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Original Article

Six-month abdominal transplant recipient outcomes from donation after circulatory death heart donors: A retrospective analysis by procurement technique



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ABSTRACT

Standard US practice for donation after circulatory death (DCD) abdominal organ procurement is superrapid recovery (SRR). A newer approach using thoracoabdominal normothermic regional perfusion (TA-NRP) shows promise for better recipient outcomes for all organs, but there are few reports of abdominal recipient outcomes from TA-NRP donors. We used the United Network for Organ Sharing data to identify all cardiac DCD donors from October 1, 2020, to May 20, 2022, and categorized them by recovery procedure (SRR vs TA-NRP). We then identified all liver, kidney, and pancreas recipients of these donors for whom 6-month outcome data were available and compared patient and graft survival, kidney delayed graft function (DGF), and biliary complications between TA-NRP DCD and SRR DCD organ recipients. Patient and graft survival did not differ significantly between groups for either kidney or liver recipients. Significantly fewer TA-NRP kidney recipients developed DGF (12.7% [15/118] vs 42.0% [84/200], $P < .001$), and TA-NRP and pumped kidneys had lower odds for DGF on multivariate analysis. No liver recipients in either group had biliary complications or were relisted for transplantation for ischemic cholangiopathy. Although long-term outcomes need to be investigated, our early results show similar outcomes for recipients of TA-NRP DCD abdominal organs versus recipients of SRR DCD abdominal organs. We believe that TA-NRP is an effective approach to expand the use of DCD organs.

Abbreviations: A-NRP, abdominal normothermic regional perfusion; BMI, body mass index; CI, confidence interval; DCD, donation after circulatory death; DGF, delayed graft function; IQR, interquartile range; KDPI, kidney donor profile index; NA, not applicable; OR, odds ratio; SD, standard deviation; SRR, super rapid recovery; STAR, standard transplant analysis and research; TA-NRP, thoracoabdominal normothermic regional perfusion; UNOS, United Network for Organ Sharing.

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1. Introduction

Given the supply-demand mismatch for organs for transplant, allografts for donation after circulatory death (DCD) donors now make up approximately 30% of the US deceased donor pool, and there is increasing utilization of cardiac grafts from these donors.¹⁻³ One limitation to the wider utilization of DCD donors for abdominal transplantation is an increased risk of biliary complications, primary nonfunction, and hepatic artery thrombosis in liver transplant recipients and delayed graft function (DGF) in kidney recipients.^{4,5} A technique that has shown promise in decreasing complications in abdominal transplant recipients of DCD donors is thoracoabdominal normothermic regional perfusion (TA-NRP), which involves sternotomy, clamping (and diversion or ligation) of the aortic arch vessels (innominate, left common carotid, and left subclavian), central cannulation, and oxygenated perfusion of the thoracic and abdominal organs using a modified extracorporeal membrane oxygenation circuit.

One advantage of TA-NRP over the standard DCD procedure of superrapid recovery (SRR), in which there is immediate cannulation, flushing with cold preservation solution, and cooling of the organs, is that organ quality and function can be evaluated with visualization, biopsy, and laboratory analysis while they are being perfused with warm, oxygenated blood and before cross-clamp, which starts the clock on cold ischemic time (Fig. 1)

Although the TA-NRP procedure was only introduced in the US in October 2020, earlier European studies have shown that the perfusion of organs with warm oxygenated blood before procurement using TA-NRP or abdominal NRP (A-NRP) has the potential to decrease complications in liver and kidney DCD recipients as compared with SRR: liver recipients from NRP donors have lower rates of biliary complications and graft loss versus SRR liver recipients⁶⁻¹⁰ and similar outcomes to hypothermic and normothermic oxygenated perfusion DCD liver recipients.^{10,11} In addition, compared with donation after brain death liver recipients, TA-NRP DCD liver recipients have similar patient and graft

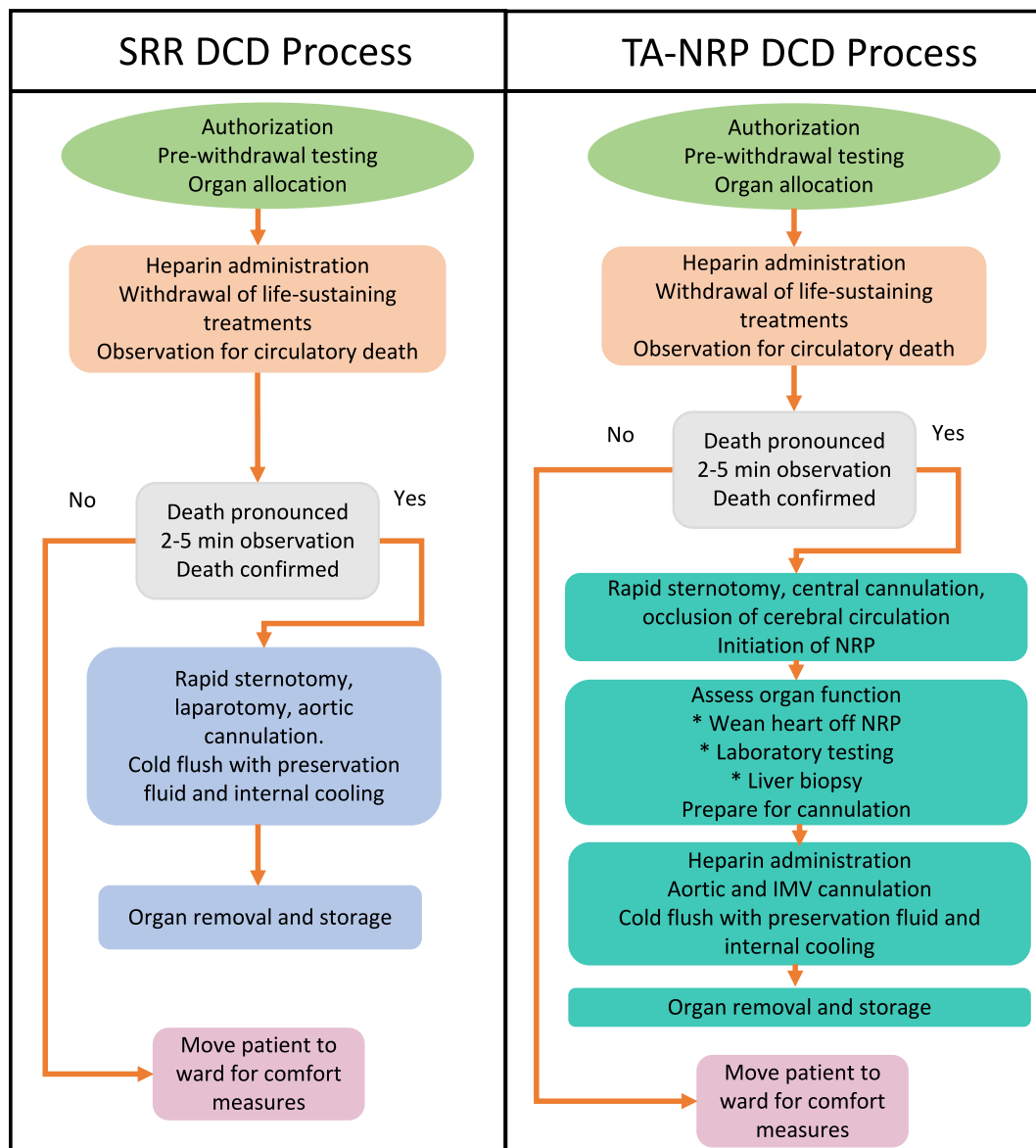


Figure 1. Comparison of superrapid recovery and thoracic normothermic regional perfusion donation after circulatory death processes.

survival rates as well as biliary complication rates.^{9,12} Reports of liver transplant outcomes in the US have shown promising results with TA-NRP DCD, especially in finding no development of ischemic cholangiopathy in these recipients to date.^{13,14} Furthermore, NRP kidney transplant recipients have been shown to have lower rates of DGF compared with SRR DCD kidney recipients.^{15,16}

Because European studies are a combination of abdominal (femoral or iliac cannulation) NRP and TA-NRP with differing protocols, the outcomes of these studies may not be generalizable to the US. Moreover, European abdominal transplant populations differ in severity of illness, waiting times, and, for liver transplantation, model of end-stage liver disease scores. Currently, there are only single and multicenter case series of liver transplant outcomes from TA-NRP DCD donors reported in the US.^{13,14,17} This study compares the entire early US experience of abdominal transplant recipient outcomes from grafts obtained from TA-NRP versus a comparison group of SRR heart donors, using a novel strategy to distinguish between TA-NRP DCD donors and SRR DCD donors in the United Network for Organ Sharing (UNOS) Standard Transplant Analysis and Research (STAR) file.

2. Materials and methods

2.1. Data collection

This study was determined to be exempt from institutional review board oversight. Using the UNOS STAR file, we identified all DCD donors from which hearts were transplanted from October 1, 2020, to May 20, 2022, and obtained the outcomes of the abdominal transplant recipients from these donors that had either 6-month outcomes reported or had met the end points of patient death or graft loss before 6 months. The beginning of the study timeframe corresponded with the first TA-NRP DCD procurement performed in the US.² Because the UNOS STAR file does not identify the procurement type (TA-NRP vs SRR), we developed a method for differentiating these 2 donor types. First, we identified all DCD cardiac transplants during the study period because TA-NRP is almost exclusively used by heart procurement teams at the current time. We did not include DCD donors from whom the heart was procured or procurement was attempted because we would not be able to clearly determine what type of procurement procedure was used or when, for example, NRP was attempted and then aborted. We intentionally limited our data set to cardiac donors for the following 3 reasons: (1) this captures the majority of NRP donors; (2) the SRR donors are similar in terms of graft quality and warm ischemic times; and (3) the SRR recovery procedure used in the comparison cases is similar in that it involves both cardiac and abdominal teams and requires draining blood from the donor before cross-clamping for the heart pump. We calculated death to cross-clamp time, knowing that SRR donors would have shorter times than TA-NRP donors. The time of death is the time recorded using the organ procurement organization coordinator when the physician or other provider caring for the patient declared or confirmed circulatory death based on hospital protocol. There is no uniform standard for the declaration of death by circulatory criteria in the

US or whether the initial declaration of death or the end of the observation period is recorded as the time of death. We conservatively set the cutoff between groups at 30 minutes but found that there was a clear difference between groups with the SRR DCD median death to clamp time of 6 minutes (interquartile range [IQR]: 4–8 minutes) and the TA-NRP DCD group median death to clamp time of 67 minutes (IQR: 57–99 minutes). Warm ischemia time was calculated for SRR donors from the start of agonal phase time (Fig. 2), which is a variable collected in the UNOS STAR file based on the time recorded by operating room staff rather than a defined physiologic parameter, to cross-clamp time. Because the start time of perfusion is not recorded in the UNOS data set for TA-NRP DCD donors, the warm ischemic time for these donors could not be calculated. We collected donor and kidney, liver, and pancreas transplant recipient data, including patient and graft survival, kidney DGF, and biliary complications, from these 2 groups. Pumped kidneys were defined as having been placed on a pump before transplantation in the UNOS data set. Pump type, duration, and other more specific characteristics were not available.

2.1.1. Primary outcomes

The primary outcomes studied were patient and graft survival for liver, kidney, and pancreas transplant recipients.

2.1.2. Secondary outcomes

For liver transplantation, secondary outcomes included the rates of retransplantation, hepatic arterial thrombosis, and biliary complications. For kidney transplantation, the secondary outcome of interest was DGF.

2.2. Analysis

Continuous variables were analyzed with a median and IQR (25th percentile to 75th percentile). Categorical variables were analyzed as counts and percentages. Variables were compared between the following 2 groups: TA-NRP DCD donors versus SRR DCD donors. A continuous Kruskal-Wallis test was used to compare continuous variables. The chi-square test, or Fisher exact test was used to compare categorical variables. Significance was defined as a *P* value of <.05. A logistic regression model was used to analyze the association between perfusion type and DGF in kidney transplant recipients. The effect of perfusion type on the incidence of DGF was presented as an adjusted odds ratio (OR) with a 95% confidence interval (CI). Kaplan-Meier survival curves were used to present organ recipient survival and organ survival since the date of transplant. In addition, log-rank tests were used to compare time to patient death or organ failure between groups. All statistical analyses were performed in R (version 4.1.0).

3. Results

3.1. Donor characteristics

Table 1 compares TA-NRP and SRR DCD donor characteristics. There was no significant difference between donor age, gender, kidney donor profile index (KDPI), or body mass index

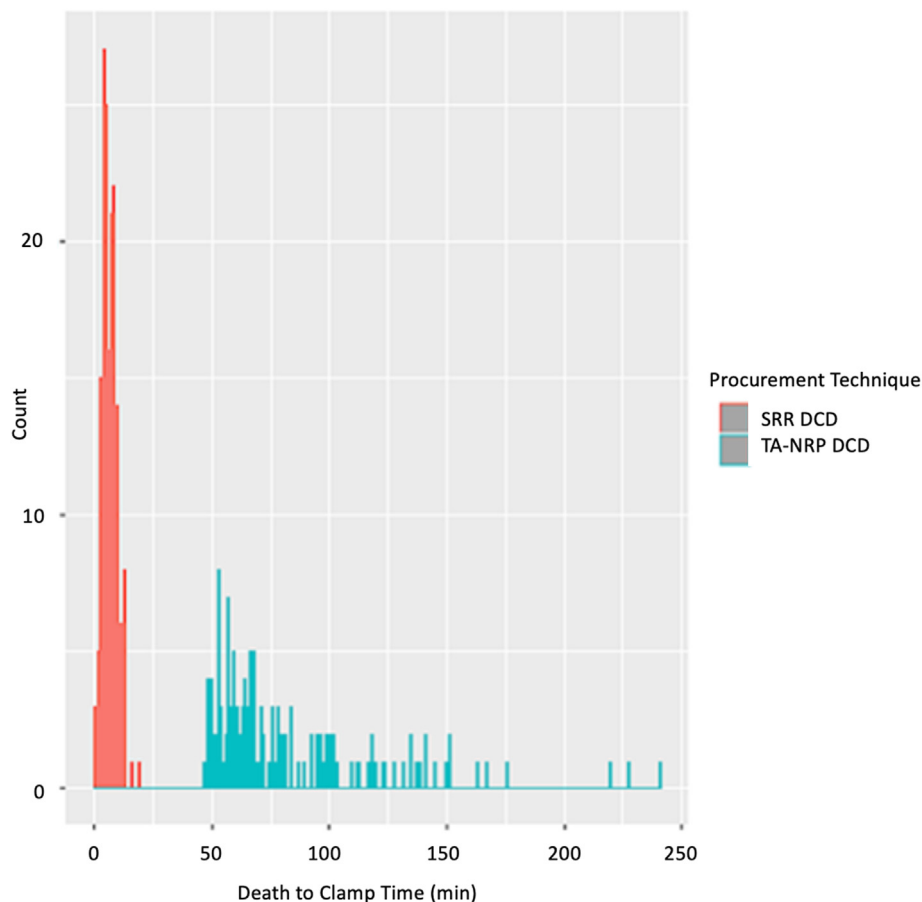


Figure 2. Frequency plot of death to cross-clamp times demonstrating the rationale for 30 minutes as the distinction between superrapid recovery and thoracoabdominal donation after circulatory death groups. SRR DCD, Superrapid recovery donation after circulatory death; TA-NRP DCD, thoracoabdominal normothermic regional perfusion donation after circulatory death.

(BMI). There was no difference in the mean number of organs transplanted per donor: 3.93 organs in the TA-NRP group and 3.79 organs in the SRR group. Although not statistically significant, a higher percentage of livers were used for transplantation in the TA-NRP group (61/87, 71.8% TA-NRP vs 68/117, 58.1% SRR, $P = .065$). Of the livers recovered for transplant but not transplanted, 5 (33.3%) of 15 in the SRR group and 1 (50.0%) of 2 in the TA-NRP group were not used because of prolonged warm ischemic time. Reasons for nonutilization of livers that were not recovered or recovered but were not suitable for transplant were not available. Both 157 (92.3%) of 170 and 221 (94.4%) of 234 of kidneys from TA-NRP donors and SRR donors, respectively, were used for transplantation ($P = .793$). There was a difference ($P < .001$) in death to clamp time: 67 minutes in the TA-NRP group and 6 minutes in the SRR group. Median follow-up was 338 days (IQR: 185–364 days) for kidney recipients, 209 days (IQR: 182–363 days) for liver recipients, and 362 days (IQR: 178–369 days) for kidney-pancreas recipients. The overall follow-up was 318 days (IQR: 183–364 days).

3.2. Kidney transplant recipient primary and secondary outcomes

There was no difference in patients with disease and graft survival in TA-NRP versus SRR DCD recipients. [Figure 3](#) and

[Table 2](#) compare TA-NRP and SRR DCD kidney donor characteristics and recipient outcomes. There were no differences in the donor's age, gender, BMI, cold ischemia time, and the number of pumped kidneys. There were statistical differences ($P < .001$) in median KDPI (TA-NRP, 18%; SRR, 28%) and recipient DGF rates (TA-NRP, 15/188; 12.7%; SRR, 84/200; 42.0%).

We examined factors associated with DGF. After adjusting for KDPI ([Fig. 4](#)), donor age, and donor gender, the odds of DGF were 80.2% lower in TA-NRP recipients (OR, 0.198; 95% CI, 0.101–0.365) and 50.7% lower with pumped kidneys (OR, 0.493; 95% CI, 0.274–0.879). The odds of DGF were 5.1% higher with longer cold ischemic time (OR, 1.051; 95% CI, 1.017–1.090).

3.3. Liver transplant recipient primary and secondary outcomes

There was no difference in patients with liver disease and graft survival in TA-NRP versus SRR DCD recipients. [Figure 5](#) and [Table 3](#) show the donor and recipient characteristics for liver transplants. There was no difference in any other measured categories, including donor age, gender, cold ischemia time, model of end-stage liver disease, hepatocellular carcinoma exception, recipient length of stay, retransplant, recipient death, donor BMI, and simultaneous liver-kidney transplants. None of the liver grafts in either group utilized ex situ machine perfusion.

Table 1
Comparison of TA-NRP and SRR DCD heart donor characteristics.

| Donor characteristics | TA-NRP DCD (n = 85) | SRR DCD (n = 117) | P value |
|---|---------------------|--------------------|---------|
| Donor age, median (IQR), y | 28 (21-34) | 31 (25-36) | .020 |
| Male gender, no. (%) | 76 (89.4) | 96 (82.1) | .211 |
| Donor BMI, median (IQR), kg.m ⁻² | 26.6 (24.1-29.3) | 26.8 (24.9-31.1) | .161 |
| Kidney donor profile index, median (IQR) | 0.19 (0.10-0.31) | 0.23 (0.14-0.39) | .051 |
| Death to clamp time, median (IQR), mins | 67 (57-99) | 6 (4-8) | <.001 |
| Organs transplanted | | | |
| Heart, no. (%) | 85 (100) | 117 (100) | |
| Liver, no. (%) | 61 (71.8) | 68 (58.1) | .065 |
| Kidneys, no. (%) | | | .753 |
| 1 Kidney | 5 (5.9) | 7 (6.0) | |
| 2 Kidneys | 76 (89.4) | 107 (91.5) | |
| Double lung, no. (%), single lung, no. (%) | 4 (4.7), 10 (11.8) | 1 (0.9), 16 (13.7) | .247 |
| Pancreas, n (%) | 7 (8.2) | 4 (3.4) | .136 |
| Organs transplanted per donor, median (IQR) | 4 (3-4) | 4 (3-4) | .254 |
| Warm ischemia time, median (IQR), mins | NA | 21.0 (18.0-24.5) | NA |
| Liver nonutilization disposition | | | |
| Authorization not obtained | 1 (1.2) | 0 (0) | .735 |
| Organ not recovered | 13 (15.3) | 26 (22.2) | |
| Recovered for transplant but not transplanted | 2 (2.4) | 15 (12.8) | |
| Recovered not for transplant | 8 (9.4) | 8 (6.8) | |

BMI, body mass index; DCD, donation after circulatory death; IQR, interquartile range; NA, not applicable; SD, standard deviation; SRR, superrapid recovery; TA-NRP, thoracic normothermic regional perfusion.

There were 2 early retransplants in each group. There were no reported biliary complications in either group.

3.4. Kidney-pancreas recipient primary and secondary outcomes

We also evaluated simultaneous kidney-pancreas transplant outcomes for TA-NRP versus SRR DCD. There were 7 recipients of simultaneous kidney-pancreas grafts in the TA-NRP DCD group and 5 in the SRR group. Two recipients in the SRR group and 1 recipient in the TA-NRP group (TA-NRP 1/7; 14.3% vs SRR 2/5; 40.0%) had delayed kidney graft function ($P = .311$). One recipient (1/5; 20%) in the SRR group had a pancreas graft loss secondary to bleeding. One recipient in the TA-NRP group died on postoperative day 369 from an infection.

4. Discussion

In this study, we show the outcomes of abdominal transplant recipients from TA-NRP DCD donors in the US. Overall patient and graft survival for abdominal transplant recipients of organs from TA-NRP DCD donors was no different than that of SRR DCD donors.

In terms of kidney transplant recipient outcomes, there was 100% graft survival at 30 days and a significantly lower DGF rate in TA-NRP DCD donor kidney recipients. Our findings are similar to those of a systematic review from multiple European countries in which TA-NRP DCD recipients had 64% lower odds for DGF versus other DCD donor techniques.¹⁵ Our findings are also similar to a single-center study from the United Kingdom that showed 20.7% DGF in TA-NRP kidney recipients versus 35% DGF in SRR kidney recipients.¹⁶ The current study showed that TA-NRP is not only safe for kidney transplant recipients but superior with respect to DGF, which will reduce the costs associated with kidney transplantation. Further follow-up is needed to determine if the 1- and 5-year graft survival differs between groups.

The current study also found no significant difference in the patient and graft survival outcomes of TA-NRP versus SRR liver transplant recipients. Also, there was no significant difference in early graft loss in the TA-NRP and SRR liver recipients (3.6% vs 3.1%). In comparison, a United Kingdom study comparing NRP and SRR found 2% graft loss in NRP liver recipients versus 12% in SRR liver recipients, but this is likely a function of the differences in the SRR comparison donor groups between studies.⁷ Neither group in our study had any reported biliary complications,

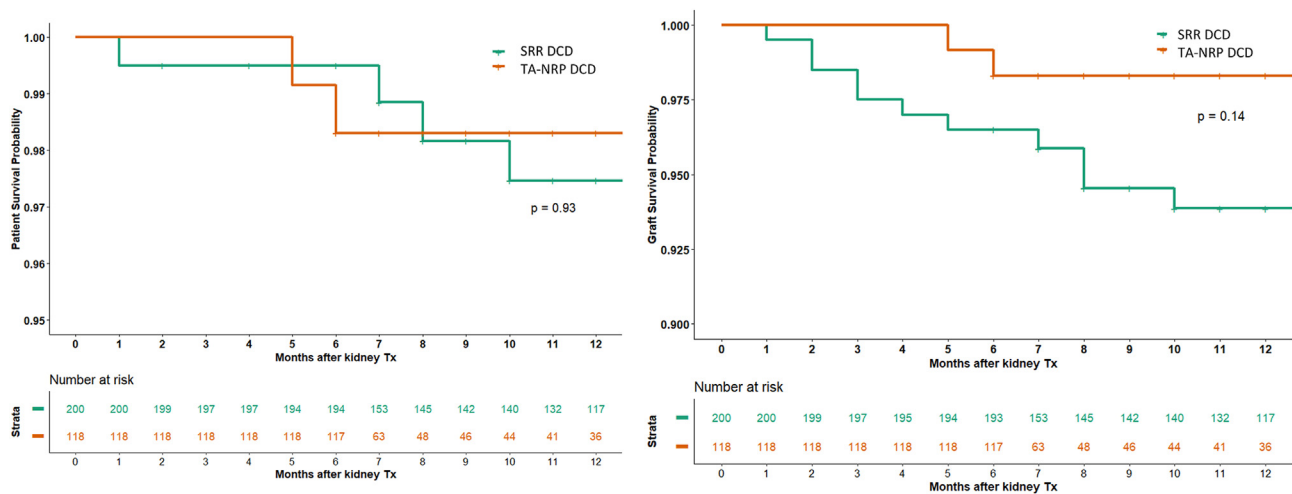


Figure 3. Kidney transplant recipient patient and graft survival of thoracic normothermic regional perfusion versus superrapid recovery donation after circulatory death cardiac donors.

which may be a function of follow-up being limited to 6 months or incomplete data reporting to UNOS. Longer follow-up, multi-center studies are needed to accurately determine the biliary complication rates of TA-NRP recipients and provide data to help liver transplant teams determine donor acceptance thresholds.

The utilization rate for TA-NRP DCD livers was higher than that for SRR DCD livers in the current study but did not reach statistical significance. The lower utilization of SRR DCD livers may be because of delays in starting liver preservation while waiting for the cardiac team to drain blood to prime the pump for machine perfusion in SRR recoveries. Five of the recovered livers in the SRR group of this study were not utilized because of prolonged warm ischemic time, although only 1 liver from the TA-NRP group was not used for this reason. This finding is supported by reports of nonutilization of livers from SRR heart DCD donors because of prolonged warm ischemic time and recommendations for setting ground rules for multiorgan procurement procedures.^{18,19} However, because the reasons for the nonutilization of nonrecovered livers and livers recovered not for transplantation were not available in our dataset, further research

is needed to determine if nonutilization is impacted by procurement technique. Moreover, this study was not able to identify attempted TA-NRP cases that either resulted in technical failures or nonutilization of the heart after functional assessment, both situations that may also result in nonutilization of abdominal organs.

The current study shows that the primary outcomes of TA-NRP DCD abdominal transplant recipients are equivalent to, although not better than, those of SRR DCD. Beyond the promise of better recipient outcomes, the TA-NRP procurement is a more controlled operative procedure, which is important for safety from sharps injuries in the setting of multiple procurement teams. There is more time for organ evaluation while the organs are being perfused before cross-clamp, which may increase the utilization of abdominal grafts from DCD donors, particularly liver and kidney donors. Moreover, TA-NRP is cost-effective compared with machine perfusion of all organs separately.

This study also demonstrates limitations in how UNOS data are reported for DCD donation given the 2 different pathways of TA-NRP and SRR DCD. As TA-NRP is being adopted more

Table 2

Comparison of TA-NRP and SRR kidney donor characteristics and recipient outcomes.

| Kidney donor characteristics and recipient outcomes | TA-NRP DCD (n = 118) | SRR DCD (n = 200) | P value |
|---|----------------------|-------------------|---------|
| Donor age, median (IQR), y | 27.0 (21.0-34.0) | 31.0 (25.0-36.0) | .001 |
| Donor male gender, no. (%) | 106 (89.8) | 168 (84.0) | .198 |
| Donor BMI, median (IQR), kg.m ⁻² | 27.2 (24.4-29.9) | 27.2 (24.9-31.4) | .224 |
| Kidney donor profile index, median (IQR) | 0.18 (0.10-0.31) | 0.28 (0.14-0.41) | <.001 |
| Cold ischemic time, median (IQR), h | 17.8 (13.7-22.7) | 18.7 (14.0-22.4) | .411 |
| Recipient delayed graft function, no. (%) | 15 (12.7) | 84 (42.0) | <.001 |
| Recipient death with a functioning graft, no. (%) | 2 (1.7) | 4 (2.0) | 1.000 |
| Kidney pumped, no. (%) | 79 (66.9) | 140 (70.4) | 0.611 |

BMI, body mass index; DCD, donation after circulatory death; IQR, IQR, interquartile range; NA, not applicable; SRR, superrapid recovery; TA-NRP, thoracic normothermic regional perfusion.

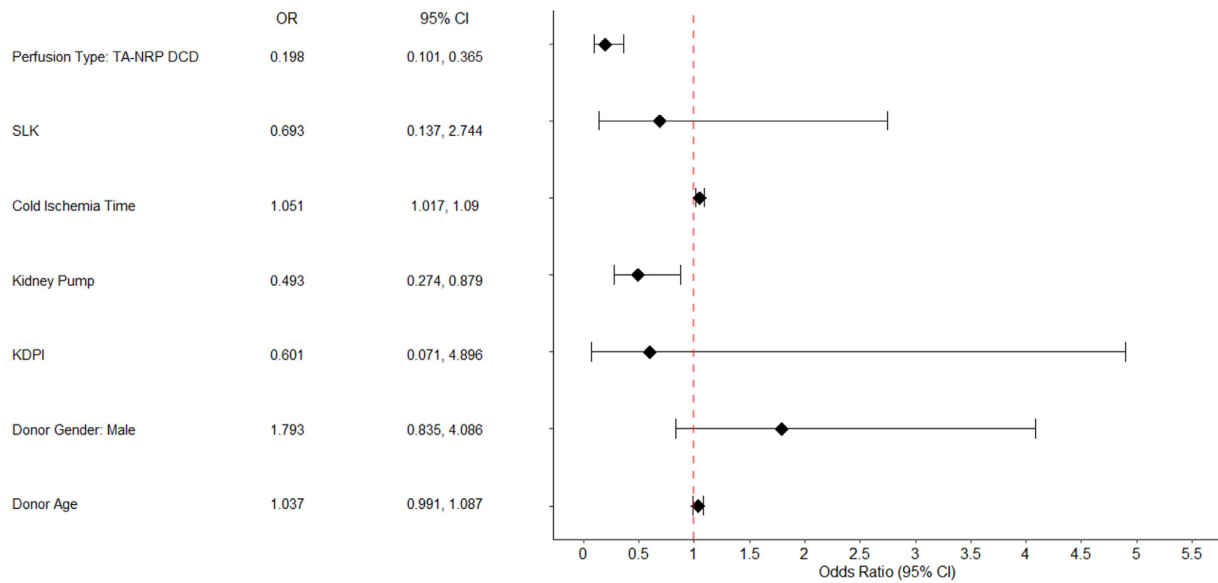


Figure 4. Forest plot of the logistic regression analysis of factors impacting delayed graft function. TA-NRP DCD, thoracic normothermic regional perfusion donation after circulatory death; KDPI, kidney donor profile index.

broadly across the US, we recommend that UNOS data collection should include procurement procedure type as well as the time that NRP is initiated. This would allow for further studies comparing donor types and an accurate calculation of warm ischemic time for NRP donors, which is a crucial variable for risk assessment for biliary complications. Moreover, as noted in the discussion on nonutilization, the UNOS data collection should also include an attempted procurement technique and reasons for nonutilization of organs in DCD donation so that cases in which technical failures and poor heart function on NRP resulting in the nonutilization of abdominal organs are identified.

Although TA-NRP DCD organ procurement is promising, there are ethical and legal concerns about the conduct of this procedure, which focus on whether the donor is truly dead, when the heart can be restarted, and whether the exclusion of cerebral circulation is an acceptable component of the procedure.²⁰⁻²³

Given that there is a strong potential for TA-NRP DCD to expand the organ donor pool and increase the number of organs per DCD donor, ethical and legal concerns must be addressed with all essential stakeholders to maintain public trust in organ transplantation. Moreover, there is an opportunity to expand the utilization of NRP with A-NRP procedures, which isolate NRP perfusion to the abdominal organs and do not restart the heart. The A-NRP procedure is considered less ethically problematic by some scholars because the heart is not restarted and perfusion is more limited. Both the American Society of Transplantation and the American Society of Transplant Surgeons have made written statements in support of NRP-DCD procedures.^{24,25}

This study is limited by the data available from UNOS and the duration of follow-up. It is also limited in that the TA-NRP DCD technique is not standardized, so a more detailed study of techniques within this subset of donor procurements is needed.

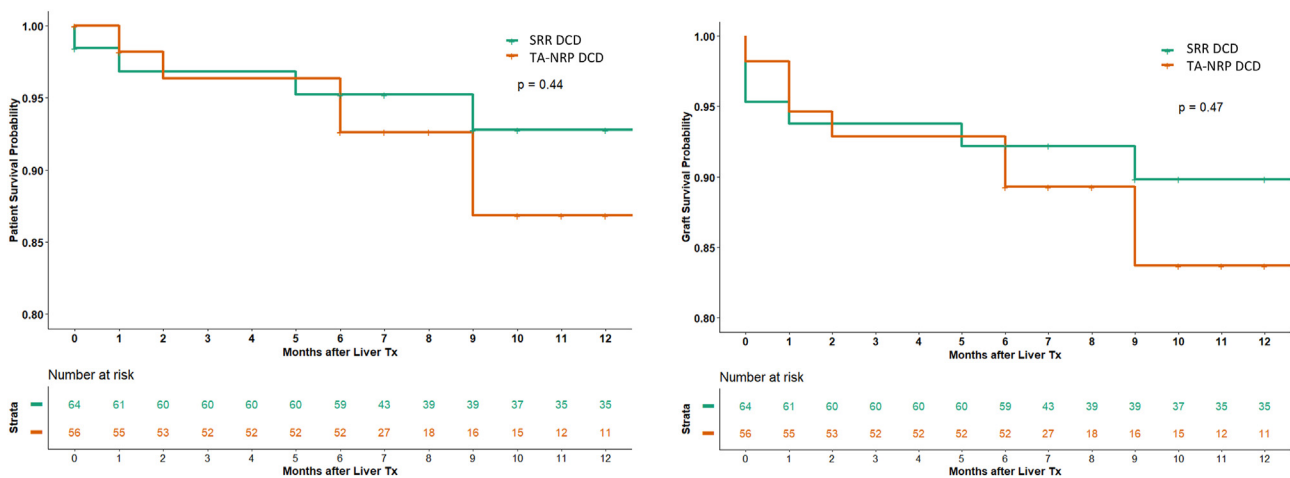


Figure 5. Liver transplant recipient patient and graft survival of thoracic normothermic regional perfusion versus superrapid recovery donation after circulatory death cardiac donors.

Table 3

Comparison of TA-NRP and SRR DCD liver donor characteristics and recipient outcomes.

| Liver donor characteristics and recipient outcomes | NRP DCD (n = 56) | SRR (n = 64) | P value |
|--|------------------|------------------|---------|
| Donor age, median (IQR), y | 26.0 (20.0-34.0) | 29.5 (23.0-34.2) | .085 |
| Donor male gender, no. (%) | 49 (87.5) | 53 (82.8) | .645 |
| Cold ischemic time, median (IQR), h | 4.78 (4.02-6.06) | 5.00 (4.55-5.80) | .320 |
| Recipient MELD, median (IQR) | 19.5(16.0-25.0) | 18.0 (13.8-25.2) | .554 |
| Recipient HCC exception, no. (%) | 12 (21.4) | 18 (28.1) | .526 |
| Recipient length of hospital stay, median (IQR), d | 8.0 (6.0-11.0) | 8 (6.0-13.5) | .402 |
| Donor BMI, median (IQR), kg.m ⁻² | 26.3 (23.8-28.7) | 26.1 (24.6-29.6) | .320 |

BMI, body mass index; DCD, donation after circulatory death; HCC, hepatocellular carcinoma; IQR, IQR, interquartile range; MELD, model for end-stage liver disease; NA, not applicable; SRR, superrapid recovery; TA-NRP, thoracic normothermic regional perfusion.

However, the findings of early graft survival and lower DGF rates are important to demonstrating the safety of using TA-NRP DCD grafts. A subsequent longer-term follow-up study of 1-year outcomes is planned to further compare biliary complications, grafts, and patient survival between these 2 groups. In addition, because the UNOS STAR database does not definitively identify TA-NRP versus SRR donors, our methods of identification of these groups could be questioned. Given the clear difference in death to cross-clamp time in the 2 groups, we believe that our identification of the 2 groups is accurate. Moreover, our analysis certainly missed additional recipients of TA-NRP DCD in which the heart was declined in the OR after evaluation on NRP. We intentionally chose our study population to compare the outcomes of similar donors and be sure that a heart procurement was part of the DCD procedure. However, in future studies, we will be able to expand the study population. Ideally, NRP utilization will be collected using UNOS in the future so that the outcomes of these donors can be analyzed.

Our analysis of UNOS STAR data found equivalent early outcomes for abdominal transplant recipients of TA-NRP DCD versus SRR DCD donors from whom the heart was also used for transplantation in terms of patient and graft survival and lower rates of delayed kidney graft function. The TA-NRP DCD organ recovery technique shows promising results for abdominal transplant recipients in the US as compared with SRR DCD but is limited to cardiac donors. We believe that NRP DCD procedures, both TA- and A-NRP, have the potential to expand the donor pool as well as the utilization of abdominal organs from DCD donors, but further research is needed to evaluate recipient outcomes and organ utilization rates.

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Data availability statement

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

Disclosure

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