



Setting Up an NRP Program: From Ethics to Education

TODAY'S PANELISTS



Anji Wall MD, PhD

Abdominal Transplant Surgeon



Aleah Brubaker MD, PhD

Transplant and Hepatobiliary
Surgeon



Jeff Trageser MSN, RN, CPTC

Executive Director



Bradley Adams JD, CPA

President & CEO



Tuesday, October 17, 2023, 2:00pm – 3:00pm ET

The Alliance is not an advocacy organization and always intends to maintain an objective and unbiased perspective.



Kristina Wheeler
Program Consultant



Need Assistance?

Contact Us via Zoom Chat, or
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786-866-8730

Meet Our Moderator



Brendan Parent JD

Director, Transplant Ethics & Policy Research



Meet Our Presenters



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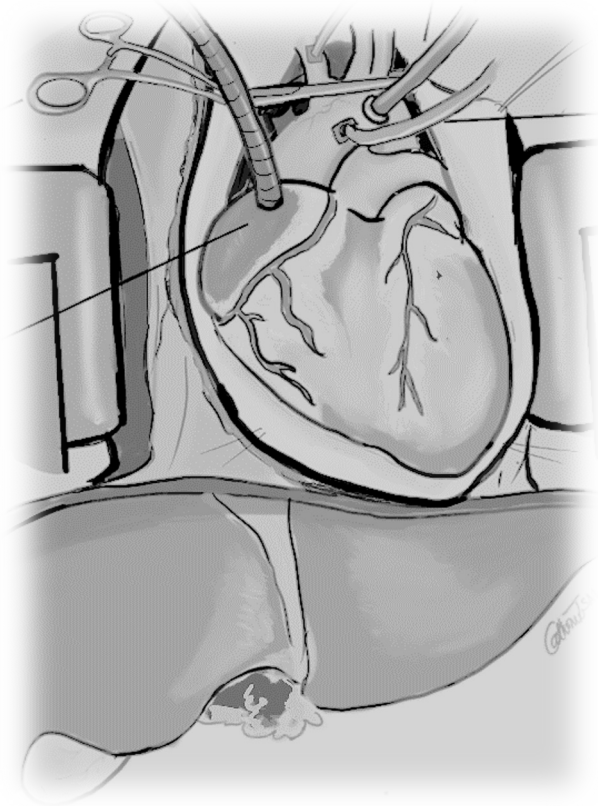


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Brad Adams, JD

Moderator:

Brendan Parent, JD



Clinical Need

DCD organs are one of the most immediate ways to increase the pool of transplantable organs

The organs are there. They are not being used.

NRP is a recovery technology that makes increasing DCD utilization feasible, and with good outcomes.

So– how do we do it??

Normothermic regional perfusion



- Post-mortem in situ oxygenated perfusion to the organs intended for transplantation
- A-NRP: Abdominal cavity only
- TA-NRP: thoracic and abdominal cavity
- Process: Cannulation, occlusion of blood vessels to the head, initiation of perfusion with warm, oxygenated blood, organ evaluation and intervention, cold perfusion and crossclamp

International NRP Outcomes

TABLE 4 Controlled DCD posttransplant complications and outcomes

| | A-NRP (N = 545) | SRR (N = 258) | Unadjusted | | Adjusted ^a | |
|--|--------------------|------------------|---|---------|---|---------|
| | | | Risks estimate (95% CI) ^b | p value | Risks estimate (95% CI) ^b | p value |
| EAD (%) | 81 (15) | 60 (23) | 0.576 (0.397-0.837) | .004 | 0.562 (0.363-0.871) | .010 |
| PNF (%) | 16 (3) | 15 (6) | 0.490 (0.238-1.007) | .052 | 0.573 (0.252-1.303) | .184 |
| HAT (%) | 22 (4) | 19 (7) | 0.529 (0.281-0.996) | .049 | 0.452 (0.219-0.932) | .032 |
| All biliary complications (%) ^c | 63 (12) | 75 (29) | 0.319 (0.219-0.464) | <.001 | 0.300 (0.197-0.459) | <.001 |
| ITBL (%) | 6 (1) | 24 (9) | 0.109 (0.044-0.269) | <.001 | 0.112 (0.042-0.299) | <.001 |
| Re-transplantation (%) | 19 (3.5) | 31 (12) | 0.265 (0.146-0.478) | <.001 | 0.279 (0.147-0.531) | <.001 |
| Graft loss ^d (%) | 77 (14) | 88 (34) | 0.422 (0.311-0.574) | <.001 | 0.371 (0.267-0.516) | <.001 |
| Patient death (%) | 65 (12) | 66 (26) | 0.494 (0.350-0.696) | <.001 | 0.540 (0.373-0.781) | .001 |

American Journal of Transplantation

Abdominal normothermic regional perfusion in controlled donation after circulatory determination of death liver transplantation: Outcomes and risk factors for graft loss

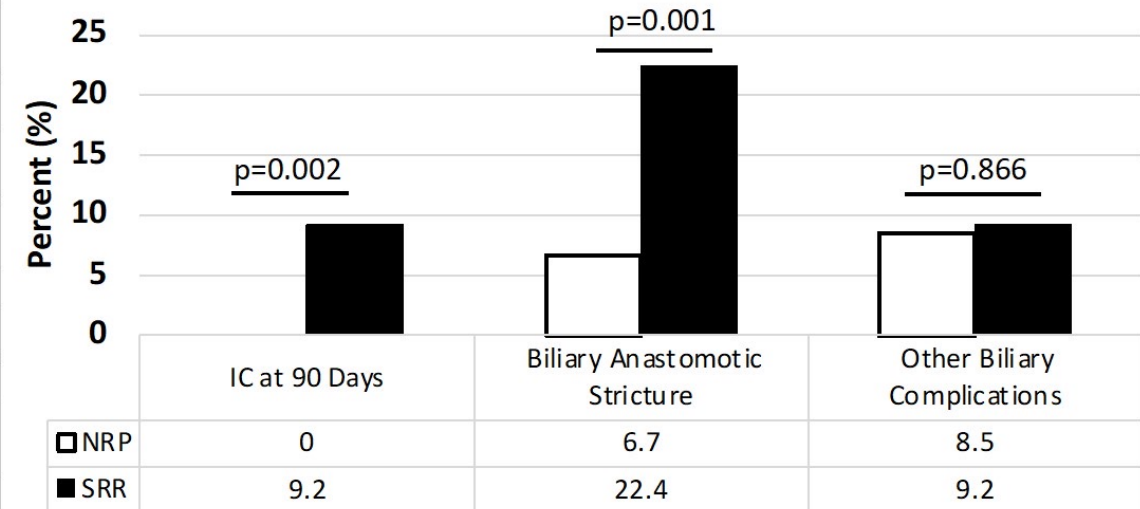
Amelia J. Hessheimer et al, 2022



CONCORD: US Liver Transplant Outcomes

| TABLE 3 | NRP (n = 106) | SRR (n = 136) | P value |
|---------------------------------------|------------------------|------------------------------|---------|
| Cold ischemic time (minutes) | 289 (IQR: 218-355) | 298.5 (IQR: 247-349) | 0.701 |
| Intra-op PRBC transfusion | 6 (IQR: 3-9) | 6 (IQR: 3-10) | 0.601 |
| Early allograft dysfunction (%)* | 36.4 | 56.1 | 0.007 |
| Peak AST | 930 (IQR: 419-1768) | 1905.5 (IQR: 1187.5-4660) | < 0.001 |
| Peak ALT | 646 (IQR: 315-1085) | 1055.5 (IQR: 586-1896.5) | < 0.001 |
| Primary non-function (%) | 0 | 1.5 | 0.210 |
| Reoperation for bleeding (%) | 8.3 | 9.6 | 0.759 |
| RRT within 7 days (%) | 9.8 | 8.9 | 0.830 |
| Post-transplant length of stay (days) | 7 (IQR: 5-11) | 10 (IQR: 7-16) | 0.001 |
| Readmission (%) | 38.0 | 47.8 | 0.182 |

* N=123 (SRR) and 77 (NRP)



US Heart Transplant Outcomes

| Recipient Outcomes | All DCD (n=88) | DPP (n=20) | TA-NRP (n=68) |
|--|----------------|---------------|---------------|
| Survival | | | |
| 30 day, n (% survival) | 83 (98.8) | 20 (100.0) | 63 (98.4) |
| 90 day, n (% survival) | 76 (98.7) | 18 (100.0) | 58 (98.3) |
| 1 year, n (% survival) | 58 (98.3) | 14 (100.0) | 44 (97.7) |
| Immediate Cardiac Index in ICU (L/min/m ²), median (IQR) | 2.9 (2.4-3.5) | 2.8 (2.4-4.2) | 2.9 (2.5-3.4) |
| Primary Graft Dysfunction (Moderate-Severe) | | | |
| Overall, n (%) | 24 (27.3) | 7 (35.0) | 17 (25.0) |
| IABP, n (%) | 23 (26.1) | 7 (35.0) | 16 (23.5) |
| ECMO, n (%) | 9 (10.2) | 2 (10.0) | 7 (10.3) |
| Ventilator Days, median (IQR) | 2 (1-3) | 3 (2-3) | 2 (1-3) |
| Renal Replacement Therapy, n (%) | 15 (15.9) | 2 (10.0) | 12 (17.6) |
| ICU Length of Stay (days), median (IQR) | 5 (4-7) | 6 (5-7) | 5 (3-7) |
| Hospital length of Stay (days), median (IQR) | 16 (13-24) | 16 (15-21) | 16 (13-25) |

Why start an A-NRP program



5% OF DCD DONORS ARE CARDIAC DONORS



NON-CARDIAC DCD DONORS ARE OLDER WITH MORE COMORBIDITIES AND HIGHER RISK



MOST LIVER TRANSPLANT CENTERS HAVE PERFUSION STAFF THAT CAN BE UTILIZED FOR NRP

Advantages of NRP for abdominal organs



IN SITU ORGAN VISUAL
ASSESSMENT



IN SITU ORGAN FUNCTIONAL
ASSESSMENT



BIOPSY PRIOR TO CROSS-CLAMP
WITHOUT IMPACTING COLD
ISCHEMIC TIME

How we started: Setting and staffing

- In-house, pre-mortem cannulation (controlled environment, consistent team, controlled procedure)
- Staff needed for an in-house program
 - 1:1 ICU nurse during comfort care
 - ICU attending for declaration and confirmation of death
 - ECMO surgeon and assistant for cannulation
 - Abdominal transplant surgeon and assistant for procurement
 - 2 perfusionists for NRP circuit management and POC lab testing
 - OR circulator and scrub tech
 - OPO staff

| | 9/2021 - 9/2022 Implementation | 10/2022 - 12/2022 Local Expansion | 1/2023 - 3/2023 Regional Expansion | 4/2023 - 8/2023 Donor Acceptance Expansion |
|----------------------------------|--|---|--|---|
| | | | | |
| Technical | Pre-Mortem Cannulation | Tandem Rapid Recovery Lung Central Cannulation | Intra-abdominal Cannulation | Aortic Balloon Occlusion |
| Logistical | In House Donors | Mobile Program | Flyout Program | |
| Donor Acceptance Criteria | Donor Age < 60 yrs fWIT 30 min from 80/80 | Donor Age ≥ 60 yrs | fWIT 45 min from 80/80 | Total WIT 90 min or fWIT 30 min SBP 50 |
| NRP Equipment | Initial Circuit Design: Maquet Rotoflow Termo CDI 500 LiNovo Oxygenator | Circuit Alteration: (+) Termo Hemoconcentrator (Manages congested livers) (+) Venous Reservoir w/ craniotomy filter to allow for air in venous system | Circuit Alteration: (-) Termo CDI 500 | Circuit Alteration: (+) 2nd Venous Reservoir (For lung cases) (+) Pump Suction x 3 (To improve volume return) |

With increasing comfort, there is a decrease in non-utilization.

Dry runs still happen but have become less frequent

September 2023: 100% utilization of liver grafts from donors that expired within the hospital timeframe for donation

Our DCD approach

Abdominal-only expansion

- Age limit: 70
- BMI limit: none
- Warm ischemic time limit (from SBP 50): 30 minutes

Program mentality

- NRP is the default option for all donors- we work with the OPO, hospital and other procurement teams to establish the acceptable procedure and approach
- Unable to do NRP (distance, logistics)- machine perfusion (at donor site)
- Cold ischemic time concerns (e.g., recipient anatomy or illness severity)- NRP plus machine perfusion (back to base)

How we make it happen



COMMUNICATION



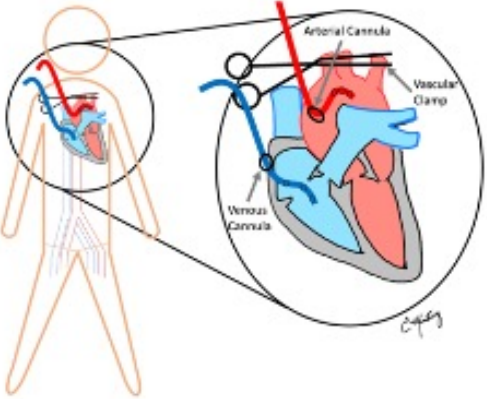
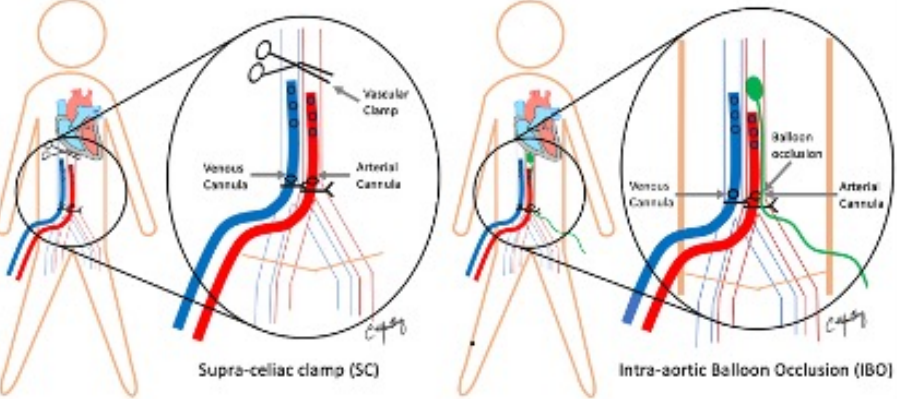
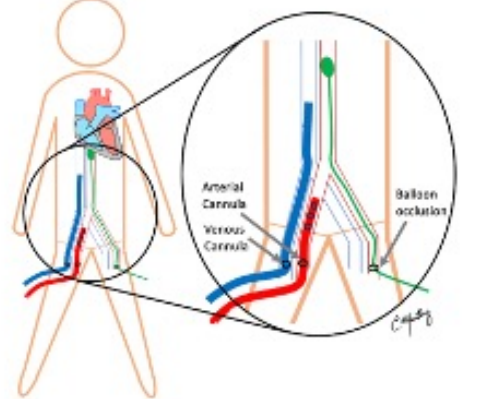
FLEXIBILITY



CASE REVIEWS

Every DCD offer

- Coordinators ask: What other organs are being allocated? Is NRP allowed?
- If yes: Protocol is sent to the on-site coordinator
- Phone pre-brief with OPO and procurement teams
- In person preoperative briefing with OR, OPO and procurement teams
- Surgeon and perfusion postoperative debriefs
- Remember OPO doesn't have complete control of timeline on DCDs

| | Central Cannulation | Abdominal Cannulation | Femoral Cannulation |
|--|--|--|---|
| Cannulation Techniques |  |  |  |
| Organs perfused | Thoracic: Heart, Lungs Abdominal: Liver, Intestine, Pancreas, Kidneys | Abdominal: Liver, Intestine, Pancreas, Kidneys | Abdominal: Liver, Intestine, Pancreas, Kidneys |
| Surgical Personnel (Minimum ; Typical) | Surgeon: 1 ; 2 Assistant: 1 ; 1 | Surgeon: 1 ; 1 Assistant: 1 ; 2 | Surgeon: 1 ; 1 Assistant: 1 ; 2 |
| NRP Instrumentation (Avg Time Incision-to- Flow) | Arterial & Venous Cannulas Vascular Clamp (4 minutes) | Arterial & Venous Cannulas Vascular Clamp or Intra-aortic Balloon Occlusion (IBO) catheter (7 minutes) | Arterial & Venous Cannulas IBO catheter (3 minutes) |
| Cannulation Location | Arterial: Ascending Aorta Venous: Right Atrial Appendage | Arterial: Distal Abdominal Aorta Venous: Caudal Inferior Vena Cava | Arterial: Common Femoral Artery Venous: Common Femoral Vein |
| Clamp Location | Occlusion of Aortic Arch Vessels | With or Without prior IBO, Clamp the Descending Aorta – Thoracic or Supra-Celiac | After IBO, Clamp the Descending Aorta – Thoracic or Supra-Celiac; |
| Indications | Obese, Hostile abdomen | Pre-mortem sheath placement not permitted Thoracic supra-rapid recovery planned | Obese, Hostile chest or abdomen, Thoracic supra-rapid recovery planned |
| Contraindications | Hostile chest, Thoracic supra-rapid recovery planned | Hostile abdomen | Pre-mortem sheath placement not permitted |

OPO Implementation and Updates

Jeffrey Trageser

Executive Director

Lifesharing

OPO Implementation and Updates

Then

- Confer with OPO Legal Counsel
- Confer with OPO Ethics
- Review with Advisory Boards
- Communicate with Hospitals
- Add new language for families
- Develop protocols/checklists for clinical team

Now

- New protocol for aNRP
- Adapt protocol to be more broad
 - New teams with different models
- Manage conflicts in real time
 - Lung teams, etc.
- OPTN ethics white paper
 - Family-centric communication plan
- Financial Considerations

Recent Developments: Ethics and the Law

Bradley L. Adams, JD

President & CEO

Southwest Transplant Alliance

Dallas, Texas



Recent Developments: Ethics and the Law

OPTN Ethics Committee

White Paper: The Ethical Analysis of NRP
July, 2023

JA Frontera, MD, N Moazami, MD, et. al

TA-NRP in DCD Does Not Restore Brain Blood Flow
J. Heart Lung Transplant
Vol. 42, Iss. 9, Sep, 2023, pp 1161-1165

American Academy of Neurology

Pediatric and Adult BD/DNC Consensus Guideline
July 20, 2023

Uniform Law Commission

Updates to the Uniform Determination of Death Act
132nd Annual Meeting, July 21–26, 2023

A Special Thanks to Our Presenters



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