.

risk of death among the transplant recipients during the first 2 weeks after transplantation was 2.8 times as high as that among the patients on the waiting list and remained elevated until 106 days after transplantation. After this time, the risk was lower among the transplant recipients, but the likelihood of survival did not become equal in the two groups until day 244, because of the initially higher risk among the transplant recipients. The long-term mortality risk for the transplant recipients was estimated to be 68 percent lower than that of the patients on the waiting list (relative risk, 0.32; 95 percent confidence interval, 0.30 to 0.35;  $P < 0.001$ ). The long-term risk was estimated on the basis of three to four years of follow-up.

The outcomes among the various subgroups of patients who received a cadaveric transplant are shown in Table 3. Overall, the projected years of life remaining were 10 for patients who remained on the waiting list and 20 for those who received a transplant. The greatest difference in long-term survival was found among patients who were 20 to 39 years old at the

time of placement on the waiting list: those who underwent transplantation were projected to live almost 17 years longer than those who remained on the waiting list. Among the patients who were 60 to 74 years old, the cumulative survival rate improved after the first year after transplantation, with a projected increase in the life span of four years and a decrease in the long-term risk of death of 61 percent. When this subgroup was further subdivided into patients who were 60 to 64 years of age, those who were 65 to 69 years, and those who were 70 to 74 years, the projected increases in the life span were 4.3 years, 2.8 years, and 1.0 year, respectively. When the results were analyzed according to race, transplantation reduced the long-term relative risk of death more among Asians and whites than among Native Americans and blacks. However, in all four racial groups, transplantation significantly reduced the long-term risk of death, with initially higher mortality in the transplantation groups disappearing within less than half a year. The cumulative mortality rate was

lower within 10 months after transplantation in all racial groups except Asians, who had the lowest mortality rate while receiving dialysis on the waiting list and for whom it required two years after transplantation for the mortality rate to return to this level.

The relative survival benefits of transplantation were similar for men and women, with the long-term risk of death decreasing by 66 percent and 70 percent, respectively, and the initially higher mortality disappearing within eight and seven months, respectively. The results were similar for the subgroups of patients with diabetes, glomerulonephritis, and other causes of end-stage renal disease. Among patients with diabetes who were on the waiting list, the annual mortality rate was close to 11 percent. Transplantation reduced the risk of death by 73 percent (relative risk, 0.27; 95 percent confidence interval, 0.24 to 0.30;  $P < 0.001$ ). When projected long-term survival after transplantation was analyzed according to the cause of end-stage renal disease, the greatest increase occurred among patients with diabetes, with a gain of more than 11 years, as compared with an increase of 7 years among those with glomerulonephritis and 8 years among those with other causes of end-stage renal disease.

Patients with diabetes and patients who were 20 to 39 years old, 40 to 59 years old, or 60 to 74 years old at the time of placement on the waiting list were examined to assess the benefit of current practices of transplantation in these subgroups. In all these subgroups, transplantation reduced long-term mortality by over 50 percent (relative risk,  $< 0.50$ ;  $P < 0.001$ ). In all three age groups, the projected increase in the life span after transplantation was greater among patients with diabetes than among those without diabetes.

## DISCUSSION

Our findings document that there is substantial selection of healthier patients for placement on the waiting list for transplantation. The magnitude of this bias is similar to that reported previously.<sup>14</sup> The mortality rate for the patients on dialysis who were on the waiting list was about half that of all patients on dialysis when subgroups were analyzed according to age, sex, race, and cause of end-stage renal disease. Thus, studies that compared the outcome among patients who received transplants with that among all patients on dialysis were biased in favor of the former group, because high-risk patients on dialysis who were not candidates for transplantation were included in the reference group. We avoided this selection bias, and we still found large long-term benefits for cadaveric transplantation, despite the increased short-term risk of death after transplantation. Our results also demonstrate that transplantation improved longevity in all groups of recipients, including patients who were 60 to 74 years old at the time of transplantation.

Comparing survival among transplant recipients

with that among all patients on dialysis who had been on the waiting list for the same length of time but who had not yet undergone transplantation minimized the time-to-treatment bias. We found that the relative risk of death among recipients of a first cadaveric renal transplant relative to that among patients on the waiting list varies substantially with time. The risk was initially increased. This finding was not unexpected and most likely relates to risks associated with the surgery itself and to the use of high-dose immunosuppressive therapy. The subsequent decrease in the risk of death counterbalanced the initially high rates and resulted in a cumulative survival benefit beginning 244 days after transplantation overall. The long-term reduction in the risk of death was large for all subgroups of patients, averaging 66 percent, as compared with the risk of death among corresponding patients on the waiting list of the same age, sex, and race and with the same cause of end-stage renal disease. Since post-transplantation mortality was assessed independently of allograft function according to an intention-to-treat analysis, this information can be used to advise patients. This approach and methodology have previously been used in a regional registry.<sup>12,14,15</sup> Adjustments for the year of placement on the waiting list and the interval between placement on the list and transplantation minimize the potential effects of an improvement in outcomes over time. Such an improvement has been documented for both patients on dialysis<sup>11,16</sup> and transplant recipients.<sup>11,17</sup>

A major reduction in the relative risk of death does not in itself indicate the extent of the increase in life span. The latter depends on both the death rate and the relative risk. We assessed both clinically relevant measures. The projected increase in life span conferred by transplantation was 10 years overall and ranged from 3 to 17 years according to patient group. The larger estimates need to be viewed with greater caution than the shorter estimates, because the values are extrapolations. Furthermore, both short-term survival and long-term survival have been improving for patients on dialysis and transplant recipients in recent years,<sup>11</sup> and this could also affect the results. In addition, the use of transplants from living donors, which we did not study, should be encouraged, since it has a better outcome than cadaveric transplantation.<sup>18,19</sup>

Our use of the intention-to-treat analysis allows an approximate comparison of transplant recipients with candidates for transplantation who have been on the waiting list for the same length of time. Since patients were enrolled in the study at the time of initial placement on the waiting list, these results can be used to answer questions regarding the risks and benefits of cadaveric renal transplantation as of the time of placement on the list. Assessment of the risks and benefits of transplantation on the day that an organ becomes available would require complete and reliable data on temporary and permanent removal

from the waiting list.<sup>20</sup> Removing patients from the analysis at the time of removal from the waiting list would yield a biased result, as is clear from an analysis of the result after the removal of all patients on the waiting list just before death. The latter approach would cause the death rate among patients on the waiting list to be zero, a biased estimate.

Our analysis of U.S. data demonstrates that the patients on dialysis who were placed on the waiting list for transplantation were those with a markedly better likelihood of survival. Recipients of a first cadaveric renal transplant had an initially higher risk of death than those who remained on dialysis but a subsequent long-term benefit. Elderly patients also benefited from transplantation, although the survival benefit was less than that for younger patients.

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