BRIEF REPORT

Rapid Recovery of Donor Hearts for Transplantation after Circulatory Death

Aaron M. Williams, M.D.,[1] John M. Trahanas, M.D.,[1] Swaroop Bommareddi, M.D.,[1] Brian Lima, M.D.,[1] Stephen A. DeVries, P.A.-C.,[1] Joshua Lowman, P.A.-C.,[1] Awab Ahmad, M.D.,[1] Eric Quintana, M.D.,[1] Shelley R. Scholl, R.N.,[1] Stacy Tsai, M.D.,[2] Dawn Pedrotty, M.D.,[2] Matthew Warhoover, C.C.P.,[1] Harry Moneypenny, C.C.P.,[1] Stephen Tapia-Ruano, M.D.,[3] Matthew Bacchetta, M.D.,[1] Kelly Schlendorf, M.D.,[2] and Ashish S. Shah, M.D.[1]

SUMMARY

We report a method for the recovery of hearts for transplantation from deceased donors after circulatory death that obviates the need for thoracoabdominal normothermic regional perfusion or ex situ perfusion systems. After death, the aorta is clamped and a flush circuit is established to perform a controlled, extended, ultraoxygenated flush of the donor heart at a mean aortic-root pressure of 80 mm Hg. In the first three reported cases in which this method was used, the hearts were transplanted successfully with normal biventricular function, no evidence of acute cellular or antibody-mediated rejection, and excellent early postoperative outcomes. No adverse events were reported during the perioperative period. By avoiding the limitations of ex situ perfusion platforms as well as the controversial aspects of thoracoabdominal normothermic regional perfusion, this method of heart recovery offers the possibility of broad application.

Author affiliations are listed at the end of the article.

Drs. Williams and Trahanas contributed equally to this article.

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Cardiac allografts from deceased donors after circulatory death (i.e., DCD [donation after circulatory death] cardiac allographs) are typically recovered with either direct procurement and perfusion or with normothermic regional perfusion. Both techniques have been shown to yield acceptable outcomes.[1-3]

The direct procurement and perfusion technique involves the use of commercially available ex situ devices that can be complicated, labor intensive, and associated with an increased risk of primary graft dysfunction. In addition, direct procurement and perfusion does not provide resuscitation for the abdominal organs. As such, many programs prefer the use of normothermic regional perfusion for DCD organ recoveries. Normothermic regional perfusion is more easily adopted, increases organ yield, and has also been shown to have superior outcomes in heart and abdominal organ transplantation as compared with direct procurement and perfusion.[4-8] However, normothermic regional perfusion has been the subject of ethical controversy, and many hospitals, organ-procurement organizations, and countries prohibit its use.[9-11] Thoracoabdominal normothermic regional perfusion is controversial for two reasons: it results in reanimation of the heart in the donor, which critics argue negates the definition of circulatory death, and it involves clamping the aortic-arch vessels to prevent brain perfusion, which some critics

argue creates the possibility of brain perfusion by way of collaterals, although there is no evidence for this in studies in animals or humans.[12-16]

Given that both the direct procurement and perfusion technique and the normothermic regional perfusion technique have inherent limitations, we sought to develop a method that allows for rapid recovery of cardiac allografts to be used in situations in which thoracoabdominal normothermic regional perfusion is not permitted. Our goal was to accomplish rapid recovery of allografts without the use of a commercial ex situ perfusion device while also eliminating the controversial aspects of thoracoabdominal normothermic regional perfusion. Our technique involves the use of a flush circuit to oxygenate 2 liters of a cold preservation solution consisting of packed red cells, del Nido cardioplegia, and other additives. The solution is administered at a mean aortic-root pressure of 80 mm Hg over a period of approximately 10 to 12 minutes. We have named this technique rapid recovery with extended ultraoxygenated preservation (REUP). Here we describe the technique and the early outcomes in the first three recipients of hearts recovered using this method.

CASE REPORTS

The donor information for this case series was collected from UNet (an online database system developed by the United Network for Organ Sharing), and the baseline and perioperative information regarding the recipients was collected from electronic medical records with the approval of the Vanderbilt University Medical Center institutional review board, which allows for the collection and reporting of deidentified patient data. Full characteristics of the donors and recipients are shown in Table 1. The representativeness of the population of patients with heart failure is shown in Table S1 in the Supplementary Appendix (available with the full text of this article at NEJM.org). In all three cases, thoracoabdominal normothermic regional perfusion was not permitted by the donor hospital or by the organ-procurement organization.

RECIPIENT AND DONOR 1

A 40-year-old man with advanced nonischemic cardiomyopathy and heart failure caused by sarcoidosis and with end-stage renal disease caused by hypertension and diabetes mellitus was listed for dual heart and kidney transplantation. An echocardiogram revealed a left ventricular ejection fraction of 25%, a pulmonary vascular resistance (PVR) of 2.2 Woods units (normal value, 0 to 2.0), a cardiac index of 1.8 liters per minute per square meter of body-surface area (normal, 2.4 to 4.0), and a maximal oxygen consumption of 8.9 ml per kilogram of body weight per minute (normal, 27 to 50). The donor was a 16-year-old boy who had sustained gunshot wounds to the anterior neck and had permanent loss of neurologic function. An echocardiogram showed a structurally normal heart with normal biventricular function and a predicted heart mass (a ratio that conveys the appropriate donor-to-recipient size match in heart transplantation) of 0.84. The normally accepted range of predicted heart mass is between 0.8 and 1.2, but excellent outcomes have been reported in patients when the predicted heart mass is outside this range.[17]

RECIPIENT AND DONOR 2

A 60-year-old man with nonischemic cardiomyopathy, heart failure, and recurrent ventricular arrhythmias despite medical management and several catheter ablations for his arrhythmias was listed for heart transplantation. An echocardiogram revealed a left ventricular ejection fraction of 25%, a PVR of 1.3 Woods units, and a cardiac index of 2.0 liters per minute per square meter. The donor was a 31-year-old man who had had a drug overdose, had received 20 minutes of cardiopulmonary resuscitation, and had permanent loss of neurologic function. The echocardiogram revealed normal biventricular function and structurally normal valves. The predicted heart mass was 0.76.

RECIPIENT AND DONOR 3

A 56-year-old man with ischemic cardiomyopathy and chronic kidney disease (stage 4) underwent placement of a Heartmate III (Abbott) left ventricular assist device in 2019 as a bridge to transplantation. He was listed for heart and kidney transplantation. An echocardiogram revealed a left ventricular ejection fraction of 5 to 10%, mildly reduced right heart function, and a PVR of 1.6 Woods units. The donor was a 25-year-old man who had sustained a gunshot wound to the head and had undergone external ventricular drain placement, with subsequent permanent loss of neurologic function. An echocardiogram revealed nor-

Table 1. Characteristics of the Recipients and Donors at Baseline.*

Characteristic	Recipient 1	Recipient 2	Recipient 3	Donor 1	Donor 2	Donor 3
Age — yr	40	60	56	16	31	25
Sex	Male	Male	Male	Male	Male	Male
Body-mass index†	35.5	31.6	20.8	28.4	24.8	24.7
Blood type	A positive	A positive	A positive	A positive	A positive	A positive
Donor cause of death	—	—	—	Head trauma from gunshot wound	Anoxia	Head trauma from gunshot wound
Donor CPR duration — min	—	—	—	41	17	NA
Diabetes mellitus	Type 2, insulin dependent	Type 2, insulin dependent	No	No	No	No
Hypertension	Yes	No	Yes	No	No	No
Donor previous MI	—	—	—	No	No	No
Donor chest trauma	—	—	—	No	No	Yes
Smoking history — pack-yr	5	None	20	None	None	8
Donor HBV status	—	—	—	Negative	Negative	Negative
Donor LVEF — %	—	—	—	60	60–65	70
Donor distance from transplantation center — nautical miles	—	—	—	222.72	523.47	221.20
Recipient PHM ratio‡	0.84	0.76	0.93	—	—	—
Recipient heart-failure cause	NICM (sarcoidosis)	NICM	ICM	—	—	—
Recipient chronic kidney disease	Yes (stage 5)	No	Yes (stage 4)	—	—	—
Recipient wait-list status§	4	6	4	—	—	—
Recipient preoperative MCS	None	None	LVAD HM3	—	—	—
Recipient multiorgan transplant (other organ)	Yes (kidney)	No	Yes (kidney)	—	—	—
Recipient previous sternotomies — no.	0	0	1	—	—	—

* CPR denotes cardiopulmonary resuscitation, HBV hepatitis B virus, HM3 Heartmate 3, ICM ischemic cardiomyopathy, LVAD left ventricular assist device, LVEF left ventricular ejection fraction, MCS mechanical circulatory support, MI myocardial infarction, NA not applicable (CPR not administered), and NICM nonischemic cardiomyopathy.
† The body-mass index is the weight in kilograms divided by the square of the height in meters.
‡ The predicted heart mass (PHM) is a ratio that conveys the appropriate donor-to-recipient size match in heart transplantation. The normally accepted range of predicted heart mass is between 0.8 and 1.2.
§ Status on a wait list for transplantation ranges from 1 to 6, with higher numbers indicating less urgent need.

Table 2. Organ Recovery.*

Organ	Organ or Organs Recovered? (Procurement Method)		
	Donor 1	Donor 2	Donor 3
Heart	Yes (REUP)	Yes (REUP)	Yes (REUP)
Lungs	No	No	Yes (DPP)
Liver	Yes (DPP)	Yes (DPP)	Yes (A-NRP)
Pancreas	No	No	Yes (A-NRP)
Right kidney	Yes (DPP)	Yes (DPP)	Yes (A-NRP)
Left kidney	Yes (DPP)	Yes (DPP)	Yes (A-NRP)

* A-NRP denotes abdominal normothermic regional perfusion, DPP direct procurement and perfusion, and REUP rapid recovery with extended ultra-oxygenated preservation.

mal biventricular function and valves. The predicted heart mass was 0.93.

ORGAN RECOVERY

Before withdrawing life-sustaining care, we constructed our flush circuit consisting of a standard normothermic regional perfusion circuit along with an additional reservoir and a heater and cooler.[18] The extracorporeal circuit was primed with 2 units of crossed packed red cells, 500 cc of PlasmaLyte crystalloid solution, and 2 liters of del Nido cardioplegia solution (13 mmol of bicarbonate per liter). We also added heparin (30,000 units), mannitol (3125 mg), rocuronium (50 mg), solumedrol (125 mg), ciprofloxacin (50 mg), cefazolin (250 mg), *N*-acetyl-L-cysteine (30 g), 25% albumin (50 ml), a multivitamin formula, and levothyroxine (50 mg). After the components were mixed, the preservation solution was oxygenated through the extracorporeal circuit, and sweep gas at a rate of 2 liters per minute and 100% fraction of inspired oxygen (FiO_2) was maintained for 5 minutes. Samples were drawn to test arterial blood gases, and bicarbonate was added as needed to target a pH level of 7.5, bicarbonate level of 30 mmol per liter, and a partial pressure of oxygen above 500 mm Hg. The heater and cooler ensured a flush temperature of 4°C.

A final declaration of death in the context of DCD was made after a 5-minute standoff period. A sternotomy was performed, and the left and right heart were vented with incisions in the right pulmonary veins or the interatrial groove and in the inferior vena cava. A cross-clamp was placed across the ascending aorta in the same manner as during a standard procurement, which eliminates any possibility of systemic or brain perfusion. A bifurcated aortic-root cardioplegia needle was placed proximal to the cross-clamp, and the root was manually deaerated. A flush line was placed on one limb of the root needle, and a pressure line was placed on the other. We delivered 2 liters of the extended oxygenated flush through the aortic-root needle at a mean pressure of 80 mm Hg. This correlated to a flow of approximately 200 ml per minute and thus required approximately 10 to 12 minutes to complete. During the flush, 10°C saline was placed on the heart. A donor cardiectomy was then performed in standard fashion, and the heart was placed in a 10°C cooler for transport.[19] There were no cases in which this technique was attempted and the donor heart was subsequently discarded. The time from the first declaration of death to flush ranged from 8 to 10 minutes.

Full details regarding organ recovery are shown in Table 2. Other organs that were recovered included the lungs, liver, pancreas, and kidneys. Abdominal organs were recovered by means of direct procurement and perfusion or rapid recovery in two of the donors and with the use of abdominal normothermic regional perfusion in the third donor.

HEART TRANSPLANTATIONS

Recipients underwent sternotomy with central aortic and bicaval venous cannulation. After cardiopulmonary bypass was initiated, recipient cardiectomy was performed. The donor heart was inspected for normal valve structures. The donor heart anastomoses were then performed in the following order: left atrium, inferior vena cava, pulmonary artery, and aorta. After the aorta was anastomosed, the aortic cross-clamp was removed, and the superior vena cava anastomosis was performed while the heart was being reperfused. After reperfusion, patients were weaned from cardiopulmonary bypass. Intraoperative echocardiography revealed normal biventricular function in recipients 1 and 2 and normal left ventricular and mildly depressed right ventricular function in recipient 3. Epicardial pacing wires and mediastinal and pleural chest tubes were placed, and the chests were closed. Intraoperative details are shown in Table 3.

Table 3. Intraoperative Details and Postoperative Outcomes.

Variable	Recipient 1	Recipient 2	Recipient 3
Intraoperative details*			
Cardiopulmonary bypass duration — min	107	153	164
Time from donor cross-clamp placed to recipient cross-clamp removed — min	235	240	204
Left ventricular ejection fraction after cardiopulmonary bypass — %	>55	>55	55
Right ventricular function after cardiopulmonary bypass	Normal	Normal	Mildly depressed
Postoperative outcomes			
Mean lactate level — mmol/liter	1.6	1.5	2.3
Mechanical circulatory support	None	None	None
Severe primary graft dysfunction within 24 hr†	No	No	No
Cardiac index — liters/min/m^2			
24 Hr after transplantation	3.3	2.9	3.5
72 Hr after transplantation	3.1	3.3	3.6
Inotrope score‡			
24 Hr after transplantation	13	8	14.8
72 Hr after transplantation	6	5	3
Left ventricular ejection fraction — %			
7 Days after transplantation	65	65	65
120 Days after transplantation	65	65	65
Right ventricular function			
7 Days after transplantation	Normal	Normal	Normal
120 Days after transplantation	Normal	Normal	Normal
Acute cellular rejection 14 and 120 days postoperatively	None	None	None
Antibody-mediated rejection 14 and 120 days postoperatively	None	None	None

* Shown are results for the period from the start of anesthesia administration to the end of anesthesia administration.
† Primary graft dysfunction was defined according to Kobashigawa et al.[20]
‡ The inotrope score is an assessment of hemodynamic stability calculated as follows: dopamine dose + dobutamine dose + amrinone dose + (15 × milrinone dose) (100 × epinephrine dose) + (100 × norepinephrine dose), with all doses measured in micrograms per kilogram of body weight per minute. Scores have a lower limit of 0 and no upper limit.

POSTOPERATIVE OUTCOMES

Postoperatively, all three recipients recovered well and had uncomplicated stays in the intensive care unit. The cardiac index in the recipients ranged from 2.8 to 4.4 liters per minute per square meter during the first postoperative week, and all three were weaned from ionotropic drips by day 7 after transplantation. Follow-up postoperative echocardiography revealed normal biventricular function. Recipient 1 received temporary continuous renal-replacement therapy followed by intermittent hemodialysis but later had full renal recovery. All the patients received a standard immunosuppression regimen that included prednisone, mycophenolate mofetil, and tacrolimus. The recipients underwent postoperative serial echocardiography and right heart catheterizations with biopsy. They continued to have normal biventricular function and no evidence of acute cellular or antibody-mediated rejection as of 6 months after heart transplantation. Full postoperative outcomes are shown in Table 3.

DISCUSSION

We showed that heart recovery from a donor after circulatory death can be performed safely with the use of our technique without thoracoabdomi-

nal normothermic regional perfusion or commercial ex situ perfusion platforms. This brief report of outcomes in the first three recipients of hearts recovered with the use of this technique has several points worth highlighting.

First, these three cases lend support to previous translational work that suggests that there is a window of reversibility of the cellular-death process that commences after circulatory death. When human hearts recovered for research after circulatory death were flushed with 1 liter of del Nido cardioplegia, the hearts had minimal myocardial edema, inflammation, and injury despite a warm ischemic time of 20 minutes and cold static storage time of 4 hours.[21] In addition, laboratory data have suggested that DCD hearts have the potential to be recovered without thoracoabdominal normothermic regional perfusion or ex situ perfusion systems. Direct transplantation of DCD cardiac allografts has been shown in nonhuman primate models,[22] and rapid recovery of DCD donor hearts has been attempted previously, with success in pediatric patients.[23] There are also reports of the use, without success, of a crystalloid-only nonoxygenated cardioplegic technique for donor heart arrest in animal models.[24] Our protocol differs from these earlier techniques in that our preservation solution is a new mixture that is oxygenated in an effort to restore the energy debt incurred by the myocardium during the process of donor death. We hypothesized that substrate replenishment is essential in DCD heart recovery and preservation, which is the premise for this technique. In addition, our method uses temperature- and pressure-based regulation of the flush, targeting a temperature of 4°C and a mean aortic pressure of 80 mm Hg. The extended duration of the flush allows for physiologic coronary perfusion to prevent endothelial damage that may occur with shorter duration high-pressure infusion.[22] Unlike the pediatric series in which donors and recipients were colocated to minimize transport and cold ischemia times,[23] the use of preservation at 10°C allowed for a total ischemic time of 240 minutes (the longest ischemic time reported for a rapid-recovery DCD cardiac allograft) and is a technique that has not previously been used in an adult heart-transplant recipient.

Second, our findings suggest that the reanimation of a donor heart with thoracoabdominal normothermic regional perfusion or ex situ perfusion systems may be unnecessary. We used del Nido cardioplegia as the base for our preservation solution to ensure that the heart remained in a relaxed, arrested state. Thus, by deliberately preventing cardiac reanimation, we not only avoided additional myocardial energy depletion, but also circumvented the ethical dilemmas associated with reanimation of the donor heart in situ. This process differs from both normothermic regional perfusion and the current commercially available ex situ device, which both actively seek to reanimate the donor allografts. At present, ex situ devices provide an imperfect physiological assessment based on visual assessment and lactate levels, which remain difficult to interpret. One practical detriment to our technique is that the donor allograft must be transplanted after circulatory death with no opportunity to perform any additional physiological evaluation or to visualize allograft function. However, donor heart recovery appears to be moving away from reanimation, because hypothermic oxygenated perfusion systems have been used for DCD heart recovery with excellent outcomes.[25] As such, reanimation and physiological assessment may not be necessary for high-quality allografts.

Currently, commercial ex situ perfusion systems are associated with considerable financial cost. Our technique simplifies the recovery process, has substantial economic advantages, and could improve access to DCD cardiac allografts. As the use of heart transplantation expands worldwide, this technique is feasible in regions that have limited resources. It can be performed with any perfusion system that is able to oxygenate banked blood, mix a solution with additional agents, and servoregulate the delivery of cold solution over time. A system capable of completing these steps can be created easily by a perfusionist, but as with any DCD heart recovery, an experienced surgical and perfusion team is necessary to recover the heart successfully.

Although normothermic regional perfusion is associated with similar cost savings, the ethical concerns surrounding the use of thoracoabdominal normothermic regional perfusion currently prevent widespread application of this technique both in the United States and throughout the world. Our technique flushes oxygenated preservation solution to the donor heart only, without reanimation of the heart and without systemic or

brain perfusion, and does not require clamping of the aortic-arch vessels. Thus, the technical aspects of thoracoabdominal normothermic regional perfusion that arouse ethical concerns are averted with our technique. However, although the REUP technique resuscitates the cardiac allograft, it does not resuscitate abdominal organs, as thoracoabdominal normothermic regional perfusion is able to do, and requires that abdominal organs be recovered by direct procurement and perfusion or abdominal normothermic regional perfusion. Our technique does not affect the recovery of any other organ. At present, the REUP technique has applicability in well-selected donors (18 to 40 years of age) with acceptable cold ischemic times (≤4 hours). Although our group uses thoracoabdominal normothermic regional perfusion as a first-line approach, the REUP technique can be used when thoracoabdominal normothermic regional perfusion is not permitted by the organ-procurement organization, hospital, or family of the donor.

Although the recipients of the DCD hearts that are recovered with the use of our technique have had excellent early postoperative outcomes, this report represents only three cases, and further studies are needed to validate this technique. By avoiding the ethical dilemmas associated with thoracoabdominal normothermic regional perfusion and the excessive costs of commercial ex situ systems, our technique may allow for the successful recovery and transplantation of well-selected DCD donor hearts at centers and regions that have not previously had access to DCD cardiac allografts.

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.

AUTHOR INFORMATION

[1] Department of Cardiac Surgery, Vanderbilt University Medical Center, Nashville; [2] Department of Cardiology, Vanderbilt University Medical Center, Nashville; [3] Department of Cardiac Anesthesia, Vanderbilt University Medical Center, Nashville.

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