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Transplantation Outcomes with Donor Hearts after Circulatory Death

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ABSTRACT

BACKGROUND

Data showing the efficacy and safety of the transplantation of hearts obtained from donors after circulatory death as compared with hearts obtained from donors after brain death are limited.

METHODS

We conducted a randomized, noninferiority trial in which adult candidates for heart transplantation were assigned in a 3:1 ratio to receive a heart after the circulatory death of the donor or a heart from a donor after brain death if that heart was available first (circulatory-death group) or to receive only a heart that had been preserved with the use of traditional cold storage after the brain death of the donor (brain-death group). The primary end point was the risk-adjusted survival at 6 months in the as-treated circulatory-death group as compared with the brain-death group. The primary safety end point was serious adverse events associated with the heart graft at 30 days after transplantation.

RESULTS

A total of 180 patients underwent transplantation; 90 (assigned to the circulatory-death group) received a heart donated after circulatory death and 90 (regardless of group assignment) received a heart donated after brain death. A total of 166 transplant recipients were included in the as-treated primary analysis (80 who received a heart from a circulatory-death donor and 86 who received a heart from a brain-death donor). The risk-adjusted 6-month survival in the as-treated population was 94% (95% confidence interval [CI], 88 to 99) among recipients of a heart from a circulatory-death donor, as compared with 90% (95% CI, 84 to 97) among recipients of a heart from a brain-death donor (least-squares mean difference, –3 percentage points; 90% CI, –10 to 3; P<0.001 for noninferiority [margin, 20 percentage points]). There were no substantial between-group differences in the mean per-patient number of serious adverse events associated with the heart graft at 30 days after transplantation.

CONCLUSIONS

In this trial, risk-adjusted survival at 6 months after transplantation with a donor heart that had been reanimated and assessed with the use of extracorporeal nonischemic perfusion after circulatory death was not inferior to that after standard-care transplantation with a donor heart that had been preserved with the use of cold storage after brain death. (Funded by TransMedics; ClinicalTrials.gov number, NCT03831048.)

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A Quick Take is available at NEJM.org

Heart transplantation has traditionally been limited to the use of hearts obtained from donors after brain death to allow in situ assessment of cardiac function and of the suitability for transplantation of the donor allograft before surgical procurement. Because the need for heart transplants far exceeds the availability of suitable donor allografts, the use of hearts from donors after circulatory death has been further evaluated on the basis of clinical outcomes at single centers in Australia and the United Kingdom.[1-5] The ability to preserve and assess potential donor hearts in situ after circulatory death is enabled by extracorporeal machine perfusion, which allows for reanimation of the heart after circulatory death and evaluation of the heart for suitability for transplantation. Early results from ex situ perfusion of the heart, limited to either isolated cases or series at single centers, have been encouraging.[1-5] However, data from a prospective, controlled trial to assess clinical outcomes after transplantation of a heart from a donor after circulatory death as compared with a heart from a donor after brain death have been lacking. We designed the Donors after Circulatory Death Heart Trial to determine whether clinical outcomes in patients who had undergone transplantation with a heart that had been reanimated with portable extracorporeal nonischemic perfusion after the circulatory death of the donor were noninferior to outcomes in patients who had received a heart that had been preserved and transported with the use of traditional cold storage after the brain death of the donor.

Methods

Trial Design and Oversight

This multicenter, unblinded, randomized, controlled trial involved hearts that had been preserved with the use of traditional cold static storage after the brain death of the donors (standard care) and hearts that had been reanimated, preserved, and assessed with the use of a portable extracorporeal perfusion and preservation system (Organ Care System Heart, TransMedics) after the circulatory death of the donors. Adult candidates for heart transplantation who were on waiting lists at participating transplantation centers in the United States provided written informed consent and were randomly assigned in a 3:1 ratio to a group that was eligible for transplantation with a heart from a circulatory-death donor (circulatory-death group) or to a group that was eligible for transplantation with a heart from a brain-death donor (brain-death group).

Patients who were randomly assigned to the circulatory-death group could receive a heart from a circulatory-death donor or a heart from a brain-death donor, whichever was matched to the patient first according to the priority status that had been assigned to them by the United Network for Organ Sharing (UNOS). The allowance for receipt of either type of donor heart was essential to protect a candidate's chance to receive a heart transplant without unnecessary delay.

Patients who were randomly assigned to the brain-death group could undergo transplantation only of a heart from a brain-death donor. The protocol (available with the full text of this article at NEJM.org) specified that all the patients who underwent transplantation with a heart from a brain-death donor, regardless of group assignment, were to be assessed in the overall brain-death group.

Donor and Recipient Eligibility

The full list of eligibility criteria for donors and recipients is shown in Table S1 in the Supplementary Appendix, available at NEJM.org. Eligible circulatory-death donors were classified as Maastricht category III (persons who became donors after controlled withdrawal of life support and subsequent cardiac arrest and cardiocirculatory death) (Table S2), were 18 to 49 years of age, and had a functional warm ischemic time (defined as time from mean systolic arterial blood pressure <50 mm Hg or peripheral oxygen saturation <70% to aortic cross-clamp and administration of cold cardioplegia) of 30 minutes or less. Age older than 49 years was not an exclusion criterion for brain-death donors.

Potential donors were excluded if they had a history of cardiac surgery, coronary artery disease, cardiogenic shock, or myocardial infarction; terminal left ventricular ejection fraction of 50% or less; or clinically significant valve disease. Brain-death donor hearts were screened for

eligibility for transplantation according to the standard of care at each transplantation center.

Eligible recipients included primary adult heart-transplantation candidates. Potential recipients who were candidates for multiorgan transplantation, had a history of solid-organ or bone marrow transplantation, or had chronic renal failure and were receiving hemodialysis were excluded.

CRITERIA FOR THE USE OF A HEART FROM A DONOR AFTER CIRCULATORY DEATH

A heart from a circulatory-death donor that had been perfused had to satisfy the following criteria for transplantation: stable or downward-trending circulating lactate levels after adequate perfusion was established[6]; stable perfusion levels; and clinical acceptance of the donor heart for transplantation by the transplanting surgeon or cardiologist. Hearts from circulatory-death donors were flushed with cold crystalloid del Nido cardioplegia solution (containing Plasma-Lyte A, mannitol, magnesium sulfate, sodium bicarbonate, potassium chloride, and lidocaine). Donor hearts were surgically retrieved and placed on the perfusion system (Fig. S1) according to procedures that have been previously described.[7]

PRIMARY AND SECONDARY END POINTS

The primary efficacy end point was patient survival at 6 months after transplantation with adjustment for prespecified donor and recipient risk factors (Table S3). Noninferiority was assessed between recipients of a heart from a circulatory-death donor and patients who received a heart from a brain-death donor. The secondary efficacy end point was the donor-heart utilization rate, defined as the number of eligible hearts from donors after circulatory death that were transplanted divided by the total number of hearts from donors after circulatory death that had been placed on the perfusion system. Other clinical end points included patient survival with the original transplanted heart from 30 days through 1 year after transplantation. The primary safety end point was serious adverse events associated with the heart graft in the first 30 days after transplantation; these events included moderate or severe left or right ventricular primary graft dysfunction as defined by the International Society for Heart and Lung Transplantation (ISHLT)[8] and primary graft failure that resulted in retransplantation. These events were adjudicated by a clinical-events committee.

STATISTICAL ANALYSIS

For the sample-size calculation, we estimated that 6-month survival would be 85% among recipients of a heart from a circulatory-death donor and 93% among recipients of a heart from a brain-death donor, percentages that are consistent with contemporary 6-month survival among recipients of a heart from a brain-death donor in the United States.[9] We calculated that a sample size of 168 would provide the trial with 80% power to test the hypothesis that the 6-month survival among patients who received a heart from a circulatory-death donor would be noninferior to that among patients who received a heart from a brain-death donor. To account for patients who might have been lost to follow-up, who withdrew from the trial, or who did not meet final eligibility criteria, the sample size was increased to 90 patients per group.

The final analysis was to determine post-transplantation clinical outcomes from recipients of a heart from a circulatory-death donor as compared with recipients of a heart from a brain-death donor. The as-treated population of recipients of a heart from a circulatory-death donor comprised all the eligible recipients who had undergone transplantation with an eligible heart from a circulatory-death donor that had been preserved with the use of the perfusion system and did not meet exclusion criteria. The as-treated population of recipients of a heart from a brain-death donor comprised all the recipients of a heart that had been preserved with the use of cold storage after the brain death of the donor, regardless of group assignment, excluding recipients who underwent transplantation with a heart from a donor who was younger than 18 years of age. The primary analyses of efficacy and safety, with the exception of the donor-heart utilization rate, were conducted in the as-treated population, as prespecified.

The primary analysis of the primary efficacy end point was the risk-adjusted noninferiority of patient survival at 6 months among patients in the as-treated circulatory-death group as compared with that in the as-treated brain-death

group, with a noninferiority margin of 20 percentage points. The as-treated circulatory-death group was considered to be noninferior to the as-treated brain-death group with regard to 6-month survival if the upper boundary of the risk-adjusted two-sided 90% confidence interval for the between-group difference in 6-month survival was less than 20 percentage points. The analysis was performed with the use of a linear probability model, with terms for treatment and the prespecified adjustment as variables. The variables that were used for risk adjustment were known donor and recipient risk factors, which are shown in the protocol and in Table S4. The variables were removed from the model until the model converged on the two final variables in the adjusted analyses — pretransplantation mechanical circulatory support and cold ischemic time of 4 or more hours. The safety end point was assessed with the use of descriptive statistics.

Analysis of the secondary end point was not adjusted for multiplicity. Results of secondary analyses are reported as point estimates with 95% confidence intervals, the widths of which have not been adjusted for multiplicity; hence, the results should not be used in place of a hypothesis test. No imputation of missing data for trial participants was performed for any effectiveness or safety end point. All the analyses were conducted with the use of SAS software, version 9.4 (SAS Institute).

RESULTS

DONORS AND RECIPIENTS

From December 2019 through November 2020, a total of 297 adults who were listed for and awaiting heart transplantation at 15 transplantation centers in the United States were assigned to the circulatory-death group (226 patients), in which they could receive either a heart from a circulatory-death donor or a heart from a brain-death donor, or to the brain-death group (71 patients), in which they could receive a heart only from a brain-death donor. A total of 180 patients underwent transplantation (90 patients in each group; overall population). A total of 10 protocol violations occurred among the 90 transplantations of hearts from circulatory-death donors. These violations included transplantation of hearts from three donors who were younger than 18 years of age, six donors for whom the functional warm ischemic time exceeded 30 minutes, and one donor heart that was transplanted despite having had continuously increasing lactate levels. There were four protocol violations in the brain-death group, all of which were associated with the transplantation of hearts from donors who were younger than 18 years of age. Removal of these patients from the overall trial population yielded an as-treated population that included 80 patients who underwent transplantation of a heart from a circulatory-death donor and 86 patients who underwent transplantation of a heart from a brain-death donor (Fig. 1).

The characteristics of the donors at baseline and the risk factors were similar in the two groups, except that the donors of hearts after circulatory death, as compared with the donors of hearts after brain death, were younger (mean [±SD] age, 29.3±7.5 vs. 33.2±11.4 years), were more likely to be men (84 of 90 patients [93%] vs. 69 of 90 patients [77%]), and were less likely to be Black (11 of 90 patients [12%] vs. 25 of 90 patients [28%]). Among the recipients, the characteristics of the patients at baseline were similar in the two groups, except that the recipients of hearts from circulatory-death donors, as compared with the recipients of hearts from brain-death donors, were younger (51.3±12.6 vs. 55.0±11.4 years) and were more likely to be Black (28 of 90 [31%] vs. 20 of 90 [22%]). In addition, at the time of transplantation, 43 patients (48%) in the circulatory-death group had a UNOS status of 4, and 47 patients (52%) in the brain-death group had a UNOS status of 2 (status range, 1 to 6, with 1 representing the greatest urgency with regard to priority on the transplantation list) (Table 1 and Tables S5 through S7).

PRIMARY EFFICACY END POINT

The risk-adjusted 6-month patient survival in the as-treated population was 94% (95% confidence interval [CI], 88 to 99) among recipients of a heart from a circulatory-death donor, as compared with 90% (95% CI, 84 to 97) among recipients of a heart from a brain-death donor (least-squares mean difference, –3 percentage points; 90% CI, –10 to 3; P<0.001 for noninferiority; margin, 20 percentage points) (Fig. 2A). (Differences were calculated on the basis of unrounded values.) The risk-adjusted 6-month pa-

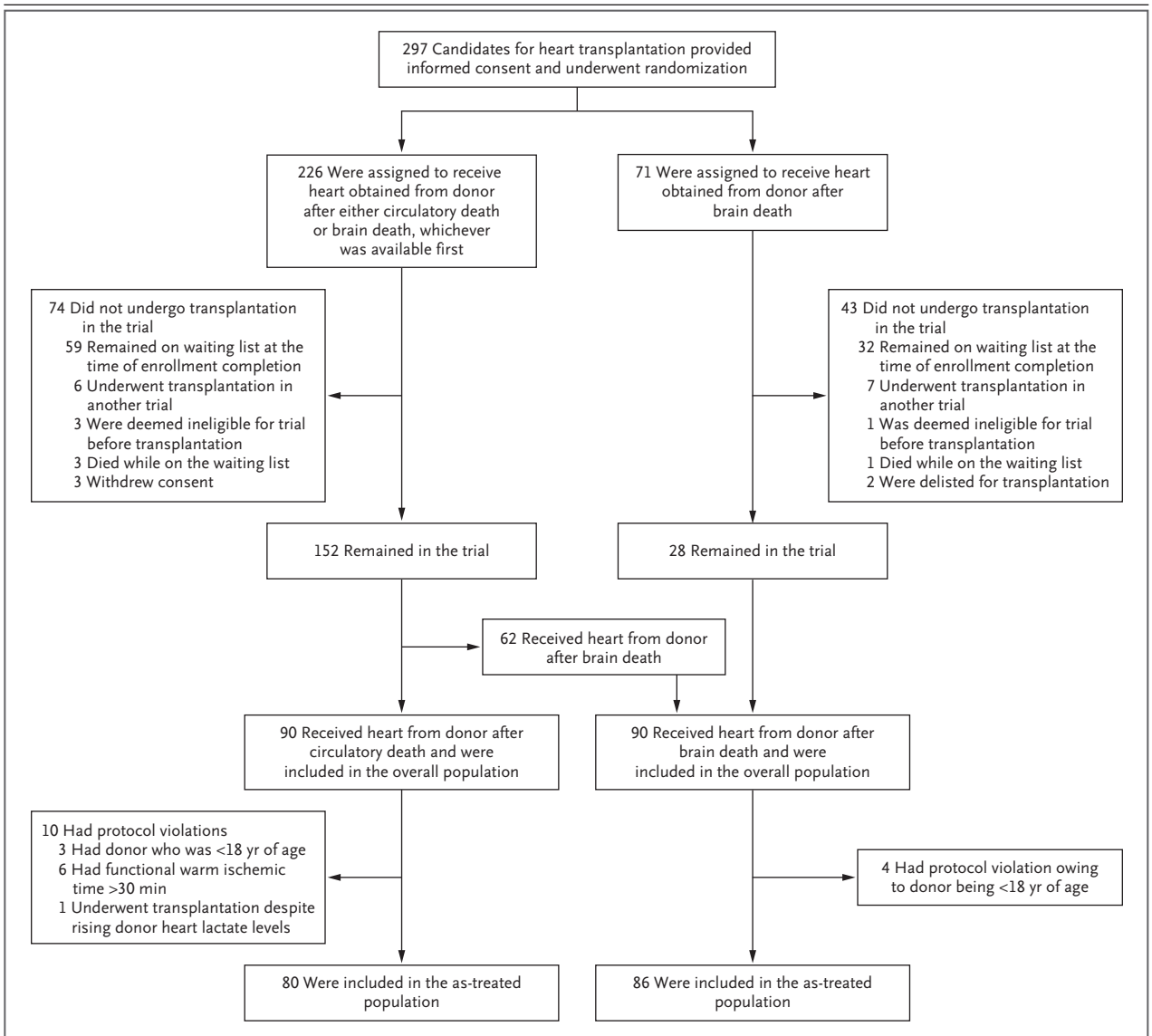


Figure 1. Enrollment and Randomization of the Patients.

tient survival in the overall population was 93% (95% CI, 88 to 99) with a heart from a circulatory-death donor as compared with 90% (95% CI, 83 to 96) with a heart from a brain-death donor (least-squares mean difference, −4 percentage points; 90% CI, −11 to 3; P<0.001 for noninferiority). The unadjusted survival at 6 months was consistent with the results in the as-treated population (among recipients of a heart from a circulatory-death donor, 76 of 80 [95%; 95% CI, 88 to 99] vs. those of a heart from a brain-death donor, 75 of 84 [89%; 95% CI, 81 to 95]) and overall population (94% [95% CI, 88 to 98] vs. 89% [95% CI, 80 to 94]) (Fig. 2B and Fig. S2).

SECONDARY END POINT AND OTHER CLINICAL END POINTS

Of 101 hearts from circulatory-death donors that were preserved with the use of the perfusion system, 90 were successfully transplanted according to the criteria for lactate trend and overall contractility of the donor heart, which resulted in overall utilization percentage of 89%. Reasons that donor hearts were not transplanted

Table 1. Characteristics of the Donors and Recipients at Baseline (Overall Population).*

Characteristic	Donation after Circulatory Death (N=90)	Donation after Brain Death (N=90)
Donor		
Age		
Mean — yr	29.3±7.5	33.2±11.4
Range — yr	15.7–47.0	12.3–65.3
≥55 yr — no. (%)†	0	3 (3)
Sex — no. (%)		
Female	6 (7)	21 (23)
Male	84 (93)	69 (77)
Race — no. (%)‡		
Black	11 (12)	25 (28)
White	70 (78)	55 (61)
Other	2 (2)	6 (7)
Not available	7 (8)	4 (4)
Ethnic group — no. (%)‡		
Hispanic or Latino	7 (8)	7 (8)
Not available	62 (69)	47 (52)
Body-mass index§		
Mean	27.3±6.21	28.5±6.5
Range	7.9–49.7	16.9–47.6
Cold ischemic time ≥4 hr — no. (%)	0	25 (28)
Sex mismatch, female donor to male recipient — no. (%)	1 (1)	6 (7)
Recipient		
Age		
Mean — yr	51.3±12.6	55±11.4
Range — yr	20.0–73.1	22.3–73.9
≥65 yr — no. (%)	13 (14)	17 (19)
Sex — no. (%)		
Male	66 (73)	66 (73)
Female	24 (27)	24 (27)
Race — no. (%)‡		
Black	28 (31)	20 (22)
White	62 (69)	66 (73)
Other	0	1 (1)
Not available	0	3 (3)
Ethnic group — no. (%)‡		
Hispanic or Latino	3 (3)	3 (3)
Not available	5 (6)	3 (3)
Heart allocation status — no. (%)¶		
1	1 (1)	5 (6)
2	18 (20)	47 (52)

Table 1. (Continued.)

Characteristic	Donation after Circulatory Death (N=90)	Donation after Brain Death (N=90)
3	16 (18)	15 (17)
4	43 (48)	14 (16)
6	12 (13)	9 (10)
Mechanical circulatory support before transplantation — no. (%)		
Left ventricular assist device	44 (49)	27 (30)
Intraaortic balloon pump	14 (16)	38 (42)
Mechanical ventilation at transplantation — no. (%)	0	0

* Plus–minus values are means ±SD. The total numbers for each group represent the overall population, which comprised the patients who underwent transplantation. Percentages may not total 100 because of rounding.
† Circulatory-death donors were eligible if they were 18 to 49 years of age; age older than 49 was not an exclusion criterion for brain-death donors.
‡ Race and ethnic group were reported by the donor, the recipient, or their legal representative.
§ Body-mass index is the weight in kilograms divided by the square of the height in meters.
¶ The heart allocation status, assigned by the United Network for Organ Sharing, ranges from 1 to 6, with 1 representing the greatest urgency with regard to priority on the transplantation list. Status 5 is assigned to patients waiting for more than one organ, which did not apply to patients in this trial.

after they were assessed with the use of the perfusion system were rising lactate levels despite adequate perfusion limits (in 5 hearts), rising lactate levels and clinician evaluation of contractility (in 5), and results of the evaluation of contractility alone (in 1) (Fig. S3). Patient survival with the original transplanted heart in the overall trial population (90 recipients in each of the two groups) as estimated with the use of the Kaplan–Meier method was 99% (95% CI, 92 to 100) among recipients of a heart from a circulatory-death donor and 92% (95% CI, 84 to 96) among recipients of a heart from a brain-death donor at 30 days, 94% (95% CI, 87 to 97) and 87% (95% CI, 78 to 92) at 6 months, respectively, and 93% (95% CI, 86 to 97) and 85% (95% CI, 76 to 91) at 1 year (Fig. 3). The mean elapsed time from informed consent to transplantation was 24 days among recipients of a heart from a circulatory-death donor and 31 days among recipients of a heart from a brain-death donor.

SAFETY

The mean number of serious adverse events associated with the heart graft that occurred per patient within the first 30 days after transplantation was 0.2 among recipients of a heart from a circulatory-death donor and 0.1 among recipients of a heart from a brain-death donor. When we assessed specific serious adverse events associated with the heart graft, more patients who received a heart from a circulatory-death donor had moderate or severe ISHLT primary graft dysfunction (18 of 80 patients [22%]) than those who received a heart from a brain-death donor (8 of 84 patients [10%]). The incidence of severe ISHLT primary graft dysfunction was 15% among recipients of a heart from a circulatory-death donor as compared with 5% among recipients of a heart from a brain-death donor; however, 2 of 86 patients (2.3%) who received a heart from a brain-death donor had primary graft failure that resulted in retransplantation, as compared with no patients who received a heart from a circulatory-death donor (Table 2 and Table S8).

DISCUSSION

The demand for heart transplantation is high and growing worldwide.[10] Until recently, brain-dead donors were the only donors for heart transplantation because brain death permitted in situ assessment of the viability and function of the heart. Advancements with in situ and ex situ perfusion of donor hearts for transplantation and the development of broad policies to allow the use of organs from donors after circulatory death in selected geographic regions enabled the transplantation of hearts from circula-

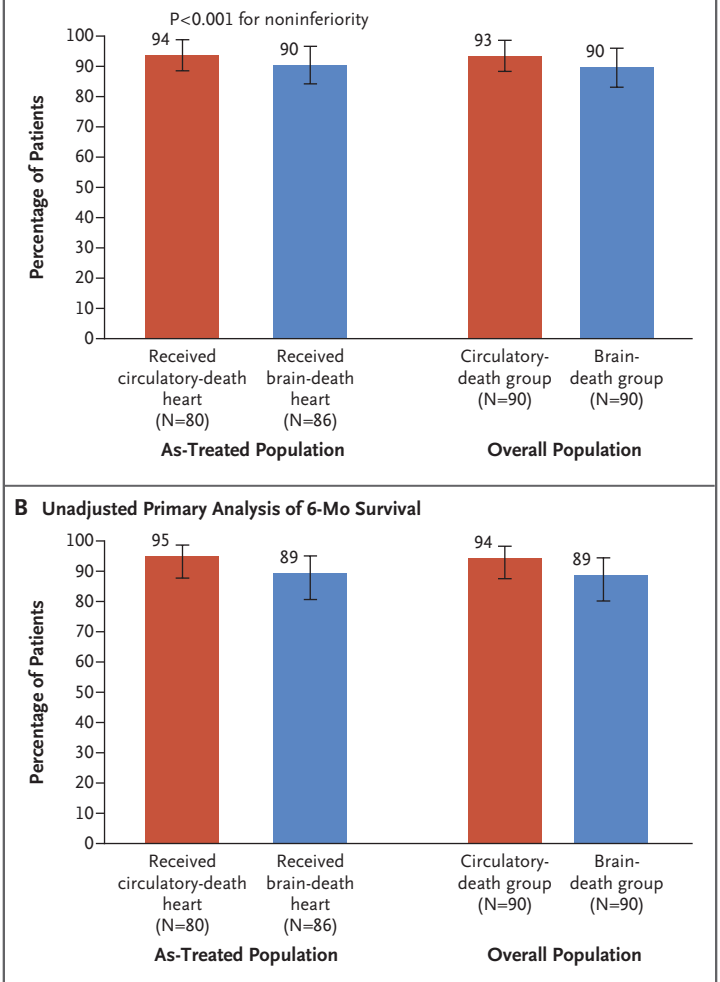


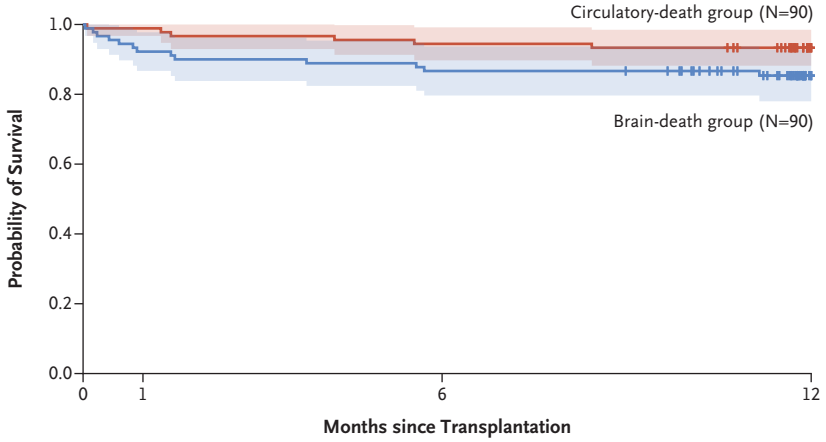
Figure 2. Primary Efficacy Outcome.

Panel A shows the 6-month survival among patients in the as-treated population (patients who remained after patients with protocol violations were excluded) and overall populations (assessed according to the type of donor heart received), with adjustment for prespecified known donor and recipient risk factors. Panel B shows the unadjusted 6-month survival among patients in the same two analysis populations. Among the 86 patients in the as-treated population that received a heart from a brain-death donor, 2 (2%) had primary graft failure that resulted in retransplantation (as compared with no patients in the as-treated population that received a heart from a circulatory-death donor) and were not included in the 6-month outcome analysis.

tory-death donors in adults to begin in 2015.[6-10] We now provide data from a randomized, controlled trial that assessed the clinical outcomes of the transplantation of a heart preserved with the use of a perfusion system after the circulatory death of the donor as compared with a heart preserved with the use of cold static storage after brain death. The trial showed that 6-month patient survival among recipients of a heart from a circulatory-death donor was noninferior to patient survival among recipients of a heart from a brain-death donor. Of note, the overall percentage of hearts from circulatory-death donors that were transplanted after reanimation and assessment with the perfusion system was 89%. The higher incidence of moderate or severe ISHLT primary graft dysfunction in the circulatory-death group than in the brain-death group was expected, given the period of warm ischemia that occurred from the beginning of the agonal phase to the infusion of cold cardioplegia solution. This incidence was consistent with the reported incidence of severe ISHLT primary graft dysfunction associated with transplantation of a heart from a circulatory-death donor, which ranged from 15 to 41%.[11-14] The higher incidence of primary graft dysfunction among recipients of hearts from circulatory-death donors did not affect patient or graft survival at 30 days or 1 year. In fact, the overall patient survival with the original transplanted heart among recipients of hearts from circulatory-death donors was higher than that among recipients of hearts from brain-death donors at 1 year after transplantation. The six donor hearts for which there were protocol deviations of functional warm ischemic time greater than 30 minutes or continuously rising lactate levels did not have primary graft dysfunction.

Since 2019, donation of hearts from circulatory-death donors has been increasing rapidly in the United States, yet donation after circulatory death accounted for only approximately 25% of all organ donations after death in the country in 2020.[15,16] Broad use of hearts from circulatory-death donors for transplantation has not been feasible owing to the limitations of cold storage, which leaves a number of patients on the waiting list without access to heart transplants. The mean waiting time from consent to transplantation was shorter in the circulatory-death group than in the brain-death group. This difference may be clinically important, since the UNOS status of patients in the circulatory-death group was also lower, which suggests that this donor source and perfusion technology may allow for increased organ utilization and matching.

Our trial had potentially meaningful limitations. Owing to the nature of transplantation



Percentage of Patients Included at Follow-up				
Circulatory-death group		99	94	93
Brain-death group		92	87	85
No. at Risk				
Circulatory-death group	90	89	85	62
Brain-death group	90	83	78	36
No. with Censored Data				
Circulatory-death group	—	0	0	22
Brain-death group	—	0	0	41
No. with Event				
Circulatory-death group	—	1	5	6
Brain-death group	—	7	12	13

Figure 3. Patient and Graft Survival through 1 Year after Transplantation (Overall Population).
The outcome of patient survival with the original transplanted heart is shown on Kaplan–Meier curves with 95% confidence intervals in shaded areas. The confidence intervals were not adjusted for multiplicity and should not be used for hypothesis testing. The tick marks indicate censored data.

and organ scarcity and to protect transplantation candidates' places on the waiting lists, the trial design was unblinded and allowed for treatment crossover in case a match with a heart from a brain-death donor was available for a candidate who had been assigned to the circulatory-death group. The investigators were unanimous in agreement that a true prospective, 1:1 randomization to receive a heart from a brain-death donor only or a heart from a circulatory-death donor only would have been unethical because it would have restricted the earliest availability of an otherwise suitable donor. A 3:1 randomization design was chosen with the expectation that most of the circulatory-death group would receive a heart from a brain-death donor, which we expected would have produced a relatively equal number of patients in each group over time. An unexpected availability of hearts from circulatory-death donors, however, resulted in apparent differences between the two groups.

First, there was a faster rate of transplantation of hearts from circulatory-death donors than of hearts from brain-death donors, which led to a more rapid accrual of recipients of hearts from circulatory-death donors. Second, patients in the circulatory-death group, as compared with patients in the brain-death group, tended to be younger, were less often hospitalized at the time of transplantation, and more often had a lower-priority UNOS transplantation status owing to less competition for hearts in the circulatory-death group than in the brain-death group. These differences may have contributed to the apparent improved survival after transplantation with a heart from a circulatory-death donor; however, the potential differences in risk factors associated with donors and recipients were addressed prospectively in the protocol and statis-

Table 2. Serious Adverse Events Associated with the Heart Graft in the 30 Days after Transplantation (As-Treated Population).*

Variable	Recipients of Heart from Circulatory-Death Donor (N=80)	Recipients of Heart from Brain-Death Donor (N=86)†
Occurrence per patient‡		
Mean (95% CI)	0.2±0.42 (0.1–0.3)	0.1±0.39 (0.0–0.2)
Median (range)	0 (0–1)	0 (0–2)
Primary graft dysfunction — no./total no. (%)		
Left or right ventricle, moderate or severe	18/80 (22)	8/84 (10)
Left ventricle, moderate	5/80 (6)	4/84 (5)
Left ventricle, severe	12/80 (15)	4/84 (5)
Right ventricle	1/80 (1)	0/84
Primary graft failure and retransplantation — no./total no. (%)	0/80	2/86 (2)

* Plus–minus values are means ±SD. The as-treated population comprised 180 patients who underwent transplantation (90 with a heart from a circulatory-death donor and 90 with a heart from a brain-death donor) minus 14 (10 recipients of a heart from a circulatory-death donor and 4 recipients of a heart from a brain-death donor) whose transplants involved protocol violations. Confidence intervals were not adjusted for multiplicity and should not be used for hypothesis testing.

† One trial site did not provide data from two recipients of brain-death hearts.

‡ For the number of graft-related serious adverse events, patients with both left ventricle moderate or severe primary graft dysfunction and right ventricle primary graft dysfunction were counted as having had one event.

tical analysis plan to include risk-adjusted analysis for the primary efficacy end point.

The reported results of this trial are short term; long-term results and potential late complications are unknown. Five-year follow-up would permit better understanding of the long-term ramifications of transplantation of a heart obtained from a donor after circulatory death.

This multicenter trial showed that 6-month survival after transplantation with a donor heart that had been reanimated and assessed with the use of extracorporeal nonischemic perfusion after circulatory death was noninferior to 6-month survival after transplantation of a donor heart that had been preserved with the use of cold storage after brain death.

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Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

A data sharing statement provided by the authors is available with the full text of this article at NEJM.org.

APPENDIX

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