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Donation After Circulatory Death Cardiac Recovery Technique: Single-Center Observational Outcomes



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ABSTRACT

BACKGROUND Recovery of hearts from donation after circulatory death donors has been performed either with direct procurement and perfusion (DPP) using the TransMedics Organ Care System or with normothermic regional perfusion (NRP) with subsequent cold storage. It remains unclear which of these 2 strategies yields optimal posttransplant outcomes.

METHODS All heart transplant recipients from donors after circulatory death donors at the Vanderbilt University Medical Center (Nashville, TN) were reviewed (February 2020 to January 2023). Recipients were stratified into an NRP or DPP cohort. All DPP recoveries were performed using the TransMedics Organ Care System. The key outcome was severe primary graft dysfunction at 24 hours, defined by the need for postoperative extracorporeal membrane oxygenation.

RESULTS A total of 118 hearts were transplanted (NRP, 87; DPP, 31). Donors recovered using NRP were younger (25 years [interquartile range {IQR}, 21–31 years] vs 31 years [IQR, 24–37 years]; $P = .008$) and had shorter distance traveled (292 miles [158–516 miles] vs 449 miles [IQR, 248–635 miles]; $P = .02$). Recipient preoperative risk factors were similar between the groups. There was no difference in the incidence of severe primary graft dysfunction at 24 hours (NRP, 5.8%; and DPP, 12.9%; $P = .24$). However, ejection fraction at 7 days after transplantation was higher in the NRP group (65% [IQR, 60%–65%] vs 60% [IQR, 60%–68%]; $P = .005$). There was no difference in inotrope scores at 24 hours ($P = 1.00$) or 72 hours ($P = .87$) or in 30-day (NRP, 95% vs DPP, 97%; $P = .75$) and 1-year (NRP, 94% vs DPP, 86%; $P = .19$) survival.

The Supplemental Tables can be viewed in the online version of this article [<https://doi.org/10.1016/j.athoracsur.2024.07.033>] on <http://www.annalsthoracicsurgery.org>.

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CONCLUSIONS NRP and DPP strategies for recovery of cardiac allografts yield comparable early allograft outcomes. Future studies are needed to confirm these findings in larger prospective cohorts.

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Abbreviations and Acronyms

DCD = donation after circulatory death
DPP = direct procurement and perfusion
ECMO = extracorporeal membrane oxygenation
IMPACT = Index for Mortality Prediction After Cardiac Transplantation
IQR = interquartile range
LVEF = left ventricular ejection fraction
NRP = (thoracoabdominal) normothermic regional perfusion
OCS = Organ Care System (TransMedics)
PGD = primary graft dysfunction
VIS = vasoactive inotrope score

In recent years, donation after circulatory death (DCD) donors have become an increasingly important source of organs for heart transplantation. Early modern use of DCD hearts began in the United Kingdom, continental Europe, and Australia,^{1–4} but it has been rapidly increasing in the United States since 2019.^{5,6} Recovery of DCD hearts generally takes place using 1 of 2 strategies: direct procurement and perfusion (DPP) using ex situ machine perfusion (Organ Care System [OCS] Heart System, TransMedics) or thoracoabdominal normothermic regional perfusion (NRP) followed by standard cold storage.^{6–10} Although DPP is more commonly used because it is commercially available and has fewer associated ethical concerns, NRP followed by cold storage has been increasingly used and offers the benefits of evaluation of the heart in a fully loaded physiologic state,^{6,10–13} improved abdominal allograft quality,^{14–18} and decreased equipment cost.¹⁹

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Early results from DCD transplantation using DPP and NRP have been encouraging, and there are several studies comparing DCD allograft performance with that of brain-dead donors. In a randomized controlled trial, recipients of DCD hearts recovered using DPP had no significant difference in survival to 6 months compared with recipients of donation after brain death hearts recovered using static cold storage.^{5,20} Additionally,

an international multicenter analysis of recipient outcomes demonstrated that NRP cardiac allografts were noninferior to those recovered from brain-dead donors.²¹ At our institution (Vanderbilt University Medical Center, Nashville, TN), we use both DPP and NRP for DCD heart recovery, and we have demonstrated no significant differences in 1-year survival between DCD and donation after brain death recoveries.²²

Recently, database analyses have compared survival of cardiac allografts recovered with NRP with DPP.^{23,24} These analyses have shown no difference in 1-year survival outcomes; however, these investigators have noted the need for granular single-center data, specifically with regard to early postoperative outcomes, sensitization, and primary graft dysfunction (PGD). Here we report observed outcomes at our center among our DCD recipients on the basis of whether DPP or NRP was used for organ retrieval.

PATIENTS AND METHODS

STUDY DESIGN. A retrospective review of all adult (aged ≥ 18 years) DCD heart transplant recipients (single and multiorgan) was performed at our institution between February 2020 and January 2023, and patients were stratified into DPP and NRP cohorts according to the method of organ recovery. DPP was preferentially used when the total cold ischemic time was expected to exceed 4 hours or when recovering organs at centers or with organ procurement organizations that did not allow for NRP. NRP was used in all other cases. Our NRP protocols have been previously described in the literature.⁶

Data on recipient, donor, and perioperative characteristics, as well as early allograft outcomes and survival, were extracted from the electronic medical record. The donor variable “case hours” was recorded as hours on the clock for staff for the recovery. Obesity was defined as a body mass index greater than or equal to 30 kg/m², consistent with the definitions established by the US Centers for Disease Control and Prevention and the World Health Organization.

Recipient characteristics were compared on the basis of the Index for Mortality Prediction After Cardiac Transplantation (IMPACT) score, a validated measure of risk of mortality after cardiac transplantation.²⁵ Key intraoperative variables included the following: warm ischemic time 1, defined as the duration between the onset of the agonal phase (systolic blood pressure less than 50 mm Hg) and the initiation of either the preservation solution flush or NRP; total preservation time, defined as the time from the agonal phase to reperfusion in the recipient; and warm ischemic time 2, defined as the duration between the first stitch and reperfusion in the recipient (time to sew in the allograft).

The key outcome was the incidence of severe primary graft dysfunction (PGD) at 24 hours, defined using the International Society for Heart and Lung Transplantation consensus definition.²⁶ Additional outcomes included the vasoactive inotrope score (VIS) at 24 and 72 hours, the left ventricular ejection fraction (LVEF) at 1 week, and 30-day and 1-year survival.

This study was approved by the Institutional Review Board at Vanderbilt University Medical Center.

STATISTICAL ANALYSIS. Analysis was conducted in R software (R Foundation), by using 2-tailed tests with an α level of 0.05. Given the small sample

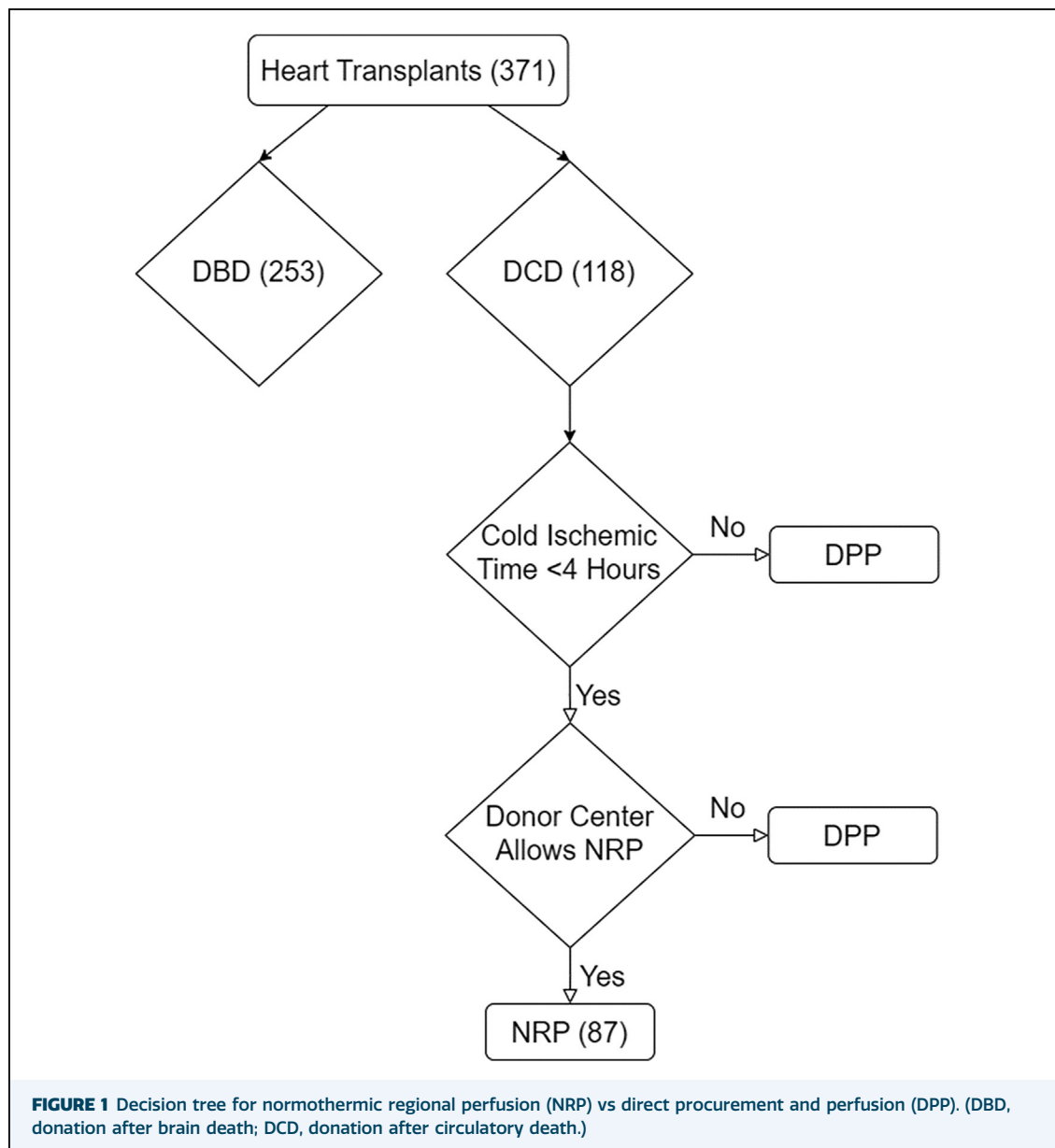


TABLE 1 Donor Characteristics

Characteristics	All N = 118 (100%)	NRP n = 87 (73.7%)	DPP n = 31 (26.3%)	P Value
Age, y	26 (21.25–32.75)	25 (21–31.5)	31 (24.5–37)	.019
Female sex	13 (11)	9 (10.3)	4 (12.9)	.742
Hepatitis C NAT+	8 (6.78)	7 (8.05)	1 (3.23)	.679
Body mass index, kg/m ²	26.1 (21.9–29.8)	26 (21.9–30.1)	26.4 (23.4–28.6)	.781
PHM ratio	0.946 (0.84–1.09)	0.959 (0.84–1.08)	0.911 (0.83–1.07)	.423
Inotropic support	2 (1.69)	2 (2.3)	0 (0)	1.000
Left ventricular EF	60 (55–66)	61 (59.5–70)	60 (55–65)	.201
Donor distance, nautical miles	335 (158–532)	292 (158–516)	449 (248–635)	.017
Case hours, h	9 (8–11)	9 (8–10)	11 (9–12)	<.001

Values are median (interquartile range [Q1–Q3]) or count (%). DPP, direct procurement and perfusion; EF, ejection fraction; NAT+, nucleic acid amplification testing positive; NRP, normothermic regional perfusion; PHM, predicted heart mass.

TABLE 2 Recipient Characteristics

Characteristics	All N = 118 (100%)	NRP n = 87 (73.7%)	DPP n = 31 (26.3%)	P Value
Age at transplantation, y	58 (46.5–64)	58 (46–64)	59 (49–64)	.917
Female sex	20 (16.9)	16 (18.4)	4 (12.9)	.586
Body mass index, kg/m ²	30.4 (26.6–34.6)	31.1 (26.2–35)	29.2 (27.5–33.5)	.509
Previous durable LVAD	41 (34.7)	29 (33.3)	12 (38.7)	.662
Previous sternotomy	66 (55.9)	48 (55.2)	18 (58.1)	.835
Cerebrovascular accident	16 (13.6)	11 (12.6)	5 (16.1)	.760
DLCO, mL/min mm Hg	62.5 (47–74)	65 (47–75.1)	56 (48.5–72)	.814
Pulmonary hypertension	57 (48.3)	40 (46)	17 (54.8)	.412
Preoperative hemodynamics				
Central venous pressure, RAP mm Hg	8 (5–13)	8 (5–13)	8 (5.5–12.5)	.550
Mean pulmonary artery systolic pressure, mm Hg	36 (27–45)	36 (27–45)	34 (26.5–47.5)	.865
Pulmonary vascular resistance, WU	2 (1.4375–2.7)	2 (1.46–2.5)	2.08 (1.29–2.9)	.698
CKD stage				.888
0	0 (0)	0 (0)	0 (0)	
1	2 (1.69)	2 (2.3)	0 (0)	
2	50 (42.4)	37 (42.5)	13 (41.9)	
3	59 (50)	42 (48.3)	17 (54.8)	
ESRD 4	7 (5.93)	6 (6.9)	1 (3.23)	
Cirrhosis	7 (5.93)	4 (4.6)	3 (9.68)	.377
Malnutrition				.950
None	92 (78)	68 (78.2)	24 (77.4)	
Mild	20 (16.9)	14 (16.1)	6 (19.4)	
Moderate	4 (3.39)	3 (3.45)	1 (3.23)	
Severe	2 (1.69)	2 (2.3)	0 (0)	
Obesity	62 (52.5)	48 (55.2)	14 (45.2)	.404
Diabetes	44 (37.3)	31 (35.6)	13 (41.9)	.666
IMPACT score	7.5 (5–10)	7 (5–10)	8 (5–10)	.494
IMPACT score categories				.959
0–2.9	12 (10.2)	9 (10.3)	3 (9.68)	
3–5.9	25 (21.2)	19 (21.8)	6 (19.4)	
6–9.9	48 (40.7)	36 (41.4)	12 (38.7)	
≥10	33 (28)	23 (26.4)	10 (32.3)	
PRA class I or II >50%	4 (3.39)	3 (3.45)	1 (3.23)	1.000
PRA class I >50%	2 (1.69)	2 (2.3)	0 (0)	1.000
PRA class II >50%	4 (3.39)	3 (3.45)	1 (3.23)	1.000
Both PRA class I and II >50%	2 (1.69)	2 (2.3)	0 (0)	1.000

Values are median (interquartile range [Q1–Q3]) or count (%). CKD, chronic kidney disease; DLCO, diffusing capacity of lung for carbon monoxide; DPP, direct procurement and perfusion; ESRD, end-stage renal disease; IMPACT, Index for Mortality Prediction After Cardiac Transplantation; LVAD, left ventricular assist device; NRP, normothermic regional perfusion; PRA, panel reactive antibody; RAP, right atrial pressure; WU, Wood units.

TABLE 3 Intraoperative Characteristics

Characteristics	All N = 118 (100%)	NRP n = 87 (73.7%)	DPP n = 31 (26.3%)	P Value
Total preservation time, min	215 (176–245)	212 (178–238)	296 (96.2–328)	.014
Warm ischemic time 1 (agonal to preservation flush or NRP), min	21 (17–28.5)	21 (17–29.5)	19 (16–23.2)	.177
Warm ischemic time 2 (sewing time), min	44.5 (30–59)	49 (31–59)	34 (29.5–49.5)	.040
Cardiopulmonary bypass time, min	148 (116–173)	147 (122–172)	148 (106–180)	.746
Intraoperative PRBC transfusion, units	3 (1–5)	3 (0.5–5)	3 (1–5)	.731
Intraoperative LVEF, %	55 (55–55)	55 (55–55)	55 (55–55)	.119

Values are median (interquartile range [Q1–Q3]). DPP, direct procurement and perfusion; LVEF, left ventricular ejection fraction; NRP, normothermic regional perfusion; PRBC, packed red blood cell.

size in the DPP group and the inability to confirm a normal distribution confidently, continuous variables were compared with Wilcoxon rank sum tests and are presented as medians with interquartile ranges (IQRs). LVEF was considered a continuous variable. Categorical variables were compared with Fisher exact tests and are presented as counts and percentages. Given that DPP was preferentially used in cases of extended travel distance, multivariable adjustment was used to adjust for donor distance. The small sample size also limited the inclusion of additional variables in multivariable analysis.

RESULTS

During the study period, 371 adult heart transplantations were performed, including 118 from DCD donors. Of these, 87 (73.7%) DCD hearts were recovered with NRP, and 31 (26.3%) DCD hearts were recovered using DPP (Figure 1). There was 1 intraoperative recipient mortality in the NRP group.

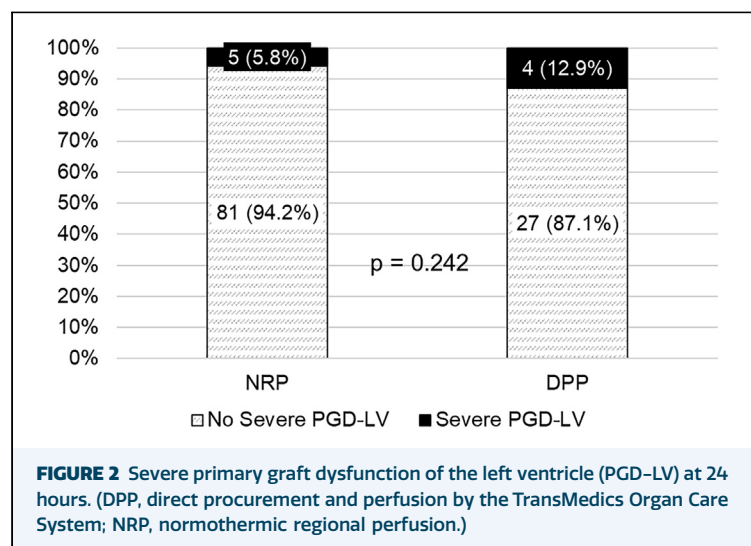
Compared with donors recovered using DPP, donors recovered using NRP were younger (25 years [IQR, 21–31.5 years] vs 31 years [IQR, 24.5–37 years]; $P = .019$). In addition, NRP donors were located at centers geographically closer to ours such that distance traveled for recovery was shorter (292 nautical miles [IQR, 158–516 nautical miles] vs 449 nautical miles [IQR, 248–635 nautical miles]; $P = .017$). There were no significant differences between cohorts in donor sex, predicted heart mass ratio, or prerecovery LVEF or right ventricular function (Table 1).

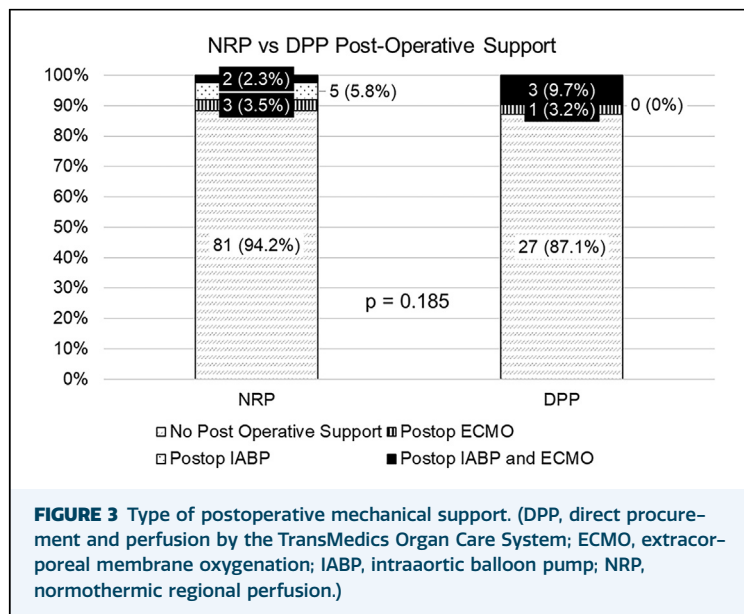
The median recipient IMPACT score in the NRP group was 7 (IQR, 5–10) vs 8 (IQR, 5–10) in the DPP group ($P = .494$). There were no significant differences between cohorts in recipient age, sex, body mass index, prevalence of chronic kidney disease, presence of left ventricular assist device,

history of previous sternotomy, time on the waitlist, pulmonary vascular resistance, or sensitization (Table 2, Supplemental Table 1). There were significant differences in waitlist status between the 2 groups ($P = .014$). The NRP group had more patients with preoperative status 1 and 3, whereas the DPP group had more patients with preoperative status 2 (Supplemental Table 1).

Consistent with our institutional use of NRP and DPP (Figure 1), NRP hearts had a shorter total preservation time at 212 minutes compared with 296 minutes for the DPP group ($P = .014$). NRP hearts were associated with a 15-minute longer period of implant time (warm ischemic time 2), with NRP at 49 minutes (IQR, 31–59) vs DPP at 34 (IQR, 29.5–49.5) minutes ($P = .014$). The warm ischemic time 1 (agonal to preservation flush or NRP), cardiopulmonary bypass time, and intraoperative transfusion requirements were all similar between the groups (Table 3).

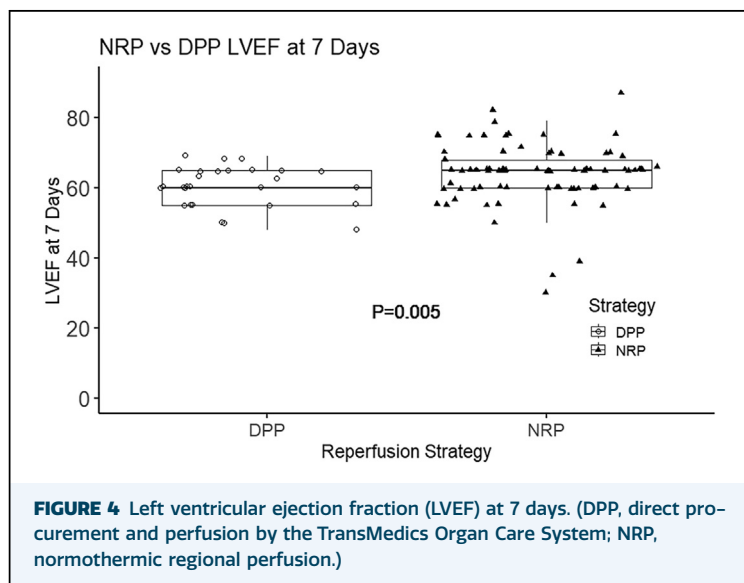
There was no difference in the rate of severe PGD requiring extracorporeal membrane





oxygenation (ECMO) at 24 hours (5.8% of NRP and 12.9% of DPP recipients; $P = .24$) (Figure 2). After controlling for donor distance, the findings remained similarly insignificant (odds ratio, 1.70; $P = .342$; 95% CI, 0.55-4.97). The type of mechanical support required was not different between the groups and is illustrated in Figure 3. The duration of mechanical support required is provided in Supplemental Table 2.

There was no difference between groups in VIS at 24 hours (NRP, 11.8 [IQR, 8.1-17.4] vs DPP, 12.5 [IQR, 8.7-15.3]; $P = .995$) and 72 hours (NRP, 5.2 [IQR, 3.1-10.0] vs DPP, 5.0 [IQR, 5.0-9.9]; $P = 0.868$). At 7 days after transplantation, LVEF was higher



in the NRP group (65% [IQR, 60%-65%] vs 60% [IQR, 60%-68%], $P = .005$) (Figure 4). There was no difference in 30-day or 1-year survival with survival at 1 year in the NRP group of 93.9% (95% CI, 88.9%-99.3%) compared with 86.1% (95% CI, 74.2%-99.8%) in the DPP group ($P = .193$) (Figure 5). Causes of death are provided in Supplemental Table 3.

There was no difference in other measured recipient outcomes, including peak post-transplantation lactate levels, need for permanent pacemaker, time to extubation, need for new tracheostomy, need for new renal replacement therapy, rejection, or intensive care unit and hospital length of stay (Table 4).

COMMENT

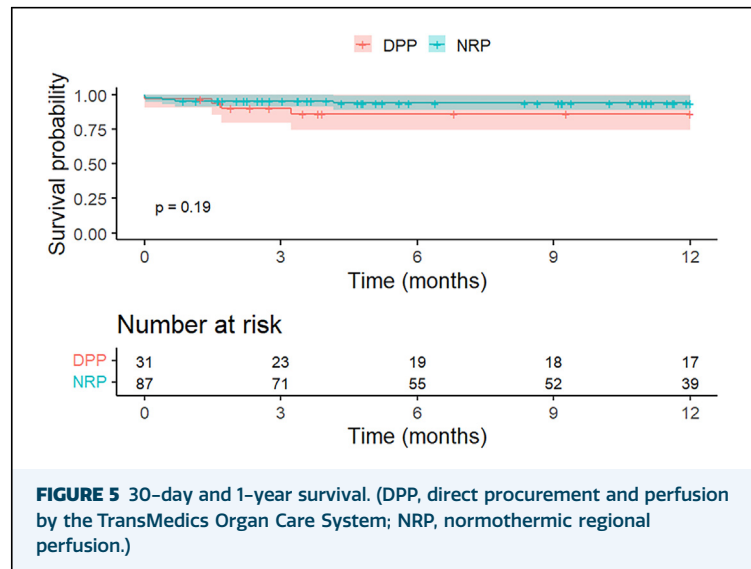
Our institution has accrued extensive experience in DCD heart transplantation and is 1 of only a handful of centers using both DPP and NRP with standardized institutional DCD protocols. In this single-center retrospective analysis, we observed no evidence of a statistically significant difference in posttransplantation clinical outcomes between patients whose allografts were recovered by NRP and patients whose allografts were recovered by DPP protocols at our center. We found no significant difference in the key outcome of severe PGD. There was also no difference in VIS at 24 or 72 hours, or in 30-day or 1-year mortality. These findings are consistent with other works that have compared survival outcomes between DPP and NRP by using the Scientific Registry of Transplant Recipients and United Network for Organ Sharing databases and found no difference.^{23,24} We did observe a significantly higher LVEF at 7 days in the NRP cohort, 65% compared with 60% in the DPP group ($P = .005$). Although this finding was statistically significant, it is likely clinically irrelevant because both groups fall within the normal LVEF range.

Our institutional default method of DCD heart recovery is NRP. We prefer this technique given the physiologic in situ assessment, the cost savings, and the benefit to the abdominal organs.^{14-19,27,28} In our study, NRP donors had shorter travel distances. The OCS allows for prolonged resuscitation and a delayed decision regarding organ quality. A final decision regarding organ quality can be made after several hours on arrival to the recipient center.⁵ As is done at other centers, we factored the advantage of continuous perfusion with the OCS into our decision making and often used DPP with the

OCS if total ischemic time was expected to exceed 4 hours.^{23,24} However, use of the OCS was not limited to extended preservation because early in our DCD experience the OCS was the only option, and later many hospitals did not allow NRP, thus necessitating use of the OCS even if travel time was short. To account for this potential bias, we did control for donor distance, and it did not appear to confound the relationship between the perfusion method and postoperative outcomes. Nonetheless, this difference is important and may contribute to some trends seen in this study. Additionally, donors in the NRP group were a median of 6 years younger than those in the DPP group. Although this difference was statistically significant, it is unlikely that it created a clinical difference given that donors were generally young in both groups and had normal ventricular function.

Even though we did not observe statistically significant differences in the outcome of severe PGD requiring ECMO, our absolute incidences of 5.8% for NRP and 12.9% for DPP were very similar to what has been reported by other investigators. Louca and colleagues²¹ reported a 5.7% incidence of severe PGD requiring ECMO after DCD recovery with NRP across 15 international centers. Schroder and colleagues²⁰ reported a 12% incidence of ECMO after recovery with DPP in a randomized multicenter US trial. Our findings are also similar to those reported by Messer and colleagues²⁹ during their initial experience with DCD heart transplantation in the United Kingdom. In their raw data, these investigators observed severe PGD requiring ECMO in 5% of their NRP cohort compared with 18% of their DPP cohort.²⁹ This difference was mitigated when the cohorts were adjusted for preoperative mechanical circulatory support, with 6% of NRP-cohort patients requiring ECMO compared with 11% of DPP-cohort patients. Of note, unlike our group, who uses NRP exclusively with cold storage for transportation, the Royal Papworth Hospital group at times recovered hearts with NRP and then used the OCS for transportation.²⁹ Thus, a direct comparison with our results is somewhat confounded. Although these data are hypothesis generating, the small sample size in the DPP group limits statistical analysis in our cohort, and larger prospective studies are needed to elucidate the incidence of severe PGD in DCD heart donation and to clarify whether this is influenced by recovery technique.

There was a significant difference in the warm ischemic time 2 (time to sew the heart in) between



NRP and DPP hearts, with NRP hearts taking 49 minutes to sew in, compared with 34 minutes in the DPP group. This difference is likely unrelated to the organ quality or anatomy of these hearts and is rather related to our faculty surgeons. As the study period progressed, there was a higher percentage of NRP cases, and several junior faculty transplant surgeons joined our staff at that time.

STUDY LIMITATIONS. This is a single-center, retrospective observational study with a limited power to detect differences between the groups. With our limited sample size, especially in the DPP group, we lacked the degrees of freedom to perform extensive multivariable analysis. In some cases, there was deliberate selection for the OCS for longer travel times, there was a difference in waitlist status between groups, and NRP donors tended to be younger, which may be a confounder. Additionally, more DPP with the OCS was used early in the study period as part of a clinical trial,^{5,20} and more NRP was used later in the study period. Although there is certainly a learning curve to these techniques, this is reflected in the ability to recover a heart successfully, and we do not believe that this issue affected the clinical outcome.

Finally, we did not review details of the postoperative trajectory beyond the index hospitalization. Therefore, longer-term outcomes, such as 1-year mortality and rates of rejection, may have been driven by many other factors not accounted for in this study.

TABLE 4 Postoperative Outcomes

Outcomes	All N = 117 (100%)	NRP n = 86 (73.5%)	DPP n = 31 (26.3%)	P Value
Postoperative support				.212
None	103 (88)	76 (88.4)	27 (87.1)	
ECMO	9 (7.69)	5 (5.81)	4 (12.9)	
IABP	5 (4.27)	5 (5.81)	0 (0)	
PGD grade at 24 h				.329
None or mild	98 (83.8)	74 (86)	24 (77.4)	
Moderate	10 (8.55)	7 (8.14)	3 (9.68)	
Severe	9 (7.69)	5 (5.81)	4 (12.9)	
Mortality with severe PGD ^a	3 (33.3)	2 (20)	1 (25)	1.000
Inotrope score at 24 h	12.1 (8.2–16.9)	11.8 (8.1–17.4)	12.5 (8.7–15.3)	.995
Inotrope score at 72 h	5.2 (3.8–10.1)	5.2 (3.1–10.0)	5.0 (5.0–9.9)	.868
Peak troponin I, ng/mL	30.6 (20.3–42.2)	32.2 (21.4–45.2)	25.6 (15.9–31.8)	.024
Peak lactate, mmol/L	11.5 (7.7–14.6)	11.5 (7.8–14.4)	11.4 (7.5–15.6)	.462
LVEF at 7 d, %	65 (60–65)	65 (60–68)	60 (55–65)	.005
Time to extubation, h	13 (9–33)	13 (10–31)	16 (9–29)	.890
Tracheostomy	12 (10.4)	8 (9.41)	4 (13.3)	.680
Cerebrovascular accident	6 (5.22)	5 (5.88)	1 (3.33)	1.000
Renal replacement therapy	32 (27.6)	24 (28.2)	8 (25.8)	1.000
Hemodialysis at discharge	7 (6.31)	6 (7.32)	1 (3.45)	.685
Pacemaker				.686
None	112 (95.7)	81 (94.2)	31 (100)	
Temporary	1 (0.855)	1 (1.16)	0 (0)	
Permanent	4 (3.42)	4 (4.65)	0 (0)	
ICU LOS, d	7 (5–13)	8 (5–13)	6 (5–13)	.195
Hospital LOS, d	17 (13.5–29.5)	18 (14–31)	17 (13–23)	.538
ACR on first biopsy				.426
OR ACR	43 (38.4)	35 (42.7)	8 (26.7)	
1R ACR	61 (54.5)	41 (50)	20 (66.7)	
2R ACR	8 (7.14)	6 (7.32)	2 (6.67)	
AMR on first biopsy				.085
Grade 0	110 (98.2)	82 (100)	28 (93.3)	
Grade 1	2 (1.79)	0 (0)	2 (6.67)	
30-d survival, %	95.8	95.4	96.8	.754
1-y survival, %	91.9	93.9	86.1	.193

^aOne intraoperative mortality excluded from the group because of a lack of outcomes. Values are median (interquartile range [Q1–Q3]), count (%), or %. ACR, acute cellular rejection; AMR, antibody-mediated rejection; DPP, direct procurement and perfusion; ECMO, extracorporeal membrane oxygenation; IABP, intraaortic balloon pump; ICU, intensive care unit; LOS, length of stay; LVEF, left ventricular ejection fraction; NRP, normothermic regional perfusion; PGD, primary graft dysfunction.

CONCLUSION. In our experience, both NRP and DPP using the TransMedics OCS have resulted in satisfactory outcomes for our transplant recipients when compared with published rates of PGD,^{20,21} and both platforms can be used safely for DCD recoveries. We did observe increased early allograft function with NRP with regard to LVEF at 7 days. Although we observed a numerically decreased incidence of severe PGD, this was not statistically significant. These observations are meant to be hypothesis generating, and larger multicenter, prospective

studies are necessary to help elucidate any differences between these recovery and perfusion strategies.

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DISCLOSURES

The authors have no conflicts of interest to disclose.

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