American Journal of Transplantation 25 (2025) 574–582

Contents lists available at ScienceDirect

American Journal of Transplantation

journal homepage: www.amjtransplant.org

Brief Communication

The current landscape of in situ and ex situ machine perfusion utilization for liver grafts from cardiac donation after circulatory death donors in the US

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ARTICLE INFO

Keywords:
donation after circulatory death
normothermic regional perfusion
liver transplantation
organ procurement and allocation
ex situ machine perfusion

ABSTRACT

Donation after circulatory death (DCD) is driving the increase in deceased organ donors in the United States. Normothermic regional perfusion (NRP) and ex situ machine perfusion (es-MP) have been instrumental in improving liver transplant outcomes and graft utilization. This study examines the current landscape of liver utilization from cardiac DCD donors in the United States. Using the United Network for Organ Sharing Standard Transplant Analysis and Research file, all adult (≥18 years old) DCD donors in the United States from which the heart was used for transplantation from October 1, 2020, to September 30, 2023, were compared by procurement technique (NRP versus super rapid recovery [SRR]) and storage strategy (es-MP versus static cold storage). One hundred eighty-eight livers were transplanted from 309 thoracoabdominal NRP donors (61% utilization) versus 305 (56%) liver transplants from 544 SRR donors. es-MP was used in 20% (n = 38) of NRP cases versus 32% (98) of SRR cases. Of the liver grafts, 281 (59%) were exposed to NRP, es-MP, or both. While there is widespread utilization of machine perfusion, more research is needed to determine optimal graft management strategies, particularly concerning the use

Abbreviations: A-NRP, abdominal normothermic regional perfusion; DCD, donation after circulatory death; es-MP, ex situ machine perfusion; IC, ischemic cholangiopathy; NM, nautical mile; NRP, normothermic regional perfusion; OPO, organ procurement organization; SCS, static cold storage; SRR, super rapid recovery; TA-NRP, thoracoabdominal normothermic regional perfusion; UNOS, United Network for Organ Sharing.

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https://doi.org/10.1016/j.ajt.2024.09.012
Received 20 May 2024; Received in revised form 11 September 2024; Accepted 12 September 2024
Available online 16 September 2024

of multiple technologies in complementary ways. More complete data collection is necessary at a national level to address these important research questions.

1. Introduction

Donation after circulatory death (DCD) has been the main driver behind the growth of deceased organ donation in the United States in the past 5 years, in part due to the utilization of in situ and ex situ machine perfusion (es-MP) technology for the assessment of graft viability.[1-3] In situ machine perfusion is also known as normothermic regional perfusion (NRP), a procedure that utilizes the donor's blood vessels to deliver oxygenated blood to the organs that are intended for transplantation inside of the donor's body shortly after the declaration and confirmation of death. es-MP can be performed at the donor hospital or the transplant center and is a procedure that attaches the donor liver vessels to a pump that delivers either oxygenated blood (normothermic machine perfusion) or a hypothermic oxygenated solution (hypothermic machine perfusion) to the liver. Liver transplantation has seen significantly improved outcomes with these technologies,[2,4] including substantial decreases in risks of liver primary nonfunction and ischemic cholangiopathy (IC).

Access to es-MP and NRP in US liver transplant centers is not universal, and the choice of utilization of these technologies is multifactorial. For NRP in the United States, access is often through cardiac recovery teams who bring the equipment and perfusionists who run the NRP circuits to donor hospitals, so abdominal recovery teams can only utilize NRP when a heart recovery with this technology is planned. If the cardiac team does not utilize NRP, then the donor recovery procedure will generally be super rapid recovery (SRR). While the procurement technique for cardiac DCD donors is determined by the cardiac transplant center, the storage modality, es-MP versus static cold storage (SCS), is determined by the liver transplant center.

Because the procurement technique impacts all organs, there is much interest in studying the outcomes of abdominal transplant recipients of cardiac DCD donors that are subjected to 1 of the 2 strategies by the heart procurement team. A study of early outcomes of thoracoabdominal NRP (TA-NRP) cardiac donors in the United States found that the delayed graft function rate of kidneys was significantly lower than with SRR cardiac donors and that 6-month liver transplant outcomes from these 2 procurement techniques were the same.[5] Due to limitations in data availability, the rates of IC could not be determined. Moreover, this study did not report the use of es-MP of liver grafts from these donors and therefore was unable to determine the impact of this technology on liver transplant outcomes or utilization. In 2021, Croome and colleagues[6] assessed the geographic distribution of TA-NRP and es-MP utilization in the United States. This study included both DCD and donation after brain death donors and showed that about 40 US centers transplanted at least 1 liver using either NRP or es-MP.

Given the growth of cardiac DCD programs using NRP and the commercial availability of es-MP over the past 3 years, the distribution of DCD liver transplant centers using grafts with these different technologies has likely changed. Therefore, determining the current landscape of liver transplant center behavior in terms of acceptance by procurement technique and storage strategy in cardiac DCD recoveries can provide insights into how approaches to DCD liver transplantation vary and identify opportunities to improve organ utilization, transplant efficiency, and value. A starting point to determine the current landscape is to focus on DCD donors from which the heart was used for transplantation because the procurement technique is determined by the cardiac team; therefore, liver transplant centers that do not require NRP teams still have access to this technology. In addition, this donor population is generally younger with fewer comorbidities, which fits within the standard criteria for DCD liver transplantation.[5] This study aimed to examine the current state of liver transplantation from cardiac DCD donors in the United States including donor, recipient, and logistical characteristics as well as donor and recipient geographic distribution by procurement technique and storage strategy.

2. Methods

2.1. Data collection

This study was deemed exempt from institutional review board oversight by the Baylor University Medical Center institutional review board. Using the United Network for Organ Sharing (UNOS) Standard Transplant Analysis and Research files, all adult (aged $\geq$18 years) DCD donors in which the heart was used for transplantation from October 1, 2020, to September 30, 2023, were identified and categorized by procurement technique. The start of the study timeframe aligns with the first reported TA-NRP DCD procurement in the United States,[7] and a subanalysis was performed starting from September 29, 2021, the day after Food & Drug Administration approval for the first es-MP device in the United States.[8] The UNOS data does not have variables that identify procurement techniques (SRR or NRP) so time data was used for this distinction, using a previously described method.[5,9] Specifically, donors with death to cross-clamp time $<$30 minutes were identified as SRR donors, and those with death to cross-clamp time $\geq$30 minutes were categorized as NRP donors. Summary statistics of DCD heart donors (ie, cardiac donors) were calculated. Further, liver transplant recipients from these DCD heart donors were identified, summary statistics were computed, and 12-month patient and graft survival analyses were performed for these patients.

2.2. Study outcomes

The primary outcomes of this study were liver transplant patient and graft survival stratified by procurement technique and storage strategy. The secondary outcomes were liver utilization

rates by procurement technique, center-level utilization of cardiac DCD liver grafts categorized by procurement technique and storage strategy combination, and organ procurement organization (OPO)-level distribution of procurement technique and storage strategy combinations for liver grafts.

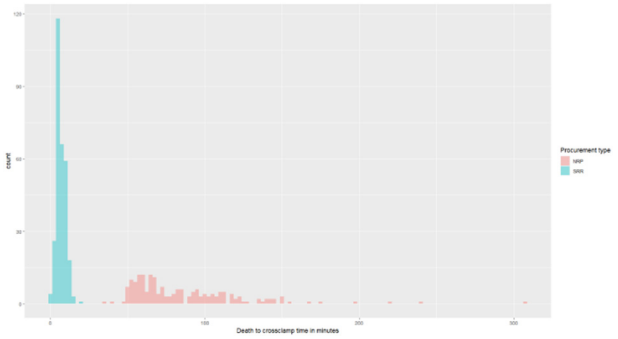

Figure 1. Histogram of the frequency of occurrences of time in minutes from cross-clamp to death showing the distinction between procurement techniques for all US cardiac DCD donors from October 1, 2020 to September 23, 2023. Super rapid recovery (SRR) clusters <30 minutes and normothermic regional perfusion (NRP) clusters above 30 minutes.

2.3. Statistical data analysis

Donor and recipient characteristics were compared between the SRR and NRP groups. Continuous variables were summarized using median and interquartile range. Categorical variables were summarized using counts and percentages. The Wilcoxon rank sum test was used to compare continuous variables. Pearson's chi-squared test or Fisher exact test was used to compare categorical variables. Statistical significance was defined as P value $< .05$. Kaplan-Meier survival curves were used for liver transplant 12-month patient survival and graft survival. Log-rank tests were used to statistically compare patient death and graft failure between the SRR and NRP groups. Statistical analyses were conducted using R version 4.3.2.

3. Results

3.1. Cohort validation

Figure 1 presents the frequency of occurrence of death to cross-clamp times by minutes, showing that there are 2 distinctly separate groupings, greater than and less than 30 minutes. Because UNOS does not collect procurement techniques, this

Table 1
Liver transplant donor and recipient characteristics by recovery technique.

Characteristic	NRP (n = 188)	SRR (n = 305)	*P*
Donor age, median (IQR), y	31 (24, 36)	31 (25, 36)	> .9
Donor male sex, n (%)	165 (88)	257 (84)	.3
Donor BMI, median (IQR), kg/m^2	27.9 (23.7, 30.5)	27.3 (23.7, 30.3)	.8
Death to clamp time, median (IQR), min	75 (60, 105)	6 (5,9)	< .001
Hepatitis C positive	15 (8)	33 (11)	.3
Terminal AST	52 (34, 83)	49 (33, 73)	.4
Terminal ALT	44 (26, 83)	39 (25, 73)	.2
Liver machine perfusion			.012
No, No. (%)	139 (74)	187 (61)	
Yes, No. (%)	38 (20)	98 (32)	
Missing, No. (%)	11 (5.9)	20 (6.6)	
Recipient age, median (IQR), y	59 (50, 64)	59 (52, 65)	.4
Recipient BMI, median (IQR), kg/m^2	28.6 (24.7, 31.8)	27.9 (24.8, 32.4)	.5
Recipient hepatocellular carcinoma diagnosis			.3
No, No. (%)	148 (79)	226 (74)	
Yes, No. (%)	39 (21)	73 (24)	
Missing, No. (%)	1 (0.5)	6 (2.0)	
MELD score at transplant, median (IQR)	20 (15, 25)	20 (15, 25)	> .9
Recipient length of hospital stay, median (IQR)	7 (5, 10)	9 (6, 13)	< .001
Distance between donor and recipient hospital	61 (12, 160)	82 (22, 142)	.3
Cold ischemia time, median (IQR)	5.3 (4.2, 7.7)	6.5 (5.0, 11.5)	< .001

ALT, alanine transaminase; AST, aspartate transaminase; BMI, body mass index; IQR, interquartile range; MELD, Model for End-Stage Liver Disease; NRP, normothermic regional perfusion; SRR, super rapid recovery.

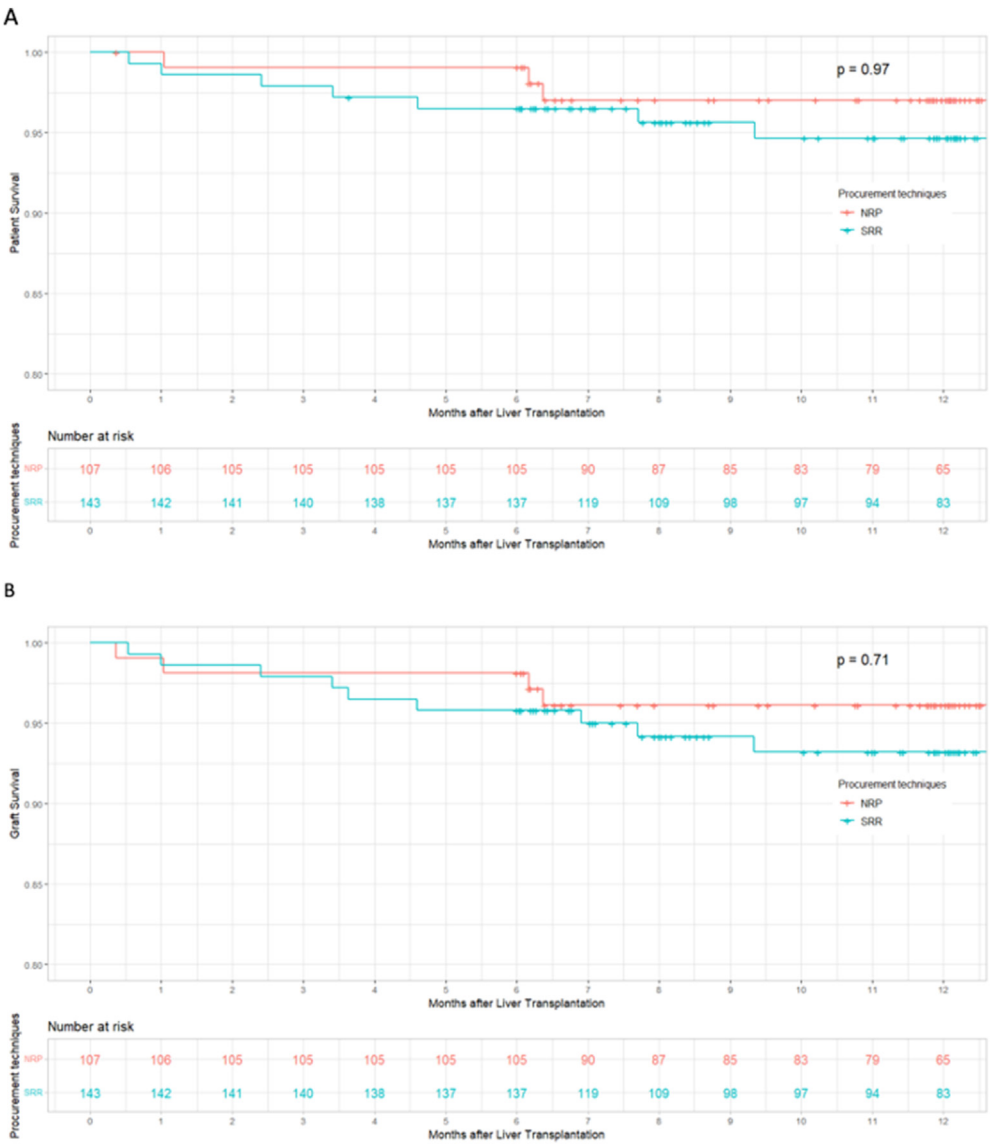

Figure 2. Comparison of 12-month liver transplant patient (A) and graft survival (B) outcomes comparing NRP and SRR donation after circulatory death recipients. NRP, normothermic regional perfusion; SRR, super rapid recovery.

was inferred from death to cross-clamp times as described in the methods section with a cutoff of 30 minutes as the differentiation between SRR and NRP.

3.2. Liver transplant donor and recipient characteristics and outcomes

Table 1 shows the characteristics of the DCD donors from which the liver was used for transplantation as well as the recipients of these transplants. There was a significant difference in the utilization of es-MP between groups, with 20% (n = 38) of NRP cases using es-MP for storage versus 32% (98) of SRR cases. In the subanalysis timeframe, during which all machine perfusion cases were performed, the percentage of cases using machine perfusion increased to 24% of NRP cases and 39% of SRR cases ($P = .005$). (Supplemental Table S1). There was no difference in mean donor age or body mass index, terminal transaminases and total bilirubin, or donor sex. There was also no difference in recipient median age, model for end-stage liver disease, hepatocellular carcinoma diagnosis, or distance between donor and recipient hospitals. NRP liver transplant recipients had shorter median length of stay (7 days vs 9 days, $P < .001$) and shorter median cold ischemia times (5.3 hours vs 6.6 hours, $P < .001$) than SRR liver transplant recipients. There was no difference in 12-month patient and graft survival between the NRP and SRR groups (Fig. 2). In a subgroup analysis that combined procurement technique and storage strategy, resulting in a comparison of 4 cohorts (NRP with es-MP, NRP with SCS, SRR with es-MP, and SRR with SCS), there was no difference in patient and graft survival, but notably, the 12-month patient survival was 100% in both es-MP groups versus 97% in the NRP with SCS group and 94% in the SRR with SCS group (Fig. 3).

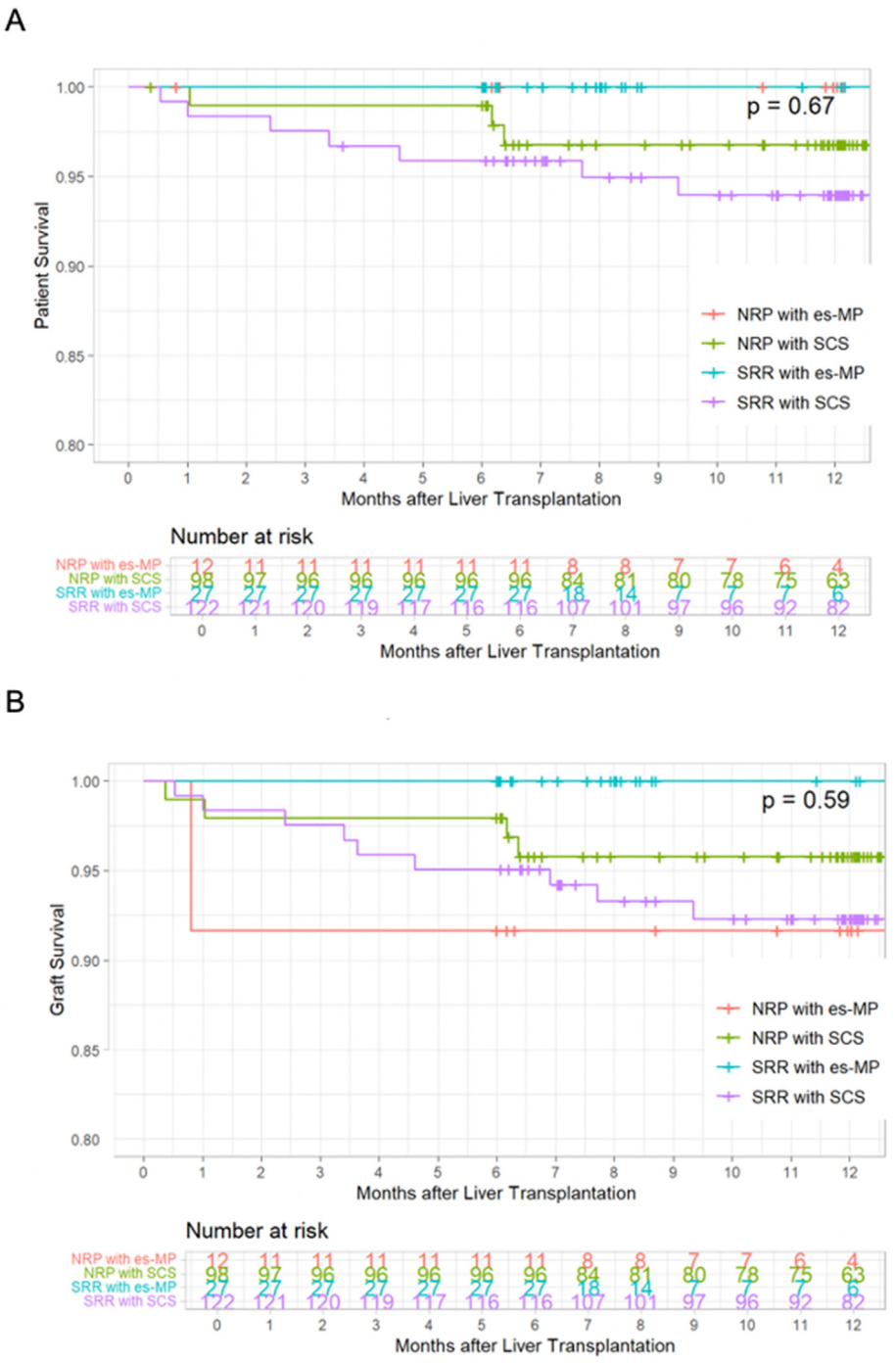

Figure 3. Comparison of 12-month liver transplant patient (A) and graft survival (B) outcomes comparing 4 combinations of procurement technique and storage strategy: normothermic regional perfection (NRP) with ex situ machine perfusion (es-MP), NRP with static cold storage (SCS), super rapid recovery (SRR) with es-MP and SRR with SCS.

3.3. Liver utilization from cardiac DCD donors

We found 309 TA-NRP donors and 544 SRR donors for which the heart was used for transplant. Of these groups, 188 livers were transplanted from the 309 TA-NRP donors (61%) versus 305 (56%) liver transplants from 544 total SRR donors. There was no significant difference in liver utilization by procurement technique ($P = .075$). Table 2 shows the number and percentage of liver grafts that were used by the combination of procurement technique and storage strategy. During the full study period, 281 grafts (58.5%) were exposed to at least 1 perfusion technology, and 37 (7.7%) were exposed to both NRP and es-MP. After the approval of es-MP, the overall number of grafts exposed to 1 perfusion technology was 251 (63.2%).

3.4. Distribution of liver transplants by procurement technique and storage modality

Eighty-four transplant centers performed at least 1 DCD liver transplant from a cardiac donor (Fig. 4). Table 3 shows the

Table 2
Distribution of liver grafts and transplant center graft utilization by the combination of procurement technique (normothermic regional perfusion versus super rapid recovery) and storage strategy (static cold storage and ex situ machine perfusion).

Liver graft management by procurement technique and storage strategy		
Full study cohort (n = 480)	SCS (n = 347)	es-MP (n = 133)
NRP (n = 185)	148 (30.8%)	37 (7.7%)
SRR (n = 295)	199 (41.5%)	96 (20.0%)
Subanalysis after FDA approval of es-MP (n = 397)	SCS (n = 264)	es-MP (n = 133)
NRP (n = 155)	118 (29.7%)	37 (9.3%)
SRR (n = 242)	146 (36.8%)	96 (24.2%)
Transplant center graft utilization by procurement technique and storage strategy		
Transplant center (n = 84)	SCS (n = 82)	es-MP (n = 29)
NRP (n = 54)	50 (59.5%)	15 (17.9%)
SRR (n = 70)	67 (79.8%)	24 (28.6%)

For liver graft management, n is representative of each individual graft, and for transplant center graft utilization, n for each combination represents the utilization of that combination of technology at least 1 time by a unique transplant center. Percentages are calculated by the denominator of total number of transplant centers (n = 84). es-MP, ex situ machine perfusion; FDA, Food & Drug Administration; NRP, normothermic regional perfusion; SCS, static cold storage; SRR, super rapid recovery.

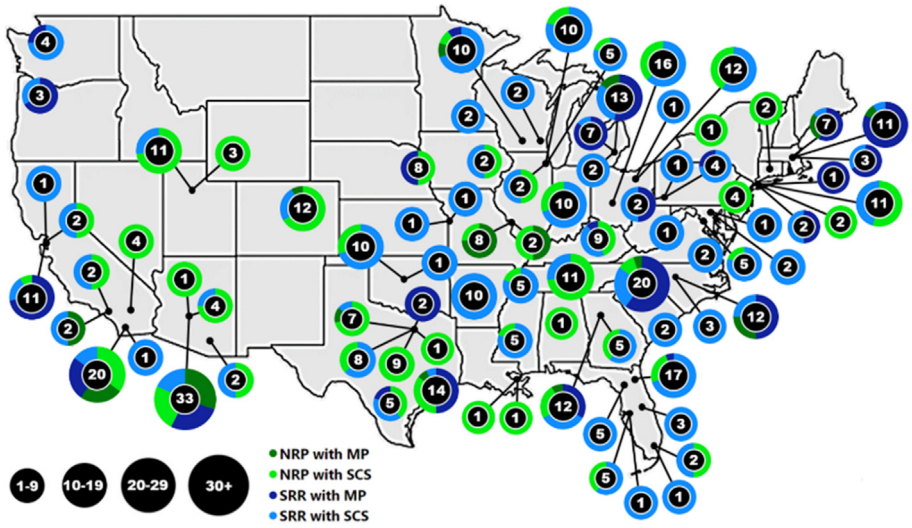

Figure 4. Center distribution of DCD liver grafts by procurement technique and storage strategy. DCD, donation after circulatory death; MP, machine perfusion; NRP, normothermic regional perfusion; SCS, static cold storage; SRR, super rapid recovery.

number of transplant centers that used each procurement technique and storage strategy at least once. Most used liver grafts from SRR donors with SCS (67/84, 79.8%) and NRP with SCS (50/84, 59.5%). Only 15 (17.9%) used livers that combined NRP with es-MP.

3.5. Distribution of DCD donors by procurement technique and storage strategy

Figure 5 shows the distribution of originating OPO by procurement technique and storage modality for successful cardiac and liver DCD donations. Thirteen of the 66 OPOs represented only performed SRR procurements and 2 only performed NRP procurements. The remaining 51 performed both NRP and SRR procurements. Overall, 80% of OPOs were involved with at least 1 TA-NRP procurement that resulted in both a liver and heart transplant.

3.6. Distance distribution

Table 3 shows the distance distribution of graft utilization by procurement technique and storage strategy. Of the grafts, 75.8% (n = 364) were transplanted within 150 nautical miles (NM) of the donor hospital. Eighty percent (161) of SRR with SCS

Table 3
Distance distribution of graft utilization by procurement technique (normothermic regional perfusion versus super rapid recovery) and storage strategy (static cold storage and ex situ machine perfusion).

	≤150 NM n = 364 (75.8%)	151–250 NM n = 52 (10.8%)	251–500 NM n = 46 (9.6%)	> 500 NM n = 18 (3.8%)
NRP plus es-MP n = 37 (7.7%)	22	6	5	4
NRP plus SCS n = 148 (30.8%)	112	24	9	3
SRR plus es-MP n = 96 (20.0%)	69	10	11	6
SRR plus SCS n = 199 (41.5%)	161	12	21	5

es-MP, ex situ machine perfusion; NM, nautical miles; NRP, normothermic regional perfusion; SCS, static cold storage; SRR, super rapid recovery.

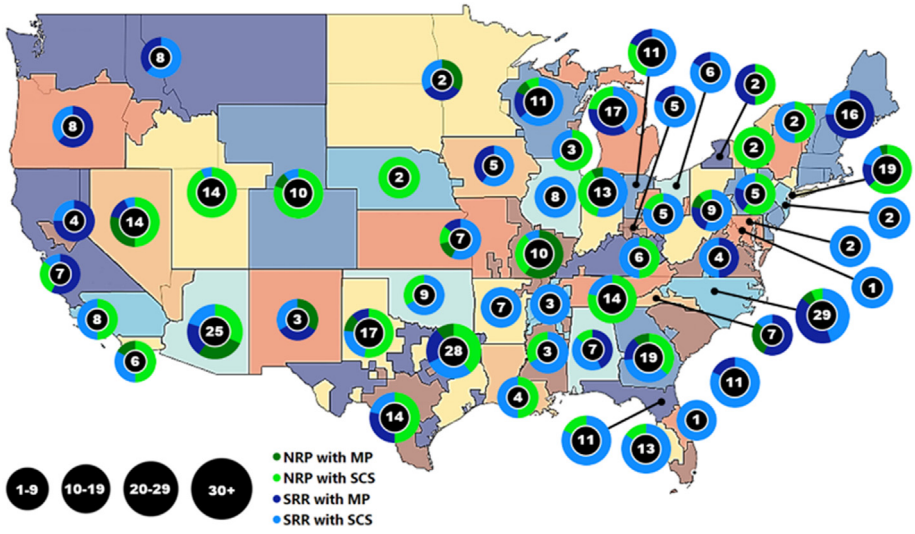

Figure 5. Distribution of DCD donors in each donor service (DSA) area by procurement technique and storage strategy. Geographic visualization of donor location by DSA. DCD, donation after circulatory death; MP, machine perfusion; NRP, normothermic regional perfusion; SCS, static cold storage; SRR, super rapid recovery.

were transplanted within 150 NM of the donor hospital versus 59% of NRP with es-MP grafts. Only 3.75% of grafts were transplanted >500 NM from the donor hospital, and all 4-procurement technique and storage strategy combinations were represented.

4. Discussion

This study demonstrates the outcomes, utilization, and distribution of DCD liver transplantation from cardiac donors, stratified by procurement technique and storage strategy. Donors, recipients, and outcomes were similar in the SRR and NRP groups, except for the use of es-MP, which was significantly higher in the SRR group.

The utilization rates of livers from SRR and NRP cardiac donors were not significantly different in this study. The findings from this study are similar to those of an earlier study of liver utilization from cardiac DCD donors, which showed no difference in the utilization of DCD liver grafts from cardiac donors by procurement technique.[5] The high utilization rates in both groups as compared to reported rates of DCD liver utilization are probably a consequence of the excellent baseline quality of these donors. Unfortunately, the reasons for decline are not provided so it is difficult to determine if there are differences in decline reasons between procurement types. Future studies are needed to determine reasons for nonutilization by procurement technique and storage modality as well as the impact of these variables on the utilization of nonstandard DCD liver grafts.

The present study found that most of the liver grafts from cardiac DCD donors were exposed to at least 1 perfusion strategy, and 37 grafts (7.7%) were exposed to a combination of NRP and es-MP. Further research is needed to determine the optimal strategies for perfusion of liver grafts from DCD donors as there have been no randomized controlled trials comparing perfusion strategies, specifically NRP and es-MP. Despite limited data, from a process standpoint, if both NRP and es-MP were universally available for all DCD donors, it seems that stacking technology makes more sense than exclusively using one over the other. If all DCD donors were performed with NRP, as recommended by the American Society of Transplant Surgeons,[10] the donation procedures would start with a higher likelihood of utilization and allow for immediate quality assessment.[3,11] Moreover, the other organs, especially kidneys would benefit from the procurement procedure.[5,11] Then, if needed for logistics or additional graft assessment, livers could be placed on es-MP. Those of adequate quality with acceptable predicted cold ischemic

Table 4
Recommendations for variable collection for donation after circulatory death.

Categorical variable	Categories	Rationale
Procurement procedure	TA-NRP	The procurement technique may impact the utilization and quality of organs.
	A-NRP without thoracic recovery	Accuracy with procurement technique allows comparisons.
	A-NRP with thoracic SRR	
	SRR	
Liver machine perfusion	Yes	
	No	
Temperature	Normothermic	
	Hypothermic	
Device	Transmedics Organ Care System	
	OrganOx Metra (add hypothermic devices when FDA approved)	
Location of perfusion initiation	At donor hospital	
	Back to base	
Time point	**Calculation**	**Rationale**
SBP80	Starting point for fWIT80	The time at which the SBP drops below 80 mmHg is a common start point for liver transplant center functional warm ischemic time
SBP50	Starting point for fWIT50	The time at which the SBP drops below 50 mmHg is a common start point for liver transplant center functional warm ischemic time
NRP start	fWIT_NRP_80 = NRP start – SBP80	The time when NRP is initiated ends the donor functional warm ischemic time period.
	fWIT_NRP_50 = NRP start – SBP50	
Abdominal cold flush (aCF)	afWIT_SRR_80 = aCF– SBP80	Ends the functional warm ischemic time for SRR recoveries. Starts the cold ischemic time.
	afWIT_SRR_50 = aCF – SBP50	
Thoracic cold flush (tCF)	tfWIT_SRR_80 = tCF – SBP80	Ends functional warm ischemic time for SRR recoveries. Starts cold ischemic time.
	tfWIT_SRR_50 = tCF – SBP50	
es-MP start	es-MP_CIT = es-MP start - aCF	The time when es-MP is initiated ends the cold ischemic time period.

aCF, abdominal cold flush; A-NRP, abdominal normothermic regional perfusion; afWIT, abdominal functional warm ischemic time; es-MP, ex situ machine perfusion; FDA, Food & Drug Administration; fWIT, functional warm ischemic time; SBP, systolic blood pressure; SRR, super rapid recovery; TA-NRP, thoracoabdominal normothermic perfusion; tCF, thoracic cold flush; tfWIT, thoracic functional warm ischemic time.

times could utilize SCS. Those with adequate quality but a need for extended cold ischemic time may benefit from hypothermic oxygenated machine perfusion.[12] Ultimately, we believe that in situ and es-MP should be viewed as complementary and that each step of the process from procurement to storage to implantation should be focused on maximizing the opportunity for utilization and ensuring or improving graft quality.

This study also found that most liver transplant centers that used a liver from a cardiac DCD donor accepted at least 1 NRP graft. In addition, most OPOs have participated in at least 1 TA-NRP DCD donation in which the heart and liver were used for transplantation. These findings suggest that ethical and legal concerns are not substantial barriers to the widespread utilization of these grafts or allowance of these procedures and that TA-NRP is a widely accepted and utilized procurement procedure in the United States.

There are limitations to this study. First, the data from the UNOS Standard Transplant Analysis and Research file are limited to what is collected and reported by OPOs and transplant centers. For example, the storage modality (SCS vs es-MP) is not reported in 5% of cases so SCS was assumed but could not be confirmed. Second, the technique used to distinguish procurement techniques has been used frequently in the literature but may not be perfectly accurate if the recorded times of death and cross-clamp are not correct. This technique assumes that short death to cross-clamp times are associated with SRR and long (>30 minutes) death to cross-clamp times represent NRP. This strategy may miscategorize short NRP runs (<25 minutes) as

SRR or NRP as SRR if the cross-clamp time is recorded as the start of NRP rather than the start of cold flush. Third, data that would be of interest are not available, such as the incidence of IC or reasons for nonutilization of liver allografts. Finally, the cold ischemia time is calculated from cross-clamp to recipient reperfusion, which does not account for the true cold ischemia time for es-MP cases, which is from cross-clamp to perfusion on the ex situ device. To obtain more accurate data, multicenter studies of DCD utilization and outcomes with different procurement and storage strategies are needed. Despite these limitations, this study is a starting point for understanding how es-MP and NRP impact liver utilization, allocation, and outcomes with high-quality DCD donors and provides a comparator for similar studies with noncardiac DCD donors.

The limitations of this study identify improvement opportunities for UNOS data collection. Table 4 provides a list of categorical and time-based variables that should be collected with the rationale, descriptions, and calculations (for time-based variables). First, a specific data field with the procurement strategy for DCD donors would allow for accurate distinction between NRP and SRR donors. Moreover, now that combined techniques are being used for procurements (eg, abdominal NRP [A-NRP] with thoracic SRR),[13] the procurement technique collected should include the body region (eg, A-NRP with thoracic SRR, TA-NRP, and A-NRP without thoracic recovery). For es-MP, collection of the device temperature, device, and location of perfusion initiation may all impact graft and patient outcomes and therefore should be collected. The time points that we recommend collecting include common starting points for functional warm ischemic time, initiation times for in situ and ex situ perfusion, and the time of cold flush.

This study found that most liver grafts from cardiac DCD donors in the United States are exposed to at least 1 perfusion strategy, either NRP, es-MP, or both, and that the outcomes by procurement technique in terms of patient and graft survival are similar. However, important data points for studying optimal machine perfusion strategies are currently unavailable but urgently needed. Our findings suggest that machine perfusion technologies, specifically NRP and es-MP, may be emerging as standards of practice for DCD liver transplantation in the United States, but more research is needed on the rationale for combining different procurement and storage strategies and optimal uses of each technology. In addition, research is needed on noncardiac DCD liver graft utilization based on procurement technique and storage strategy given the growth of noncardiac NRP programs in the United States and the increasing availability of es-MP.

Declaration of competing interest

The authors of this manuscript have no conflicts of interest to disclose as described by the American Journal of Transplantation.

Data availability

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ajt.2024.09.012.

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