MHIF FEATURED STUDY:

OCS DCD Heart CAP

OPEN and ENROLLING:

EPIC message to *Research MHIF Patient Referral*

CONDITION:	PI:	RESEARCH CONTACT:	SPONSOR:
Heart Failure / Transplant	Karol Mudy, MD	Kari Thomas Kari.M.Thomas@allina.com | 612-863-7493	TransMedics, Inc.

DESCRIPTION: The Portable Organ Care System (OCS™) Heart for Resuscitation, Preservation and Assessment of Hearts from Donors After Circulatory Death Continued Access Protocol (OCS DCD Heart CAP)

To enable continued clinical access to DCD heart transplantation in the U.S. and to continue to collect additional data on the performance of the OCS Heart System to resuscitate, preserve and assess hearts donated after circulatory death for transplantation to increase the pool of donor hearts available for transplantation.

A prospective, single arm, continues access protocol.

CRITERIA LIST/ QUALIFICATIONS:

Donor Heart Inclusion

- Maastricht Category III DCD donor, defined as expected death after the withdrawal of life-supportive therapy (WLST)
- Donor age 18-49 years old inclusive
- Warm ischemic time (WIT) ≤ 30 mins, with warm ischemic time defined as: Time from when
- mean systolic blood pressure (SBP) is < 50 mmHg or peripheral saturation < 70% to aortic crossclamp
- and administration of cold cardioplegia in the donor.

To date, MHIF has had eight successful uses of the TransMedics Organ Care System (OCS™), aka "Heart in the Box"

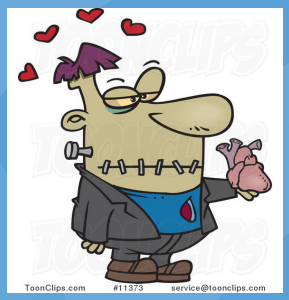
HOPE DISCOVERED HERE™

Minneapolis Heart Institute Foundation®
Creating a world without heart and vascular disease

Minneapolis Heart Institute

Allina Health ABBOTT NORTHWESTERN HOSPITAL

FRANKENSTEIN COMES TO ABBOTT: A heart failure talk.



Bassam Shukrallah, MD and Karol Mudy, MD

1

Disclosures

- No COI

Minneapolis Heart Institute

Allina Health ABBOTT NORTHWESTERN HOSPITAL

2

2

Objectives

- Organ care system (OCS) technology in greater details
- Donation after brain death (DBD) and donation after circulatory death (DCD)
- MHI OCS Data for DCD/DBD

Minneapolis Heart Institute | Allina Health Abbott Northwestern Hospital

3

Where it all began

- **Waleed Hassanein, MD**
  - Inventor and founder of TransMedics
  - Georgetown medical school, MD and residency
  - BWH/Roxbury VA, CT surgery research fellowship
  - Landmark paper Published in JCTVS 1998 Nov;116(5):821-30.
  - OCS 2014

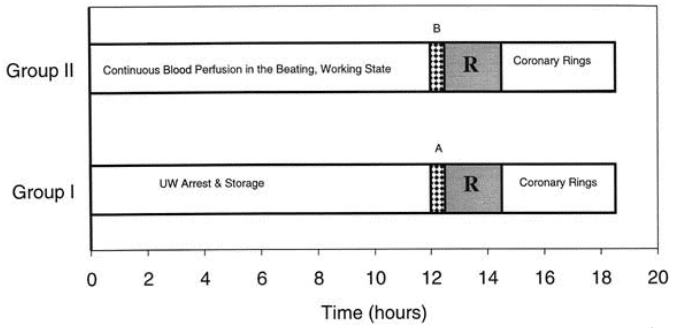
Minneapolis Heart Institute | Allina Health Abbott Northwestern Hospital

4

4

CONTINUOUS PERFUSION OF DONOR HEARTS IN THE BEATING STATE EXTENDS PRESERVATION TIME AND IMPROVES RECOVERY OF FUNCTION

Waleed H. Hassanein, MD
Lambros Zellos, MD
Tracey A. Tyrrell, BA
Nancy A. Healey, BS
Michael D. Crittenden, MD
Vladimir Birjiniuk, MD
Shukri F. Khuri, MD



Minneapolis Heart Institute | Allina Health Abbott Northwestern Hospital

5

5

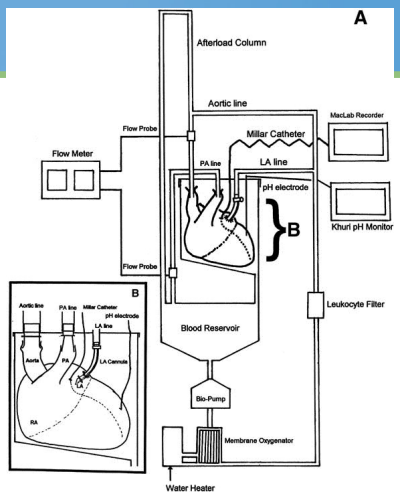
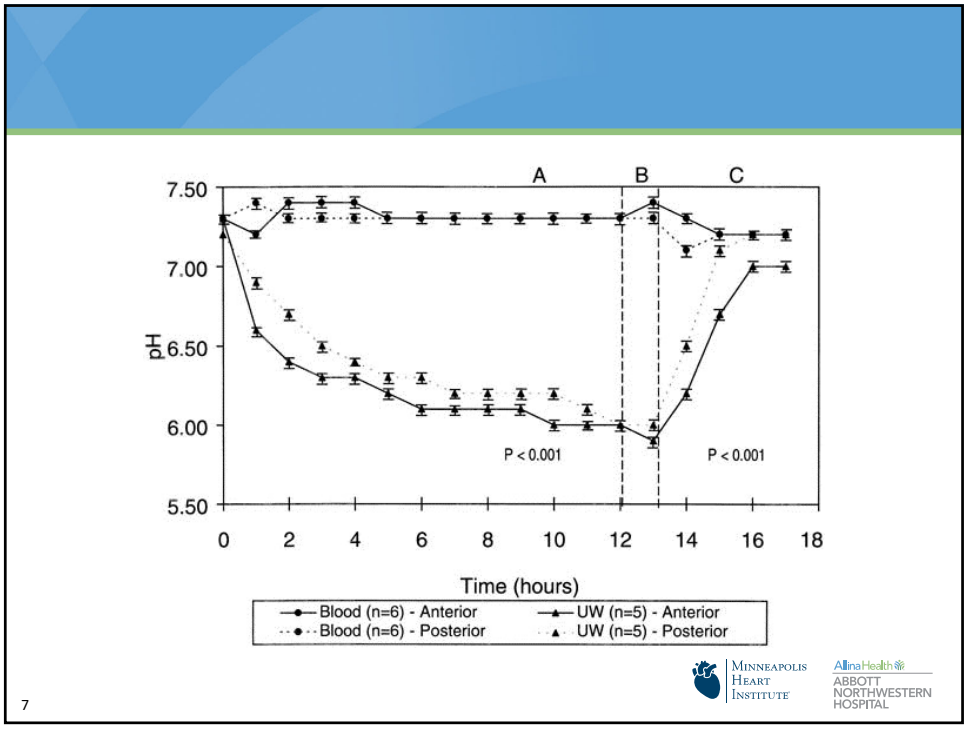


Fig 2. Schema of perfusion apparatus. Panel **A** shows the monitoring equipment and chamber for the heart. Panel **B** is a detailed enlargement of the heart chamber depicting the instrumentation. *LA*, Left atrium; *RA*, right atrium; *PA*, pulmonary artery.

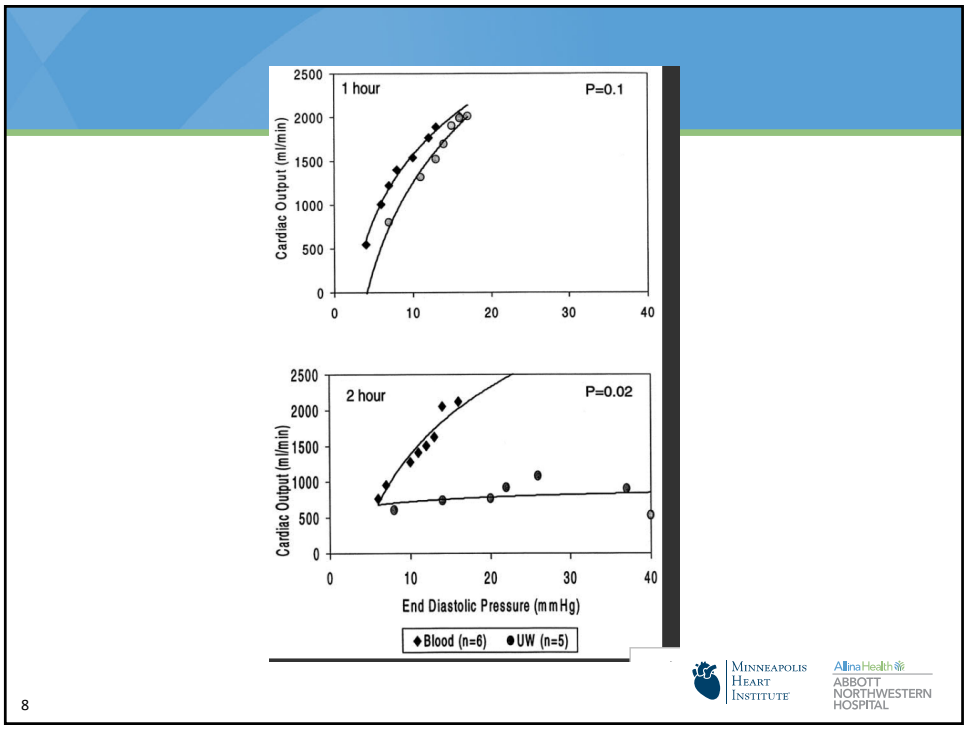
Minneapolis Heart Institute | Allina Health Abbott Northwestern Hospital

6

6


A
B
C
7.50
7.00
6.50
6.00
5.50
pH
P < 0.001
P < 0.001
0
2
4
6
8
10
12
14
16
18
Time (hours)
Blood (n=6) - Anterior
Blood (n=6) - Posterior
UW (n=5) - Anterior
UW (n=5) - Posterior
Minneapolis Heart Institute
Allina Health
Abbott Northwestern Hospital
7

7


1 hour
P=0.1
Cardiac Output (ml/min)
2500
2000
1500
1000
500
0
0
10
20
30
40
2 hour
P=0.02
Cardiac Output (ml/min)
End Diastolic Pressure (mmHg)
Blood (n=6)
UW (n=5)
Minneapolis Heart Institute
Allina Health
Abbott Northwestern Hospital
8

8

Conclusion → TIME Extended!

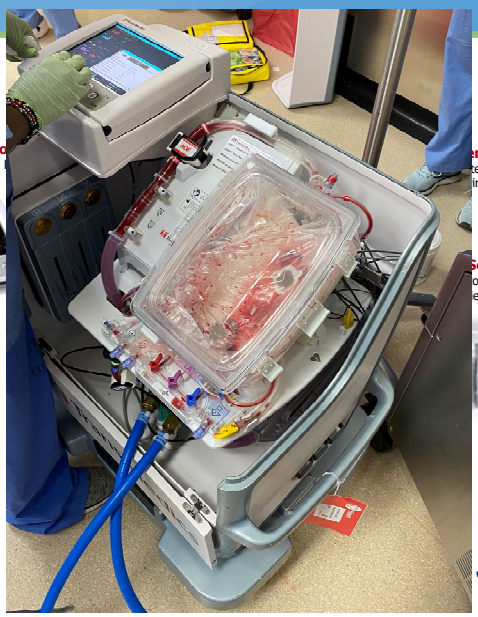
55% Δbaseline, $P = .01$). *Conclusion:* This new method extends the current preservation limit and avoids time-dependent ischemic injury, thereby allowing for distant procurement of donor organs. (J Thorac Cardiovasc Surg 1998;116:821-30)

Minneapolis Heart Institute | Allina Health Abbott Northwestern Hospital

9

9

Organ Care System



Wireless Monito
Controls and displays
parameters

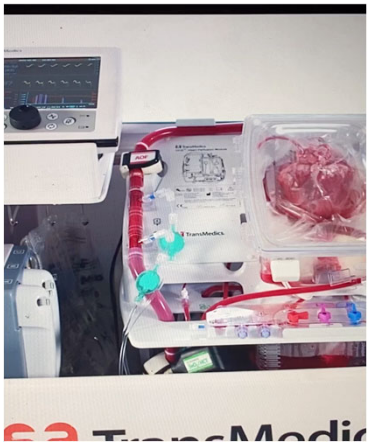
rfusion Module
erile blood circuit and
ironment for the donor
heart

olution Set
o blood circulation;
ents and substrates

Minneapolis Heart Institute | Allina Health Abbott Northwestern Hospital

10

Three main components



- Array of non-invasive, ultrasound sensors monitor critical parameters, such as blood pressure, blood flow and blood cell counts, to sustain the organ's health while in transit.
- A "solution set" infuses the organ with essential nutrients and substrates.
- Wireless control monitor allows to manipulation of above after the organ has been attached to the OCS

Minneapolis Heart Institute | Allina Health Abbott Northwestern Hospital

11

11

SBN1

DBD vs. DCD

	Donation After Brain Death (DBD)	Donation After Cardiac Death (DCD)
Injury	Severe brain injury from trauma, cerebral vascular accident, anoxic event, other – **REFERRAL TO OPO**	Severe brain injury from trauma, cerebral vascular accident, anoxic event, other - **REFERRAL TO OPO**
Meets Criteria for Brain Death	Yes: Clinical Exam (including apnea test) is consistent with brain death. If unable to fully complete any part of the clinical exam, a confirmatory test is required (i.e., Nuclear Flow).	No: Some neurological reflex is still present
Prognosis	Brain death: This is the legal time of death	As determined by hospital physician, patient has no chance of recovery from brain injury; cannot survive without mechanical ventilator.
Action	Brain death declaration is made by hospital physician (not OPO). Signed brain death note and consent form are faxed to OPO. Once brain death is declared, OPO and Hospital work cooperatively on medical management of the donor patient. Patient remains on ventilator throughout organ recovery. Anesthesiology is present for intra-operative fluid and BP management Transplant team spends three to four hours recovering organs in-situ.	Family/NOK elects to withdraw support Donation discussion with family, they consent. Signed futility note and consent form get faxed to OPO. OPO and hospital work cooperatively on medical management of the donor patient. Withdrawal of support can take place in OR or ICU • RT with a portable vent is used for OR w/d • ICU nurse administers meds for w/d Cardiac death • No blood pressure, pulse or cardiac sounds • No spontaneous respiration Wait five minutes to ensure no auto-resuscitation. After five minutes of ceased circulation, hospital physician (not OPO) declares death. Transplant team immediately begins organ recovery; takes one to two hours to recover organs en-bloc.

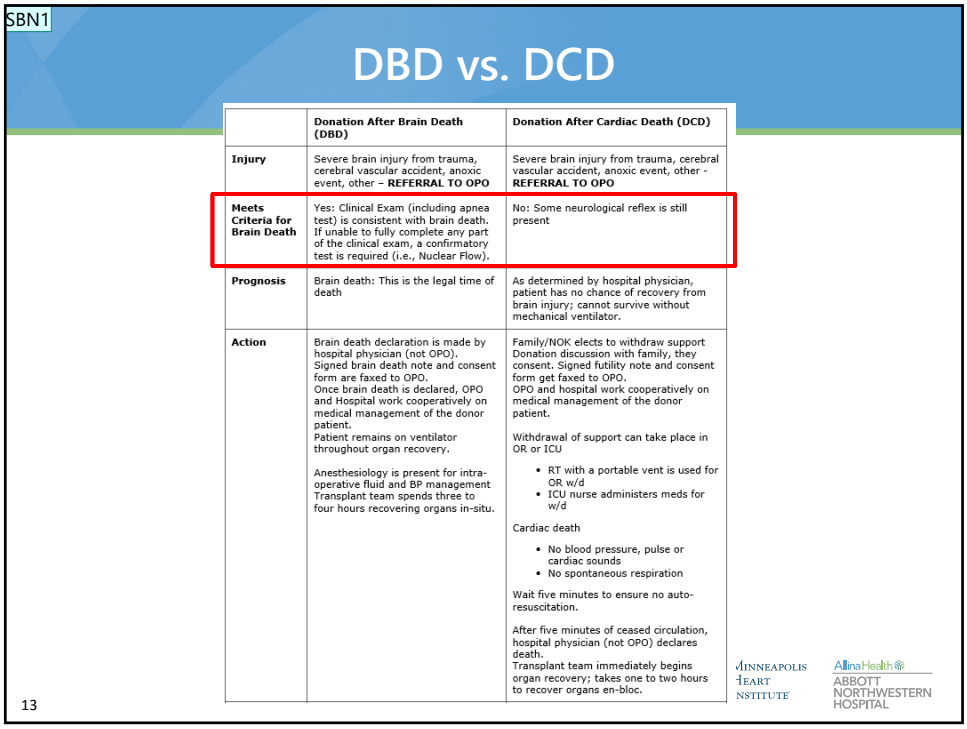
Minneapolis Heart Institute | Allina Health Abbott Northwestern Hospital

12

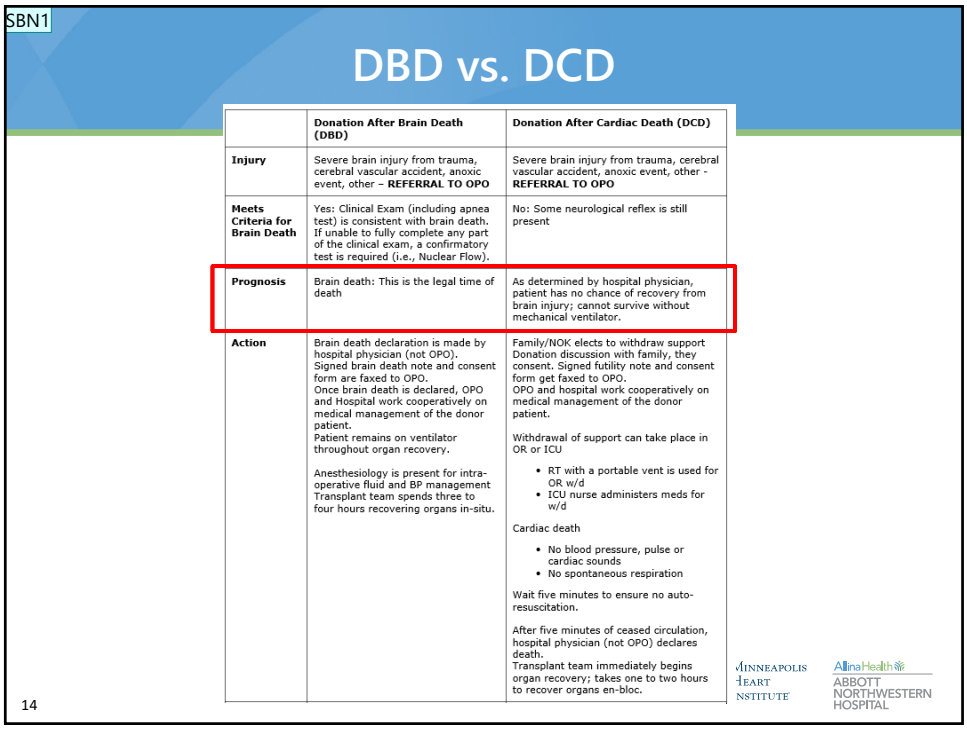
12

Slide 12

SBN1 Shukrallah, Bassam N, 3/21/2021


SBN1
DBD vs. DCD
Donation After Brain Death (DBD)
Donation After Cardiac Death (DCD)
Injury
Severe brain injury from trauma, cerebral vascular accident, anoxic event, other – REFERRAL TO OPO
Severe brain injury from trauma, cerebral vascular accident, anoxic event, other - REFERRAL TO OPO
Meets Criteria for Brain Death
Yes: Clinical Exam (including apnea test) is consistent with brain death. If unable to fully complete any part of the clinical exam, a confirmatory test is required (i.e., Nuclear Flow).
No: Some neurological reflex is still present
Prognosis
Brain death: This is the legal time of death
As determined by hospital physician, patient has no chance of recovery from brain injury; cannot survive without mechanical ventilator.
Action
Brain death declaration is made by hospital physician (not OPO).
Signed brain death note and consent form are faxed to OPO.
Once brain death is declared, OPO and Hospital work cooperatively on medical management of the donor patient.
Patient remains on ventilator throughout organ recovery.
Anesthesiology is present for intra-operative fluid and BP management
Transplant team spends three to four hours recovering organs in-situ.
Family/NOK elects to withdraw support
Donation discussion with family, they consent. Signed futility note and consent form get faxed to OPO.
OPO and hospital work cooperatively on medical management of the donor patient.
Withdrawal of support can take place in OR or ICU
RT with a portable vent is used for OR w/d
ICU nurse administers meds for w/d
Cardiac death
No blood pressure, pulse or cardiac sounds
No spontaneous respiration
Wait five minutes to ensure no auto-resuscitation.
After five minutes of ceased circulation, hospital physician (not OPO) declares death.
Transplant team immediately begins organ recovery; takes one to two hours to recover organs en-bloc.
MINNEAPOLIS HEART INSTITUTE
Allina Health
ABBOTT NORTHWESTERN HOSPITAL
13

13


SBN1
DBD vs. DCD
Donation After Brain Death (DBD)
Donation After Cardiac Death (DCD)
Injury
Severe brain injury from trauma, cerebral vascular accident, anoxic event, other – REFERRAL TO OPO
Severe brain injury from trauma, cerebral vascular accident, anoxic event, other - REFERRAL TO OPO
Meets Criteria for Brain Death
Yes: Clinical Exam (including apnea test) is consistent with brain death. If unable to fully complete any part of the clinical exam, a confirmatory test is required (i.e., Nuclear Flow).
No: Some neurological reflex is still present
Prognosis
Brain death: This is the legal time of death
As determined by hospital physician, patient has no chance of recovery from brain injury; cannot survive without mechanical ventilator.
Action
Brain death declaration is made by hospital physician (not OPO).
Signed brain death note and consent form are faxed to OPO.
Once brain death is declared, OPO and Hospital work cooperatively on medical management of the donor patient.
Patient remains on ventilator throughout organ recovery.
Anesthesiology is present for intra-operative fluid and BP management
Transplant team spends three to four hours recovering organs in-situ.
Family/NOK elects to withdraw support
Donation discussion with family, they consent. Signed futility note and consent form get faxed to OPO.
OPO and hospital work cooperatively on medical management of the donor patient.
Withdrawal of support can take place in OR or ICU
RT with a portable vent is used for OR w/d
ICU nurse administers meds for w/d
Cardiac death
No blood pressure, pulse or cardiac sounds
No spontaneous respiration
Wait five minutes to ensure no auto-resuscitation.
After five minutes of ceased circulation, hospital physician (not OPO) declares death.
Transplant team immediately begins organ recovery; takes one to two hours to recover organs en-bloc.
MINNEAPOLIS HEART INSTITUTE
Allina Health
ABBOTT NORTHWESTERN HOSPITAL
14

14

Slide 13

SBN1 Shukrallah, Bassam N, 3/21/2021

Slide 14

SBN1 Shukrallah, Bassam N, 3/21/2021

SBN1

DBD vs. DCD

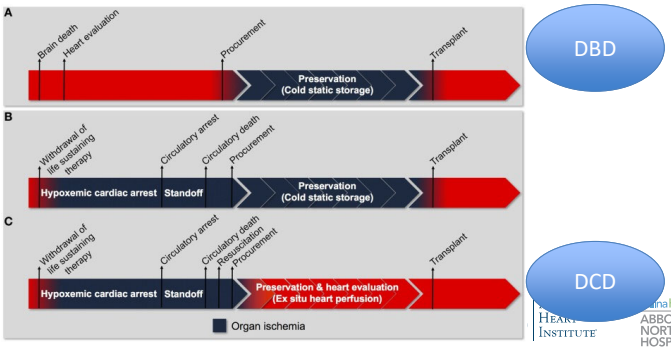
	Donation After Brain Death (DBD)	Donation After Cardiac Death (DCD)
Injury	Severe brain injury from trauma, cerebral vascular accident, anoxic event, other – **REFERRAL TO OPO**	Severe brain injury from trauma, cerebral vascular accident, anoxic event, other - **REFERRAL TO OPO**
Meets Criteria for Brain Death	Yes: Clinical Exam (including apnea test) is consistent with brain death. If unable to fully complete any part of the clinical exam, a confirmatory test is required (i.e., Nuclear Flow).	No: Some neurological reflex is still present
Prognosis	Brain death: This is the legal time of death	As determined by hospital physician, patient has no chance of recovery from brain injury; cannot survive without mechanical ventilator.
Action	Brain death declaration is made by hospital physician (not OPO). Signed brain death note and consent form are faxed to OPO. Once brain death is declared, OPO and Hospital work cooperatively on medical management of the donor patient. Patient remains on ventilator throughout organ recovery. Anesthesiology is present for intra-operative fluid and BP management Transplant team spends three to four hours recovering organs in-situ.	Family/NOK elects to withdraw support Donation discussion with family, they consent. Signed futility note and consent form get faxed to OPO. OPO and hospital work cooperatively on medical management of the donor patient. Withdrawal of support can take place in OR or ICU • RT with a portable vent is used for OR w/d • ICU nurse administers meds for w/d Cardiac death • No blood pressure, pulse or cardiac sounds • No spontaneous respiration Wait five minutes to ensure no auto-resuscitation. After five minutes of ceased circulation, hospital physician (not OPO) declares death. Transplant team immediately begins organ recovery; takes one to two hours to recover organs en-bloc.

15

15

Organ Donation after Circulatory Death

- Widely accepted in Kidney, liver and lung
- Concerns in heart DCD donation:
  - Warm ischemia
  - Inability to assess the donor heart prior to transplantation



16

16

Slide 15

SBN1 Shukrallah, Bassam N, 3/21/2021

JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY VOL. 73, NO. 12, 2019

Outcomes of Donation After Circulatory Death Heart Transplantation in Australia

Hong Chee Chew, MS,[a,b,c] Arjun Iyer, PhD,[a] Mark Connellan, FC Cardio SA,[a] Sarah Scheuer, MD,[b] Jeanette Villanueva, PhD,[b] Ling Gao, PhD,[b] Mark Hicks, PhD,[b] Michelle Harkness, RN, MCN,[b] Claudio Soto, MSc,[a] Andrew Dinale, BAppSc,[a] Priya Nair, MD,[a] Alasdair Watson, PhD,[a] Emily Granger, MBBS,[a] Paul Jansz, PhD,[a] Kavitha Muthiah, PhD,[a] Andrew Jabbour, PhD,[a] Eugene Kotlyar, MD,[a] Anne Keogh, MBBS,[a] Chris Hayward, MD,[a] R

RESULTS Hearts were retrieved from 33 of 45 DCD donors. A total of 12 donors did not progress to circulatory arrest within the pre-specified timeframe. Eight hearts failed to meet viability criteria during normothermic machine perfusion, and 2 hearts were declined due to machine malfunction. A total of 23 hearts were transplanted between July 2014 and April 2018. All recipients had successful implantation, with mechanical circulatory support utilized in 9 cases. One case requiring extracorporeal membrane oxygenation subsequently died on the sixth post-operative day, representing a mortality of 4.4% over 4 years with a total follow-up period of 15,500 days for the entire cohort. All surviving recipients had normal cardiac function on echocardiogram and no evidence of acute rejection on discharge. All surviving patients remain in New York Heart Association functional class I with normal biventricular function.

CONCLUSIONS DCD heart transplant outcomes are excellent. Despite a higher requirement for mechanical circulatory support for delayed graft function, primarily in recipients with ventricular assist device support, overall survival and rejection episodes are comparable to outcomes from contemporary brain-dead donors. (J Am Coll Cardiol 2019;73:1447-59)

17

HOSPITAL

17

A 5-year single-center early experience of heart transplantation from donation after circulatory-determined death donors

Simon Messer, PhD, Sendi Cernic, MD, Aravinda Page, MBBChir,

RESULTS: During the 5-year study, DCD heart donation increased overall heart transplant activity by 48% (79 for DCD and 164 for DBD). There was no difference in survival at 30 days (97% for DCD vs 99% for DBD, $p = 1.00$) or 1 year (91% for DCD vs 89% for DBD, $p = 0.72$). There was no difference in the length of stay in the intensive care unit (7 for DCD vs 6 for DBD days, $p = 0.24$) or in the hospital (24 for DCD vs 25 for DBD days, $p = 0.84$).
CONCLUSIONS: DCD heart donation increased overall heart transplant activity at RPH by 48%, with no difference in 30-day or 1-year survival in comparison with conventional DBD heart transplantations.

The Journal of Heart and Lung Transplantation, Vol 39, No 12, December 2020

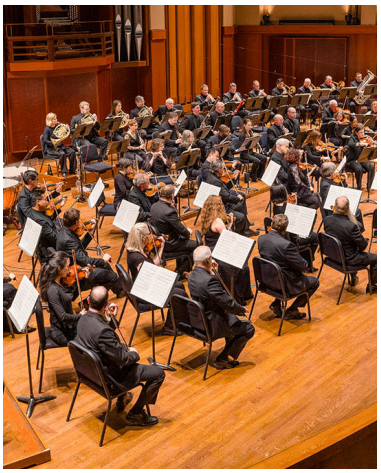
Minneapolis Heart Institute

AllinaHealth ABBOTT NORTHWESTERN HOSPITAL

18

18

DBD vs. DCD procurement

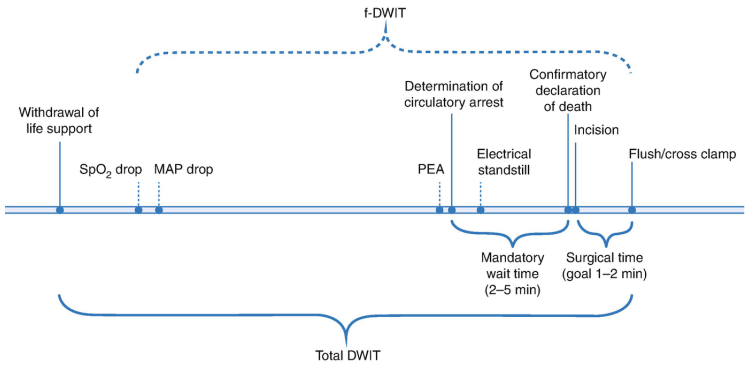


Minneapolis Heart Institute | Allina Health Abbott Northwestern Hospital

19

19

Perspective of DCD procurement



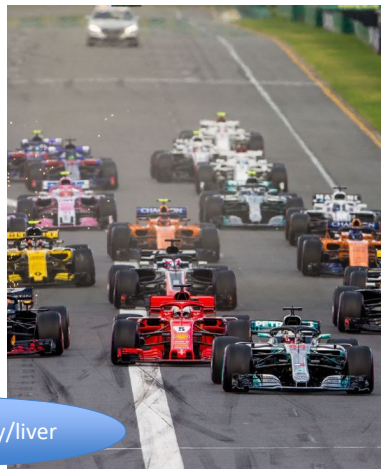
- *Warm ischemic time → SBP <50 mmHg or O2 sat <70%*
- *cardiac death must occur with 30 minutes of WIT*

Minneapolis Heart Institute | Allina Health Abbott Northwestern Hospital

20

20

DCD procurement



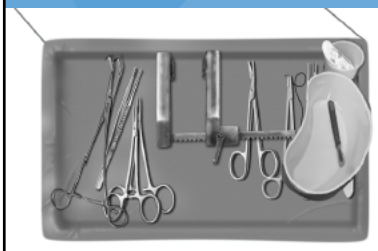
Lung/kidney/liver

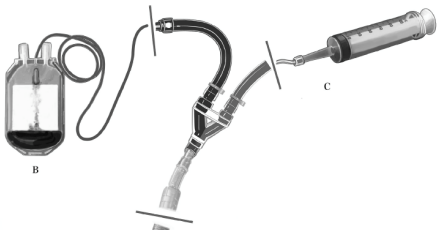
Minneapolis Heart Institute | Allina Health Abbott Northwestern Hospital

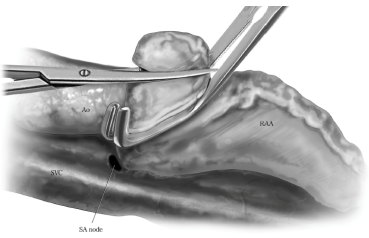
21

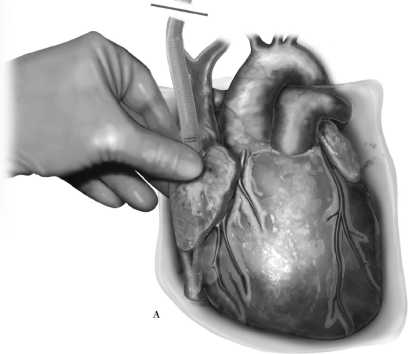
21

DCD procurement





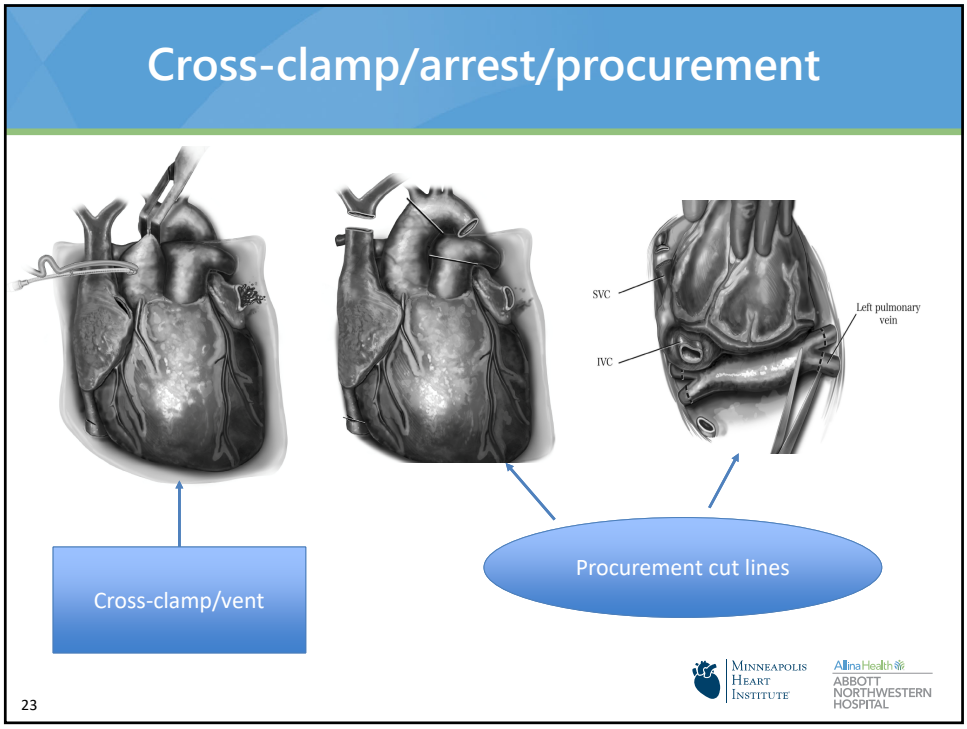




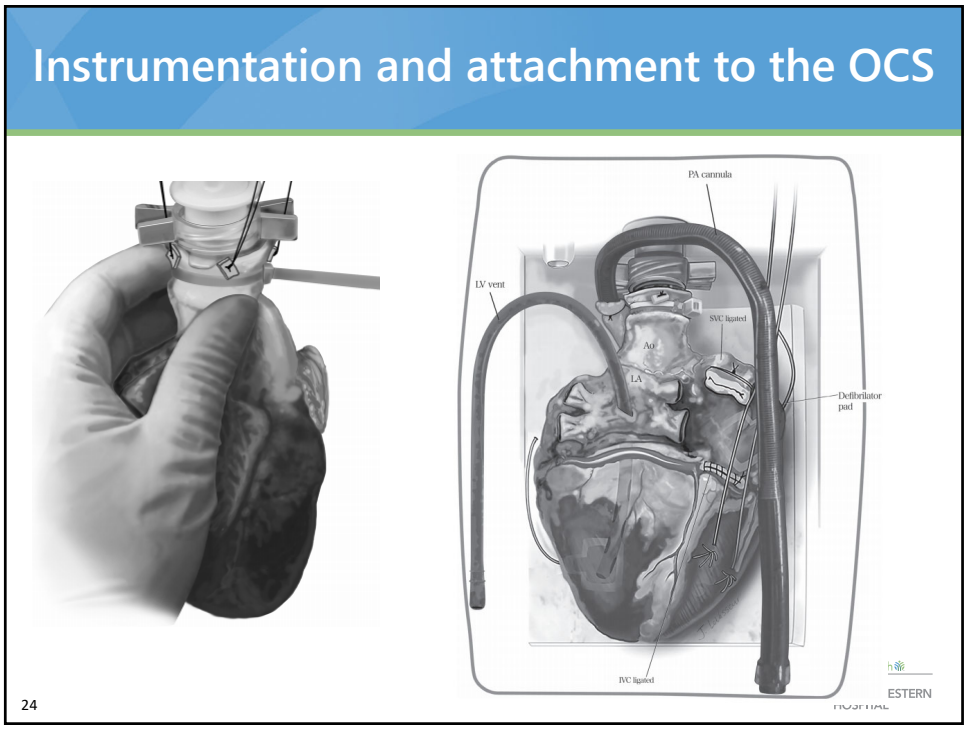
ERN

22

22


Cross-clamp/arrest/procurement
SVC
Left pulmonary vein
IVC
Cross-clamp/vent
Procurement cut lines
Minneapolis Heart Institute
Allina Health
ABBOTT NORTHWESTERN HOSPITAL
23

23


Instrumentation and attachment to the OCS
PA cannula
LV vent
SVC ligated
Ao
LA
Defibrillator pad
IVC ligated
ESTERN
24

24

Organ Care System

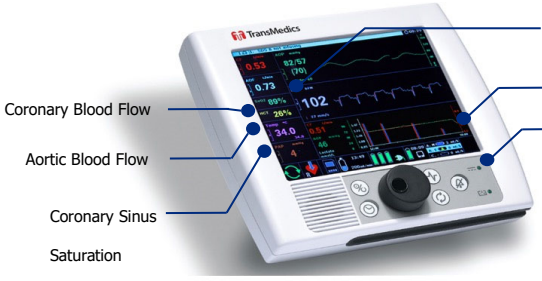
- Continuously monitoring physiological measurements:
  - coronary flow- CF
  - aortic flow- AOF
  - Aortic pressure- AOP
  - mixed venous
  - Arterial saturation
  - hematocrit
  - blood temperature
  - pulmonary artery pressure
  - electrocardiogram

Minneapolis Heart Institute | Allina Health Abbott Northwestern Hospital

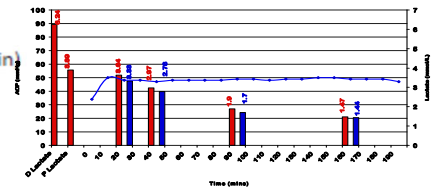
25

25

Assessing and monitoring parameters

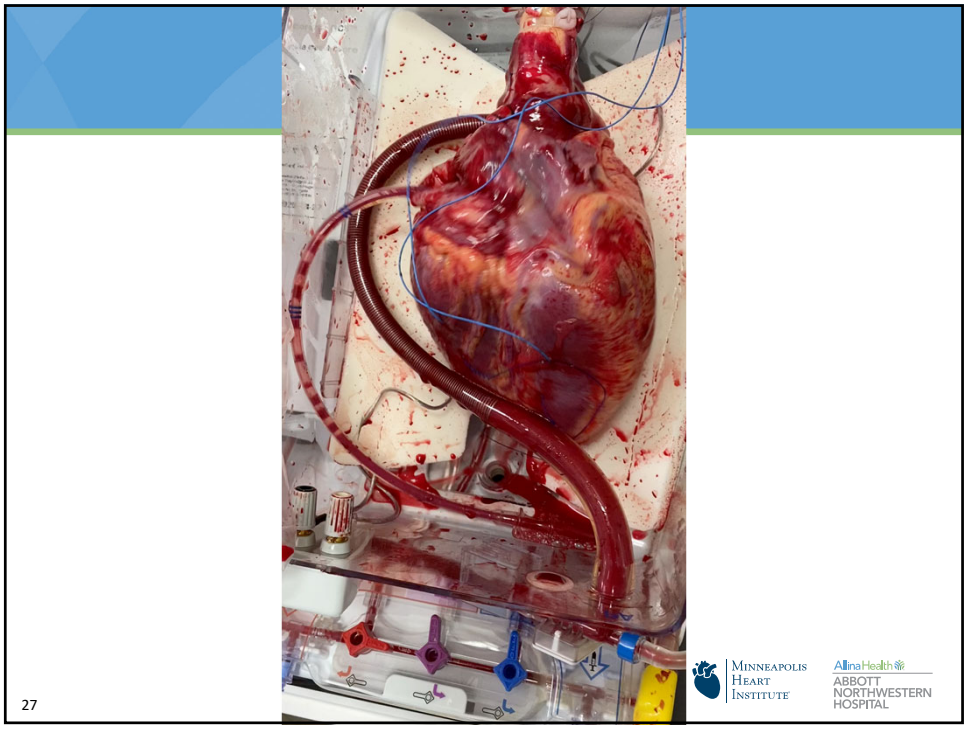


- Hemodynamic parameters:
  - Aortic pressure (goal: 65-90 mm Hg)
  - Coronary blood flow (goal: 650-900 mL/min)
- Perfusate Lactate level
  - Arterio-venous difference
  - Absolute lactate level (goal: <5 mmol/L)
- Visual Inspection



Minneapolis Heart Institute | Allina Health Abbott Northwestern Hospital

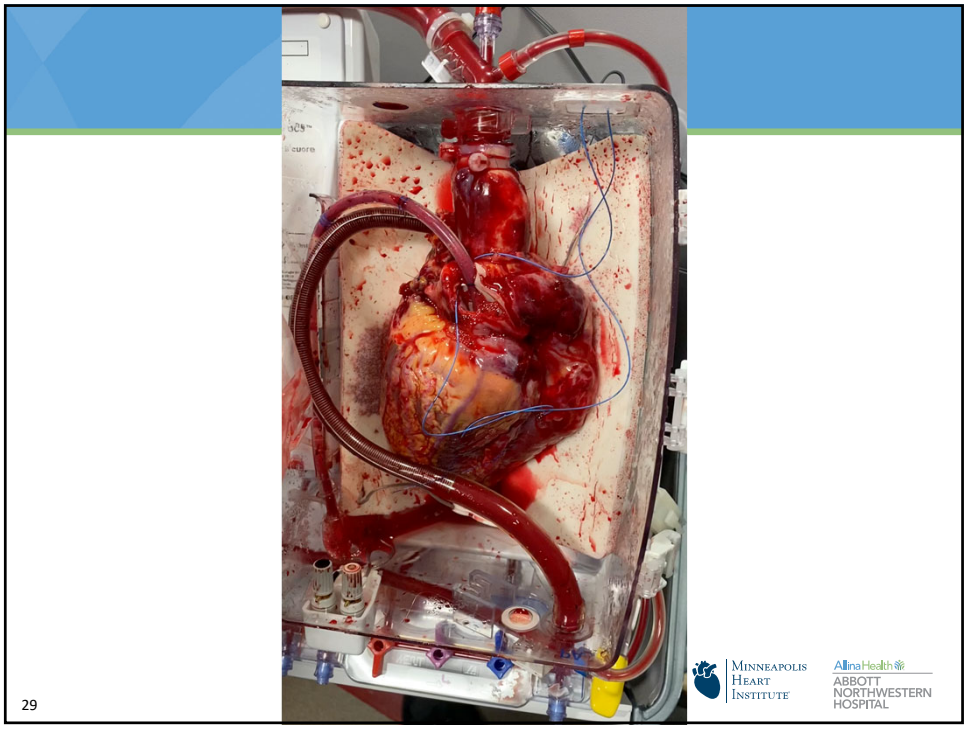
26


27
Minneapolis Heart Institute
Allina Health
Abbott Northwestern Hospital

27


TransMedics.
2021-03-18 04:49:39
02:17
AOP mmHg
92/57
(74)
Auto: 75
HR BPM
79
27 mm/s
CF L/min
0.81
AOP mmHg
74
Lactate mmol/L
28
Minneapolis Heart Institute
Allina Health
Abbott Northwestern Hospital

28


29
Minneapolis Heart Institute
Allina Health
Abbott Northwestern Hospital

29


TransMedics
05:22
0.50
170/126
(146)
1.33
97%
19%
30
33.9
1.30
146
1
30
Minneapolis Heart Institute
Allina Health
Abbott Northwestern Hospital

30

OCS Update

Bassam Shukrallah, MD Karol Mudy, MD

March , 22nd , 2021

Allina Health ABBOTT NORTHWESTERN HOSPITAL

Minneapolis Heart Institute Foundation
Creating a world without heart disease

Minneapolis Heart Institute

1

Disclosures

- Shukrallah's original accent is not really southern
- Mudy's accent is real

Allina Health ABBOTT NORTHWESTERN HOSPITAL

Minneapolis Heart Institute Foundation
Creating a world without heart disease

Minneapolis Heart Institute

2

OCS™ Heart
EXPAND Trial

Successful Utilization of Extended Criteria Donor Hearts for Transplantation – Results of The OCS Heart EXPAND Trial

- **J. N. Schroder, D. D'Alessandro, F. Esmailian, T. Boeve, P. Tang, K. Liao, I. Wang, A. Anyanwu, A. Shah, K. Mudy, E. Soltesz, J. W. Smith**

- Duke University Medical Center, Durham, NC, Massachusetts General Hospital, Boston, MA, Cedars-Sinai
- Medical Center, Los Angeles, CA, Spectrum Health, Grand Rapids, MI, University of Michigan, Ann Arbor, MI, University of Minnesota, Minneapolis, MN, Indiana University, Indianapolis, IN, Mount Sinai, New York, NY, Vanderbilt University, Nashville, TN, Minneapolis Heart Institute, Minneapolis, MN, Cleveland Clinic Foundation, Cleveland, OH, University of Washington, Seattle, WA,

JHLT, April, 2019; Volume 38, Issue 4

Allina Health ABBOTT NORTHWESTERN HOSPITAL
Minneapolis Heart Institute Foundation™ Creating a world without heart disease®
Minneapolis Heart Institute

3

OCS Heart EXPAND Trial Design & Endpoints

- **Single Arm Study:**
  - These hearts are not routinely being utilized and could not be compared to standard criteria hearts
- **Donor Criteria** – Targeted donor hearts that may benefit from perfusion
  - Extended ischemia time ≥4 hours; or
  - Older donors >45 yo; or
  - Down time ≥20 mins; or
  - LVH hearts >12 ≤16 mm thickness; or
  - Non specific CAD
- **Effectiveness Endpoints:**
  - Primary: Composite of patient survival at day 30 and freedom from severe PGD in the first 24 hours
  - Secondary: Donor hearts utilization rate
- **Safety Endpoint:**
  - Rate of moderate and severe PGD up-to day 30 post transplant

Allina Health ABBOTT NORTHWESTERN HOSPITAL
Minneapolis Heart Institute Foundation™ Creating a world without heart disease®
Minneapolis Heart Institute

4

OCS Heart EXPAND Donor Heart Utilization

OCS Heart Perfused Donor Hearts N=93

81% Utilization Rate

Did Not Meet Transplant Criteria on OCS Heart N=18

Met Transplant Criteria on OCS Heart N=75

Allina Health ABBOTT NORTHWESTERN HOSPITAL

Minneapolis Heart Institute Foundation™ Creating a world without heart disease®

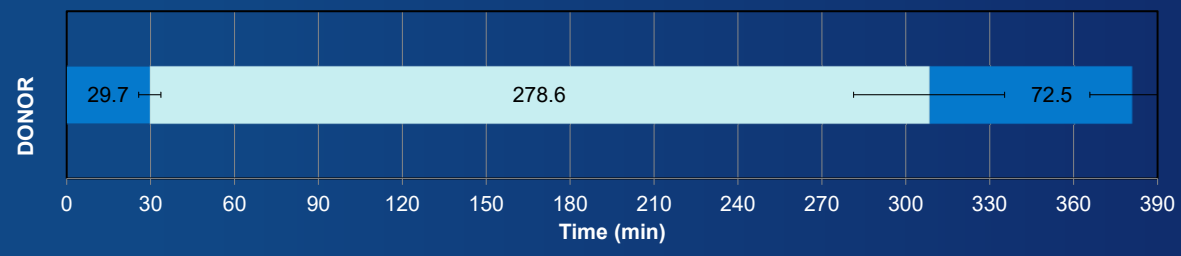
Minneapolis Heart Institute

5

OCS Reduced Ischemic Time on Donor Hearts

Total Out of Body Time

(mean ± SD) = 381 ± 93 min Range 173-682 min



- Pre-OCS Cold Ischemia (Harvest & OCS Instrumentation)
- OCS Perfusion
- Post-OCS Warm Ischemia (Reimplantation)

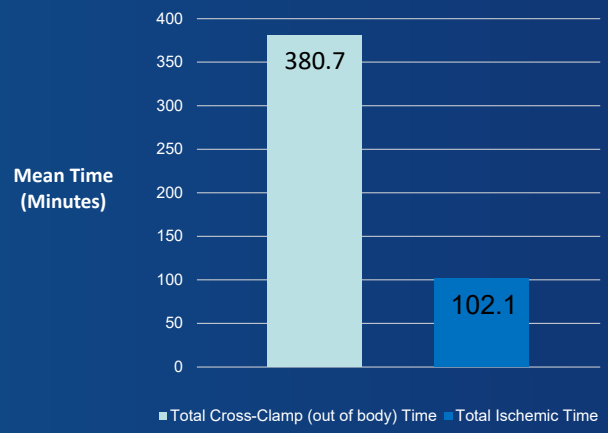
Allina Health ABBOTT NORTHWESTERN HOSPITAL

Minneapolis Heart Institute Foundation™ Creating a world without heart disease®

Minneapolis Heart Institute

6

OCS Heart EXPAND – Total Out of Body Time vs. Ischemic Time



TA11

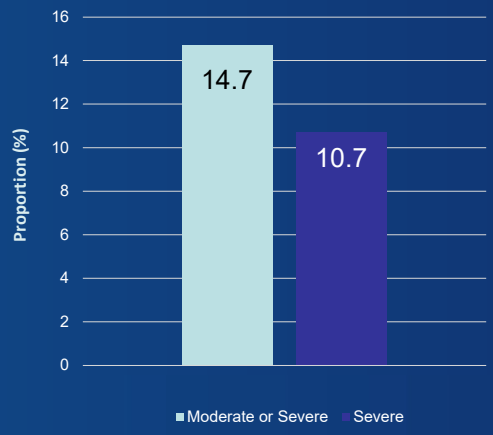
Allina Health ABBOTT NORTHWESTERN HOSPITAL

Minneapolis Heart Institute Foundation
Creating a world without heart disease

Minneapolis Heart Institute

7

OCS Heart EXPAND – Incidence of PGD



Allina Health ABBOTT NORTHWESTERN HOSPITAL

Minneapolis Heart Institute Foundation
Creating a world without heart disease

Minneapolis Heart Institute

8

Slide 7

TA11 Time to correct font size
Trevor Arneberg, 5/1/2019

OCS Heart EXPAND

30 day survival- 94.7%

Allina Health ABBOTT NORTHWESTERN HOSPITAL

Minneapolis Heart Institute Foundation™ Creating a world without heart disease®

Minneapolis Heart Institute

9

EXPAND Results

- The OCS™ Heart EXPAND Trial met its primary effectiveness and safety endpoints
- The use of OCS Heart System resulted in high utilization of ECD hearts with excellent short-term post-transplant outcomes, most notably a low rate of PGD
- These results provide clinical evidence supporting its use in ECD heart preservation and assessment, and may significantly increase donor utilization for transplantation

Allina Health ABBOTT NORTHWESTERN HOSPITAL

Minneapolis Heart Institute Foundation™ Creating a world without heart disease®

Minneapolis Heart Institute

10

OCS™ Heart
EXPAND Trial

Continued Access Protocol to collect additional evidence to evaluate the Safety and Effectiveness of The Portable Organ Care System (OCS™) Heart for preserving, resuscitating and assessing Expanded Criteria Donor Hearts for Transplantation (Heart EXPAND CAP)

- **Objectives**: To provide additional data evaluating the safety and effectiveness of the OCS Heart System to preserve and assess donor hearts that do not meet current standard donor heart acceptance criteria for transplantation to potentially improve donor heart utilization for transplantation at a range of transplant centers in the U.S. and to permit patients and physicians access to the OCS Heart System while a PMA application is under preparation and review
- **Trial Design**: A prospective single-arm trial
- **Trial Size**: A maximum of 12 participating sites with 48 transplanted heart recipients

Allina Health ABBOTT NORTHWESTERN HOSPITAL
Minneapolis Heart Institute Foundation™ Creating a world without heart disease®
Minneapolis Heart Institute

11

OCS™ Heart EXPAND Clinical Trial

Donor eligibility, at least one of the following:

- Expected total cross-clamp time ≥4 hours
- Expected cross-clamp time ≥2 hours PLUS at least one of following risk factors:
  - Donor age >55 yo.; or
  - Donor age 45 – 55 yo. without coronary catheterization data; or
  - LV septal or posterior wall thickness >12 ≤16mm; or
  - Reported down time ≥20 min; or
  - Left heart Ejection Fraction ≥ 40% - ≤50%; or
  - Donor angiogram with luminal irregularities no significant CAD; or
  - History of carbon monoxide poisoning; or
  - Social history of alcoholism; or
  - History of diabetes with negative coronary angiogram for CAD

Allina Health ABBOTT NORTHWESTERN HOSPITAL
Minneapolis Heart Institute Foundation™ Creating a world without heart disease®
Minneapolis Heart Institute

12

Heart EXPAND Clinical Trial Endpoints

Primary Endpoint: A composite endpoint of patient survival at Day-30 post-transplant and absence of severe primary heart graft dysfunction (PGD) (left or right ventricle) in the first 24 hours post-transplantation

Secondary Endpoints:

- Patient survival at day-30 post-transplantation
- Incidence of severe primary heart graft dysfunction (PGD) (left or right ventricle) in the first 24 hours post-transplantation
- Rate of donor hearts utilization that were successfully transplanted after preservation and assessment on the OCS™ Heart device

Safety Endpoint: Incidence of heart graft related Serious Adverse Events (SAEs) in the first 30 days post heart transplantation, defined as:

- Moderate or Severe primary heart graft dysfunction (PGD) (left or right ventricle), not including rejection or cardiac tamponade, according to 2014 ISHLT consensus manuscript
- Primary graft failure requiring re-transplantation

Allina Health ABBOTT NORTHWESTERN HOSPITAL | Minneapolis Heart Institute Foundation™ Creating a world without heart disease® | Minneapolis Heart Institute

13

EXPAND CAP

- **66 Extended criteria hearts have been transplanted across 6 sites. There are 9 remaining enrollment spots**
- **There have been 4 hearts declined after OCS assessment resulting in an overall utilization of 94%**
- **>45 % of the donors have had multiple inclusion criteria including longer expected cross clamp time, older age, left ventricular hypertrophy, low EF, etc.**

Allina Health ABBOTT NORTHWESTERN HOSPITAL | Minneapolis Heart Institute Foundation™ Creating a world without heart disease® | Minneapolis Heart Institute

14

EXPAND CAP

- >45% of the recipients have been on pre-transplant mechanical support (LVAD, RVAD, BiVAD, ECMO)
- Mean AOP has been in the range of 78 mmHg
- Mean CF has been in the range of 750 mL/min
- Mean perfusion time has been in the range of 4.5 hours with the longest in this study being 446 minutes
- 100% survival at 30 days and <10% incidence of severe PGD (L or R)

Allina Health ABBOTT NORTHWESTERN HOSPITAL | Minneapolis Heart Institute Foundation™ Creating a world without heart disease® | Minneapolis Heart Institute

15

EXPAND CAP- MHI

- 6 patients enrolled- August 2019- January 2021
- 100% utilization rate- 6 runs-> 6 transplants
- 0% severe PGD- No need for MCS postoperatively
- All alive- 100% survival
- 66% preoperative MCS (LVAD)

Allina Health ABBOTT NORTHWESTERN HOSPITAL | Minneapolis Heart Institute Foundation™ Creating a world without heart disease® | Minneapolis Heart Institute

16

Heart Tran
short-term

omparable
28 hearts)

ELSEVIER

The Journal of Heart and Lung Transplantation
http://www.jhltonline.org

SPECIAL FEATURE

Outcome after heart transplantation from donation after circulatory-determined death donors

Simon Messer, MBChB,[a] Aravinda Page, MBBChir,[a] Richard Axell, PhD,[a] Marius Berman, MD,[a] Jules Hernández-Sánchez, PhD,[b,c] Simon Colah, BSc,[a] Barbora Parizkova, MD,[a] Kamen Valchanov, MD,[a] John Dunning, MBChB,[a] Evgeny Pavlushkov, MD, PhD,[a] Sendhil K. Balasubramanian, MBBS,[a] Jayan Parameshwar, MBBS, MD, MPhil,[a] Yasir Abu Omar, MBChB, DPhil,[a] Martin Goddard, BMBCh,[a] Stephen Pettit, MBBS, PhD,[a] Clive Lewis, MBBChir, PhD,[a] Anna Kydd, MBBS, MD,[a] David Jenkins, MBBS, MS,[a] Christopher J. Watson, MBBChir, MD,[d] Catherine Sudarshan, MBBS, MD,[a] Pedro Catarino, BMBCh,[a] Marie Findlay,[a] Ayyaz Ali, MBBS, PhD,[a] Steven Tsui, MBBChir, MD,[a] and Stephen R. Large, MBBS, MS, MBA[a]

From the [a]Department of Transplantation, Papworth Hospital National Health Service Foundation Trust, Papworth Everard, Cambridgeshire, United Kingdom; [b]Papworth Trials Unit Collaboration, Papworth Hospital National Health Service Foundation Trust, Papworth Everard, Cambridgeshire, United Kingdom; [c]Medical Research Council Biostatistics Unit, University of Cambridge, School of Clinical Medicine, Cambridge Institute of Public Health, Cambridge, United Kingdom; and the [d]Department of Surgery, Cambridge University Hospitals National Health Service Foundation Trust and the National Institute for Health Research, Cambridge Biomedical Center, University of Cambridge, Cambridge, United Kingdom.

Messer, S. Page, A. A
2017;36(12):1311-131

ntation.

Allina Health
ABBOTT NORTHWESTE
HOSPITAL

Minneapolis Heart Institute

17

METHODS: DCD hearts were retrieved using normothermic regional perfusion (NRP) or direct procurement and perfusion (DPP). During NRP, perfusion was restored to the arrested heart within the donor with the exclusion of the cerebral circulation, whereas DPP hearts were removed directly. All hearts were maintained on machine perfusion during transportation. A retrospective cohort of DBD heart transplants, matched for donor and recipient characteristics, was used as a comparison group. The primary outcome measure of this study (set by the United Kingdom regulatory body) was 90-day survival.

Allina Health
ABBOTT NORTHWESTERN HOSPITAL

Minneapolis Heart Institute Foundation
Creating a world without heart disease

Minneapolis Heart Institute

18

METHODS: DCD hearts were retrieved using normothermic regional perfusion (NRP) or direct procurement and perfusion (DPP). During NRP, perfusion was restored to the arrested heart within the donor with the exclusion of the cerebral circulation, whereas DPP hearts were removed directly. All hearts were maintained on machine perfusion during transportation. A retrospective cohort of DBD heart transplants, matched for donor and recipient characteristics, was used as a comparison group. The primary outcome measure of this study (set by the United Kingdom regulatory body) was 90-day survival.

Allina Health ABBOTT NORTHWESTERN HOSPITAL

Minneapolis Heart Institute Foundation™ Creating a world without heart disease®

Minneapolis Heart Institute

19

Heart Transplantation from DCD heart donation provides comparable short-term outcomes to traditional DBD heart transplants (28 hearts)

Table 1 Criteria for Heart Donation After Circulatory-Determined Death

Inclusion criteria	Exclusion criteria
Category III DCD donor	Previous cardiac surgery
Participating DCD donor hospital	Previous midline sternotomy
Age ≥18 to ≤ 57 years old	Known coronary heart disease
Consent for donation from next of kin	Known congenital heart disease
Expected death within 4 hours of WLST	Previous myocardial infarct
WLST in anesthesia room or ICU	Insulin-dependent diabetes
No valvular abnormalities on echocardiogram	Epinephrine infusion
Ejection fraction > 50% before WLST	Dobutamine infusion
	Norepinephrine > 0.3 μg/kg/min
	Active malignancy
	Hepatitis B antigen-positive
	Hepatitis C antibody-positive
	Malignant melanoma
	All secondary intracerebral tumors
	Human immunodeficiency virus
	Primary intracerebral lymphoma
	Creutzfeldt-Jacob disease
	Tuberculosis

DCD, donation after circulatory-determined death; ICU, intensive care unit; WLST, withdrawal of life-supportive therapy.

Messer, S. Page, A. Axell, R. et. al. Outcome After Heart Transplant from Donation After Circulatory-Determined Death Donors. *J Heart and Lung Transplantation.* 2017;36(12):1311-1318.

Allina Health ABBOTT NORTHWESTERN HOSPITAL

Minneapolis Heart Institute Foundation™ Creating a world without heart disease®

Minneapolis Heart Institute

20

Heart Transplantation from DCD heart donation provides comparable short-term outcomes to traditional DBD heart transplants (28 hearts)

DPP vs NRP

Messer, S. Page, A. Axell, R. et. al. Outcome After Heart Transplant from Donation After Circulatory-Determined Death Donors. *J Heart and Lung Transplantation.* 2017;36(12):1311-1318.

Allina Health ABBOTT NORTHWESTERN HOSPITAL

Minneapolis Heart Institute Foundation™ Creating a world without heart disease®

Minneapolis Heart Institute

21

Table 3 Heart Transplant Outcomes

Variable[a]	DCD vs DBD: DCD ($n = 26$)	DCD vs DBD: DBD ($n = 26$)	DCD vs DBD: p-value[b]	DCD procurement method: NRP ($n = 12$)	DCD procurement method: DPP ($n = 14$)	DCD procurement method: p-value[b]
Survival						
30 days	26 (100)	26 (100)	1.00	12 (100)	14 (100)	1.00
90 days	24 (92)	25 (96)	1.00	12 (100)	12 (86)	0.48
Cardiac performance						
Cardiac index, liters/min/m^2	2.5 (2.1–2.7)	2.0 (1.8–2.4)	0.04	2.5 (2.4–2.7)	2.5 (1.7–2.8)	0.62
Cardiac output, liters/min	4.9 (4.0–5.2)	3.9 (3.2–4.4)	0.006	5.0 (4.3–5.1)	4.6 (3.4–5.5)	0.60
MAP, mm Hg	71 (64–78)	66 (60–70)	0.08	69 (64–78)	70 (69–78)	0.79
CVP, mm Hg	10 (8–11)	11 (9–12)	0.10	10 (8–11)	9 (8–11)	0.57
PAP diastolic, mm Hg	14 (12–17)	15 (12–19)	0.65	13 (12–17)	16 (13–18)	0.43
Mechanical support						
IABP	7 (27)	4 (15)	0.51	2 (17)	5 (36)	0.39
ECMO	3 (12)	1 (4)	0.63	1 (8)	2 (14)	1.00
VAD	1 (4)	0 (0)	1.00	0 (0)	1 (7)	1.00
Pharmacologic Support						
Dopamine, μg/kg/min	4.8	5.0	0.04	5.1	4.8	0.15
Adrenaline, μg/kg/min	0.04	0.04	0.65	0.04	0.03	0.73
Norepinephrine, μg/kg/min	0.01	0.03	0.09	0.00	0.00	0.43
Post-transplant outcomes						
Ventilation duration, days	0.9 (0.5–3.3)	1.8 (0.7–2.5)	0.84	0.6 (0.4–1.1)	2.5 (0.5–3.6)	0.06
Length of stay, days						
Intensive care unit	5 (3–8)	7 (4–9)	0.49	5 (4–5)	6 (3–10)	0.67
Hospital	20 (17–28)	27 (21–34)	0.09	19 (17–27)	20 (19–27)	0.58
Hemofiltration	8 (31)	7 (27)	0.51	2 (17)	5 (36)	0.39
Ejection fraction,[c] %	63 (58-63)	63 (62-63)	1.00	62 (58-65)	62 (60-63)	1.00
Treated rejection	9 (35)	15 (58)	0.15	4 (33)	5 (36)	1.00

CVP, central venous pressure; DBD, donation after brain death; DCD, donation after circulatory-determined death; DCM, dilated cardiomyopathy; DPP, direct procurement and perfusion;
ECMO, extra corporeal membrane oxygenation; IABP, intraaortic balloon pump; MAP, mean arterial pressure; PAP, pulmonary artery pressure; VAD, ventricular assist device.

[a]Continuous values are median (interquartile range) or as indicated, and continuous values as number (%).
[b]Unadjusted p-values are displayed between groups.
[c]Determined by transthoracic echocardiogram, with the first echocardiogram performed in the outpatient clinic.

Allina Health ABBOTT NORTHWESTERN HOSPITAL

Minneapolis Heart Institute

22

Table 3 Heart Transplant Outcomes

Variable[a]	DCD vs DBD			DCD procurement method		
	DCD ($n = 26$)	DBD ($n = 26$)	p-value[b]	NRP ($n = 12$)	DPP ($n = 14$)	p-value[b]
Survival						
30 days	26 (100)	26 (100)	1.00	12 (100)	14 (100)	1.00
90 days	24 (92)	25 (96)	1.00	12 (100)	12 (86)	0.48
Cardiac performance						
Cardiac index, liters/min/m^2	2.5 (2.1–2.7)	2.0 (1.8–2.4)	0.04	2.5 (2.4–2.7)	2.5 (1.7–2.8)	0.62
Cardiac output, liters/min	4.9 (4.0–5.2)	3.9 (3.2–4.4)	0.006	5.0 (4.3–5.1)	4.6 (3.4–5.5)	0.60
MAP, mm Hg	71 (64–78)	66 (60–70)	0.08	69 (64–78)	70 (69–78)	0.79
CVP, mm Hg	10 (8–11)	11 (9–12)	0.10	10 (8–11)	9 (8–11)	0.57
PAP diastolic, mm Hg	14 (12–17)	15 (12–19)	0.65	13 (12–17)	16 (13–18)	0.43
Mechanical support						
IABP	7 (27)	4 (15)	0.51	2 (17)	5 (36)	0.39
ECMO	3 (12)	1 (4)	0.63	1 (8)	2 (14)	1.00
VAD	1 (4)	0 (0)	1.00	0 (0)	1 (7)	1.00
Pharmacologic Support						
Dopamine, μg/kg/min	4.8	5.0	0.04	5.1	4.8	0.15
Adrenaline, μg/kg/min	0.04	0.04	0.65	0.04	0.03	0.73
Norepinephrine, μg/kg/min	0.01	0.03	0.09	0.00	0.00	0.43
Post-transplant outcomes						
Ventilation duration, days	0.9 (0.5–3.3)	1.8 (0.7–2.5)	0.84	0.6 (0.4–1.1)	2.5 (0.5–3.6)	0.06
Length of stay, days						
Intensive care unit	5 (3–8)	7 (4–9)	0.49	5 (4–5)	6 (3–10)	0.67
Hospital	20 (17–28)	27 (21–34)	0.09	19 (17–27)	20 (19–27)	0.58
Hemofiltration	8 (31)	7 (27)	0.51	2 (17)	5 (36)	0.39
Ejection fraction,[c] %	63 (58-63)	63 (62-63)	1.00	62 (58-65)	62 (60-63)	1.00
Treated rejection	9 (35)	15 (58)	0.15	4 (33)	5 (36)	1.00

CVP, central venous pressure; DBD, donation after brain death; DCD, donation after circulatory-determined death; DCM, dilated cardiomyopathy; DPP, direct procurement and perfusion;
ECMO, extra corporeal membrane oxygenation; IABP, intraaortic balloon pump; MAP, mean arterial pressure; PAP, pulmonary artery pressure; VAD, ventricular assist device.

[a]Continuous values are median (interquartile range) or as indicated, and continuous values as number (%).

[b]Unadjusted p-values are displayed between groups.

[c]Determined by transthoracic echocardiogram, with the first echocardiogram performed in the outpatient clinic.

Allina Health ABBOTT NORTHWESTERN HOSPITAL

Minneapolis Heart Institute

23

Messer et al. DCD Donor Transplant Outcomes 1317

Table 3 Heart Transplant Outcomes

Variable[a]	DCD vs DBD			DCD procurement method		
	DCD ($n = 26$)	DBD ($n = 26$)	p-value[b]	NRP ($n = 12$)	DPP ($n = 14$)	p-value[b]
Survival						
30 days	26 (100)	26 (100)	1.00	12 (100)	14 (100)	1.00
90 days	24 (92)	25 (96)	1.00	12 (100)	12 (86)	0.48
Cardiac performance						
Cardiac index, liters/min/m^2	2.5 (2.1–2.7)	2.0 (1.8–2.4)	0.04	2.5 (2.4–2.7)	2.5 (1.7–2.8)	0.62
Cardiac output, liters/min	4.9 (4.0–5.2)	3.9 (3.2–4.4)	0.006	5.0 (4.3–5.1)	4.6 (3.4–5.5)	0.60
MAP, mm Hg	71 (64–78)	66 (60–70)	0.08	69 (64–78)	70 (69–78)	0.79
CVP, mm Hg	10 (8–11)	11 (9–12)	0.10	10 (8–11)	9 (8–11)	0.57
PAP diastolic, mm Hg	14 (12–17)	15 (12–19)	0.65	13 (12–17)	16 (13–18)	0.43
Mechanical support						
IABP	7 (27)	4 (15)	0.51	2 (17)	5 (36)	0.39
ECMO	3 (12)	1 (4)	0.63	1 (8)	2 (14)	1.00
VAD	1 (4)	0 (0)	1.00	0 (0)	1 (7)	1.00
Pharmacologic Support						
Dopamine, μg/kg/min	4.8	5.0	0.04	5.1	4.8	0.15
Adrenaline, μg/kg/min	0.04	0.04	0.65	0.04	0.03	0.73
Norepinephrine, μg/kg/min	0.01	0.03	0.09	0.00	0.00	0.43
Post-transplant outcomes						
Ventilation duration, days	0.9 (0.5–3.3)	1.8 (0.7–2.5)	0.84	0.6 (0.4–1.1)	2.5 (0.5–3.6)	0.06
Length of stay, days						
Intensive care unit	5 (3–8)	7 (4–9)	0.49	5 (4–5)	6 (3–10)	0.67
Hospital	20 (17–28)	27 (21–34)	0.09	19 (17–27)	20 (19–27)	0.58
Hemofiltration	8 (31)	7 (27)	0.51	2 (17)	5 (36)	0.39
Ejection fraction,[c] %	63 (58-63)	63 (62-63)	1.00	62 (58-65)	62 (60-63)	1.00
Treated rejection	9 (35)	15 (58)	0.15	4 (33)	5 (36)	1.00

CVP, central venous pressure; DBD, donation after brain death; DCD, donation after circulatory-determined death; DCM, dilated cardiomyopathy; DPP, direct procurement and perfusion;
ECMO, extra corporeal membrane oxygenation; IABP, intraaortic balloon pump; MAP, mean arterial pressure; PAP, pulmonary artery pressure; VAD, ventricular assist device.

[a]Continuous values are median (interquartile range) or as indicated, and continuous values as number (%).

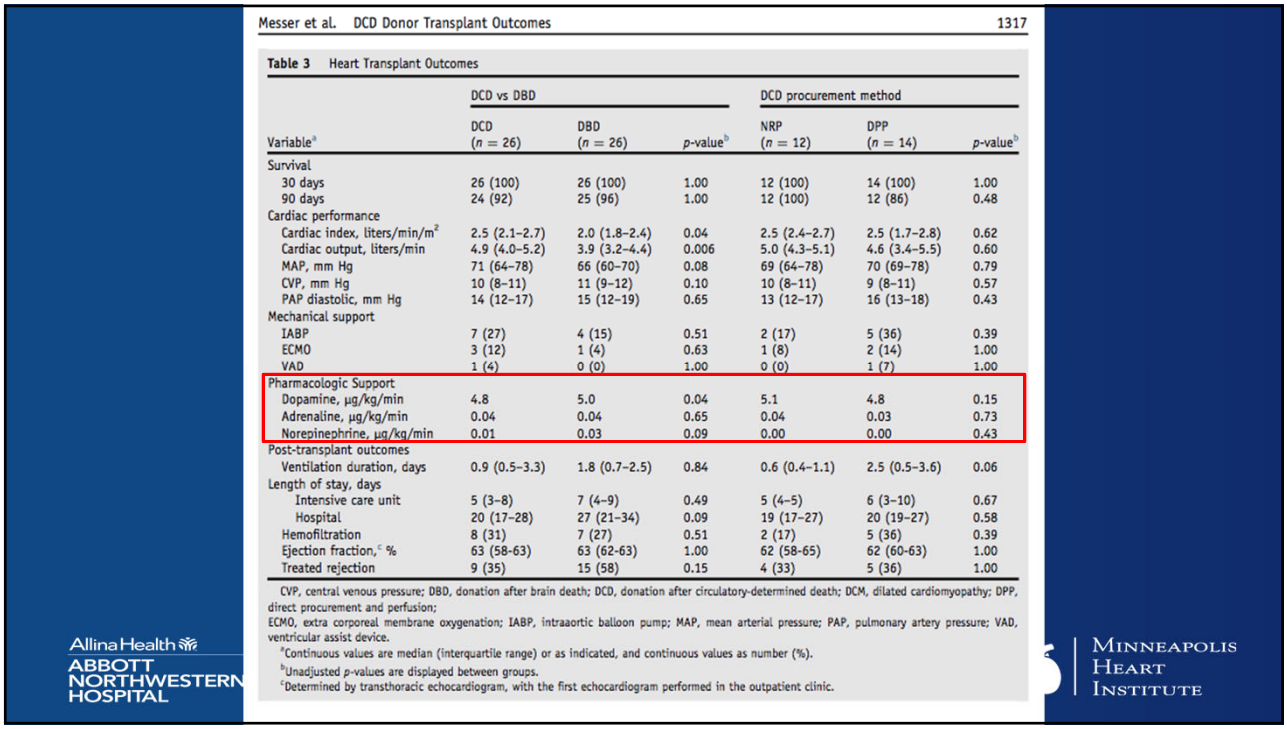
[b]Unadjusted p-values are displayed between groups.

[c]Determined by transthoracic echocardiogram, with the first echocardiogram performed in the outpatient clinic.

Allina Health ABBOTT NORTHWESTERN HOSPITAL

Minneapolis Heart Institute

24



Messer et al. DCD Donor Transplant Outcomes 1317

Table 3 Heart Transplant Outcomes

Variable[a]	DCD vs DBD			DCD procurement method		
	DCD ($n = 26$)	DBD ($n = 26$)	p-value[b]	NRP ($n = 12$)	DPP ($n = 14$)	p-value[b]
Survival						
30 days	26 (100)	26 (100)	1.00	12 (100)	14 (100)	1.00
90 days	24 (92)	25 (96)	1.00	12 (100)	12 (86)	0.48
Cardiac performance						
Cardiac index, liters/min/m^2	2.5 (2.1–2.7)	2.0 (1.8–2.4)	0.04	2.5 (2.4–2.7)	2.5 (1.7–2.8)	0.62
Cardiac output, liters/min	4.9 (4.0–5.2)	3.9 (3.2–4.4)	0.006	5.0 (4.3–5.1)	4.6 (3.4–5.5)	0.60
MAP, mm Hg	71 (64–78)	66 (60–70)	0.08	69 (64–78)	70 (69–78)	0.79
CVP, mm Hg	10 (8–11)	11 (9–12)	0.10	10 (8–11)	9 (8–11)	0.57
PAP diastolic, mm Hg	14 (12–17)	15 (12–19)	0.65	13 (12–17)	16 (13–18)	0.43
Mechanical support						
IABP	7 (27)	4 (15)	0.51	2 (17)	5 (36)	0.39
ECMO	3 (12)	1 (4)	0.63	1 (8)	2 (14)	1.00
VAD	1 (4)	0 (0)	1.00	0 (0)	1 (7)	1.00
Pharmacologic Support						
Dopamine, μg/kg/min	4.8	5.0	0.04	5.1	4.8	0.15
Adrenaline, μg/kg/min	0.04	0.04	0.65	0.04	0.03	0.73
Norepinephrine, μg/kg/min	0.01	0.03	0.09	0.00	0.00	0.43
Post-transplant outcomes						
Ventilation duration, days	0.9 (0.5–3.3)	1.8 (0.7–2.5)	0.84	0.6 (0.4–1.1)	2.5 (0.5–3.6)	0.06
Length of stay, days						
Intensive care unit	5 (3–8)	7 (4–9)	0.49	5 (4–5)	6 (3–10)	0.67
Hospital	20 (17–28)	27 (21–34)	0.09	19 (17–27)	20 (19–27)	0.58
Hemofiltration	8 (31)	7 (27)	0.51	2 (17)	5 (36)	0.39
Ejection fraction,[c] %	63 (58-63)	63 (62-63)	1.00	62 (58-65)	62 (60-63)	1.00
Treated rejection	9 (35)	15 (58)	0.15	4 (33)	5 (36)	1.00

CVP, central venous pressure; DBD, donation after brain death; DCD, donation after circulatory-determined death; DCM, dilated cardiomyopathy; DPP, direct procurement and perfusion;
ECMO, extra corporeal membrane oxygenation; IABP, intraaortic balloon pump; MAP, mean arterial pressure; PAP, pulmonary artery pressure; VAD, ventricular assist device.

[a]Continuous values are median (interquartile range) or as indicated, and continuous values as number (%).

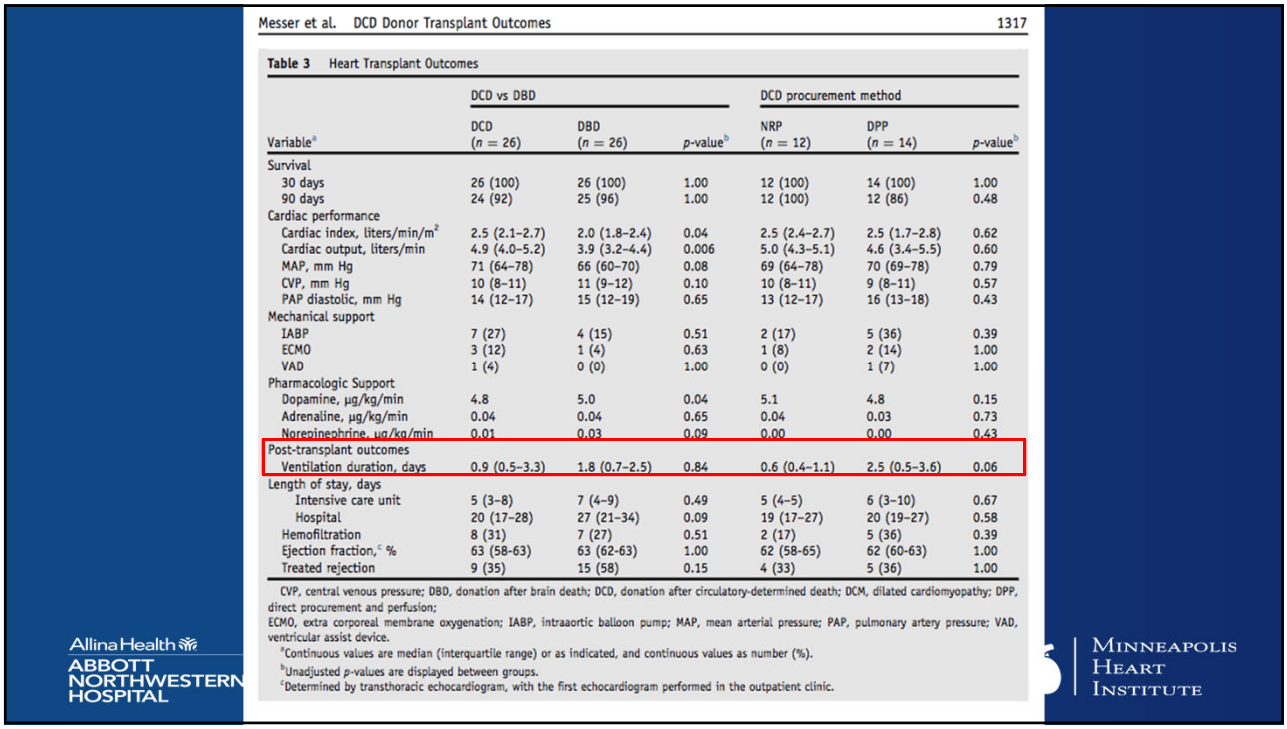
[b]Unadjusted p-values are displayed between groups.

[c]Determined by transthoracic echocardiogram, with the first echocardiogram performed in the outpatient clinic.

Allina Health ABBOTT NORTHWESTERN HOSPITAL

Minneapolis Heart Institute

25



Messer et al. DCD Donor Transplant Outcomes 1317

Table 3 Heart Transplant Outcomes

Variable[a]	DCD vs DBD			DCD procurement method		
	DCD ($n = 26$)	DBD ($n = 26$)	p-value[b]	NRP ($n = 12$)	DPP ($n = 14$)	p-value[b]
Survival						
30 days	26 (100)	26 (100)	1.00	12 (100)	14 (100)	1.00
90 days	24 (92)	25 (96)	1.00	12 (100)	12 (86)	0.48
Cardiac performance						
Cardiac index, liters/min/m^2	2.5 (2.1–2.7)	2.0 (1.8–2.4)	0.04	2.5 (2.4–2.7)	2.5 (1.7–2.8)	0.62
Cardiac output, liters/min	4.9 (4.0–5.2)	3.9 (3.2–4.4)	0.006	5.0 (4.3–5.1)	4.6 (3.4–5.5)	0.60
MAP, mm Hg	71 (64–78)	66 (60–70)	0.08	69 (64–78)	70 (69–78)	0.79
CVP, mm Hg	10 (8–11)	11 (9–12)	0.10	10 (8–11)	9 (8–11)	0.57
PAP diastolic, mm Hg	14 (12–17)	15 (12–19)	0.65	13 (12–17)	16 (13–18)	0.43
Mechanical support						
IABP	7 (27)	4 (15)	0.51	2 (17)	5 (36)	0.39
ECMO	3 (12)	1 (4)	0.63	1 (8)	2 (14)	1.00
VAD	1 (4)	0 (0)	1.00	0 (0)	1 (7)	1.00
Pharmacologic Support						
Dopamine, μg/kg/min	4.8	5.0	0.04	5.1	4.8	0.15
Adrenaline, μg/kg/min	0.04	0.04	0.65	0.04	0.03	0.73
Norepinephrine, μg/kg/min	0.01	0.03	0.09	0.00	0.00	0.43
Post-transplant outcomes						
Ventilation duration, days	0.9 (0.5–3.3)	1.8 (0.7–2.5)	0.84	0.6 (0.4–1.1)	2.5 (0.5–3.6)	0.06
Length of stay, days						
Intensive care unit	5 (3–8)	7 (4–9)	0.49	5 (4–5)	6 (3–10)	0.67
Hospital	20 (17–28)	27 (21–34)	0.09	19 (17–27)	20 (19–27)	0.58
Hemofiltration	8 (31)	7 (27)	0.51	2 (17)	5 (36)	0.39
Ejection fraction,[c] %	63 (58-63)	63 (62-63)	1.00	62 (58-65)	62 (60-63)	1.00
Treated rejection	9 (35)	15 (58)	0.15	4 (33)	5 (36)	1.00

CVP, central venous pressure; DBD, donation after brain death; DCD, donation after circulatory-determined death; DCM, dilated cardiomyopathy; DPP, direct procurement and perfusion;
ECMO, extra corporeal membrane oxygenation; IABP, intraaortic balloon pump; MAP, mean arterial pressure; PAP, pulmonary artery pressure; VAD, ventricular assist device.

[a]Continuous values are median (interquartile range) or as indicated, and continuous values as number (%).

[b]Unadjusted p-values are displayed between groups.

[c]Determined by transthoracic echocardiogram, with the first echocardiogram performed in the outpatient clinic.

Allina Health ABBOTT NORTHWESTERN HOSPITAL

Minneapolis Heart Institute

26

Table 3 Heart Transplant Outcomes

Variable[a]	DCD vs DBD: DCD ($n = 26$)	DCD vs DBD: DBD ($n = 26$)	DCD vs DBD: p-value[b]	DCD procurement method: NRP ($n = 12$)	DCD procurement method: DPP ($n = 14$)	DCD procurement method: p-value[b]
Survival						
30 days	26 (100)	26 (100)	1.00	12 (100)	14 (100)	1.00
90 days	24 (92)	25 (96)	1.00	12 (100)	12 (86)	0.48
Cardiac performance						
Cardiac index, liters/min/m^2	2.5 (2.1–2.7)	2.0 (1.8–2.4)	0.04	2.5 (2.4–2.7)	2.5 (1.7–2.8)	0.62
Cardiac output, liters/min	4.9 (4.0–5.2)	3.9 (3.2–4.4)	0.006	5.0 (4.3–5.1)	4.6 (3.4–5.5)	0.60
MAP, mm Hg	71 (64–78)	66 (60–70)	0.08	69 (64–78)	70 (69–78)	0.79
CVP, mm Hg	10 (8–11)	11 (9–12)	0.10	10 (8–11)	9 (8–11)	0.57
PAP diastolic, mm Hg	14 (12–17)	15 (12–19)	0.65	13 (12–17)	16 (13–18)	0.43
Mechanical support						
IABP	7 (27)	4 (15)	0.51	2 (17)	5 (36)	0.39
ECMO	3 (12)	1 (4)	0.63	1 (8)	2 (14)	1.00
VAD	1 (4)	0 (0)	1.00	0 (0)	1 (7)	1.00
Pharmacologic Support						
Dopamine, μg/kg/min	4.8	5.0	0.04	5.1	4.8	0.15
Adrenaline, μg/kg/min	0.04	0.04	0.65	0.04	0.03	0.73
Norepinephrine, μg/kg/min	0.01	0.03	0.09	0.00	0.00	0.43
Post-transplant outcomes						
Ventilation duration, days	0.9 (0.5–3.3)	1.8 (0.7–2.5)	0.84	0.6 (0.4–1.1)	2.5 (0.5–3.6)	0.06
Length of stay, days						
Intensive care unit	5 (3–8)	7 (4–9)	0.49	5 (4–5)	6 (3–10)	0.67
Hospital	20 (17–28)	27 (21–34)	0.09	19 (17–27)	20 (19–27)	0.58
Hemofiltration	8 (31)	7 (27)	0.51	2 (17)	5 (36)	0.39
Ejection fraction,[c] %	63 (58-63)	63 (62-63)	1.00	62 (58-65)	62 (60-63)	1.00
Treated rejection	9 (35)	15 (58)	0.15	4 (33)	5 (36)	1.00

CVP, central venous pressure; DBD, donation after brain death; DCD, donation after circulatory-determined death; DCM, dilated cardiomyopathy; DPP, direct procurement and perfusion;
ECMO, extra corporeal membrane oxygenation; IABP, intraaortic balloon pump; MAP, mean arterial pressure; PAP, pulmonary artery pressure; VAD, ventricular assist device.

[a]Continuous values are median (interquartile range) or as indicated, and continuous values as number (%).

[b]Unadjusted p-values are displayed between groups.

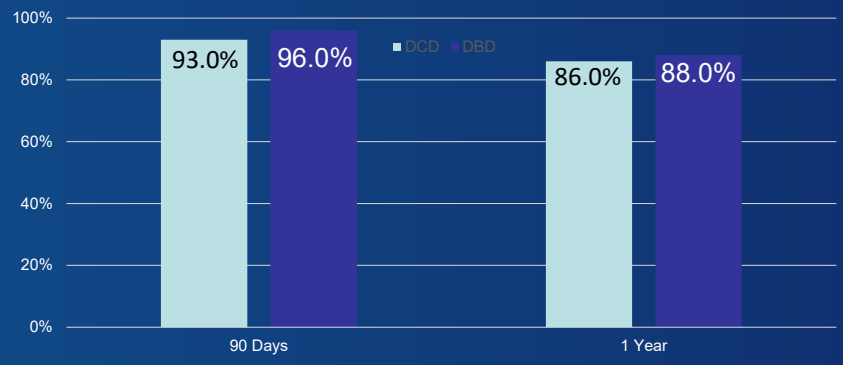
[c]Determined by transthoracic echocardiogram, with the first echocardiogram performed in the outpatient clinic.

Allina Health ABBOTT NORTHWESTERN HOSPITAL

Minneapolis Heart Institute

27

Heart Transplantation from DCD heart donation provides comparable short-term outcomes to traditional DBD heart transplants (28 hearts)



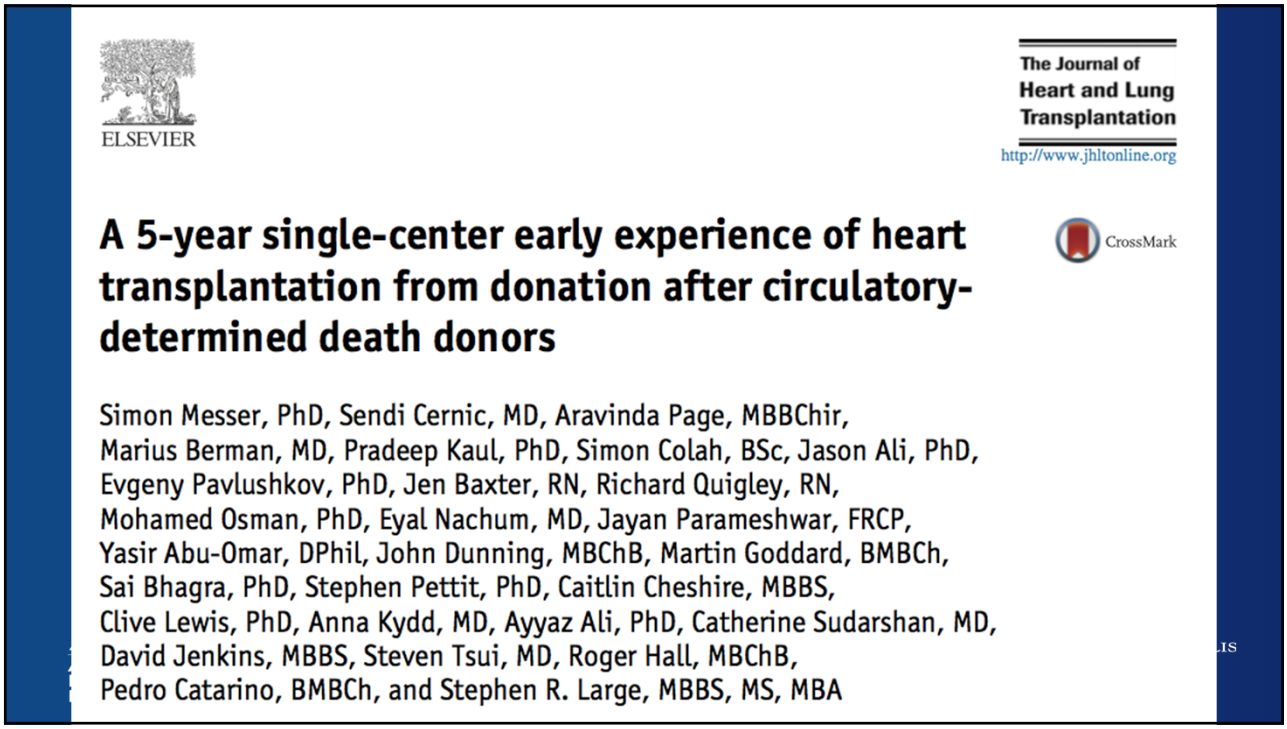
Messer, S. Page, A. Axell, R. et. al. Outcome After Heart Transplant from Donation After Circulatory-Determined Death Donors. *J Heart and Lung Transplantation.* 2017;36(12):1311-1318.

Allina Health ABBOTT NORTHWESTERN HOSPITAL

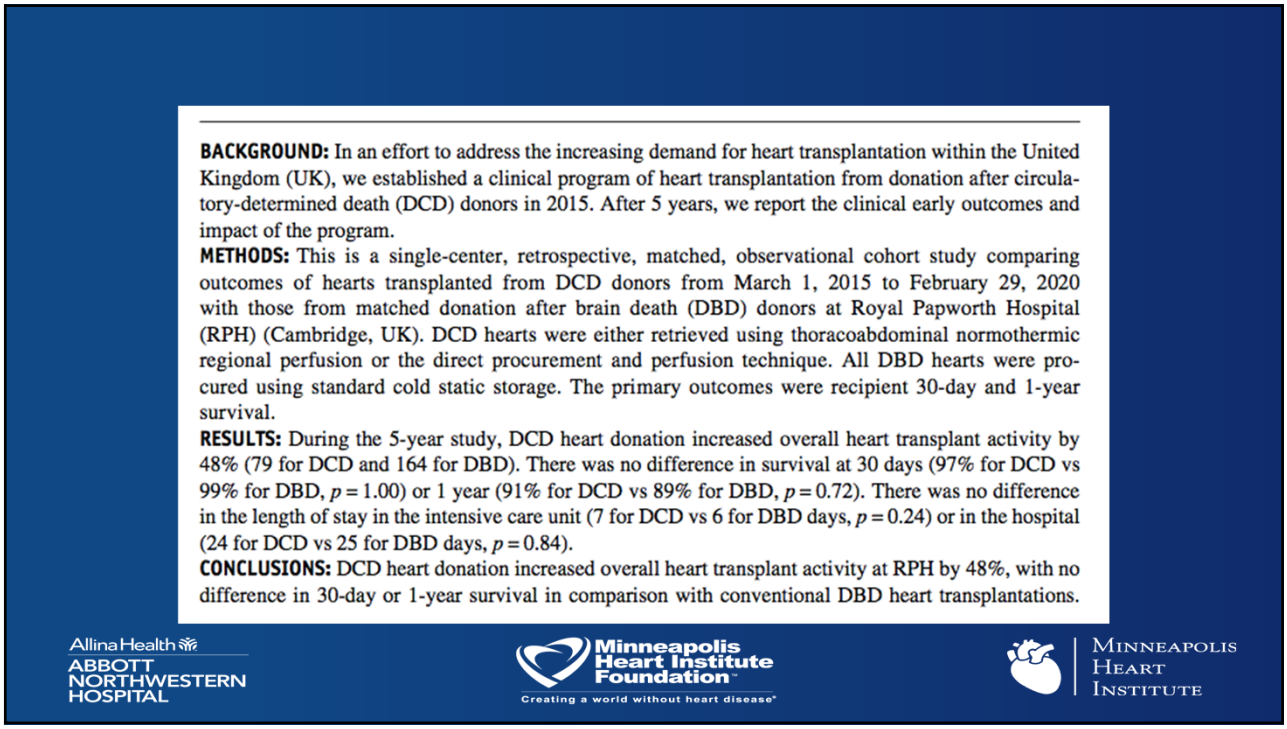
Minneapolis Heart Institute Foundation™ Creating a world without heart disease®

Minneapolis Heart Institute

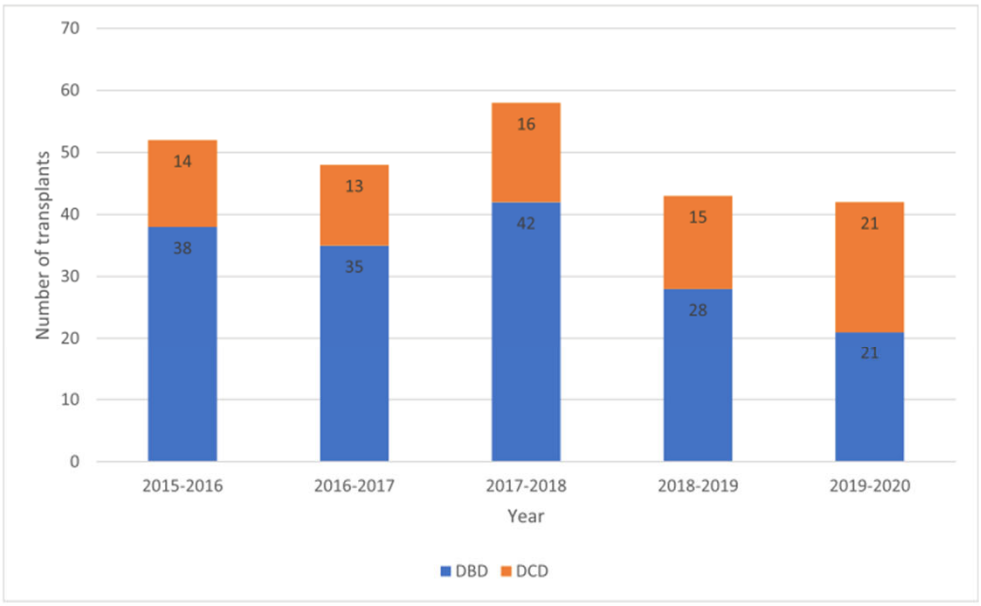
28


ELSEVIER
The Journal of Heart and Lung Transplantation
http://www.jhltonline.org
CrossMark
A 5-year single-center early experience of heart transplantation from donation after circulatory-determined death donors
Simon Messer, PhD, Sendi Cernic, MD, Aravinda Page, MBBChir, Marius Berman, MD, Pradeep Kaul, PhD, Simon Colah, BSc, Jason Ali, PhD, Evgeny Pavlushkov, PhD, Jen Baxter, RN, Richard Quigley, RN, Mohamed Osman, PhD, Eyal Nachum, MD, Jayan Parameshwar, FRCP, Yasir Abu-Omar, DPhil, John Dunning, MBChB, Martin Goddard, BMBCh, Sai Bhagra, PhD, Stephen Pettit, PhD, Caitlin Cheshire, MBBS, Clive Lewis, PhD, Anna Kydd, MD, Ayyaz Ali, PhD, Catherine Sudarshan, MD, David Jenkins, MBBS, Steven Tsui, MD, Roger Hall, MBChB, Pedro Catarino, BMBCh, and Stephen R. Large, MBBS, MS, MBA

29


BACKGROUND: In an effort to address the increasing demand for heart transplantation within the United Kingdom (UK), we established a clinical program of heart transplantation from donation after circulatory-determined death (DCD) donors in 2015. After 5 years, we report the clinical early outcomes and impact of the program.
METHODS: This is a single-center, retrospective, matched, observational cohort study comparing outcomes of hearts transplanted from DCD donors from March 1, 2015 to February 29, 2020 with those from matched donation after brain death (DBD) donors at Royal Papworth Hospital (RPH) (Cambridge, UK). DCD hearts were either retrieved using thoracoabdominal normothermic regional perfusion or the direct procurement and perfusion technique. All DBD hearts were procured using standard cold static storage. The primary outcomes were recipient 30-day and 1-year survival.
RESULTS: During the 5-year study, DCD heart donation increased overall heart transplant activity by 48% (79 for DCD and 164 for DBD). There was no difference in survival at 30 days (97% for DCD vs 99% for DBD, p = 1.00) or 1 year (91% for DCD vs 89% for DBD, p = 0.72). There was no difference in the length of stay in the intensive care unit (7 for DCD vs 6 for DBD days, p = 0.24) or in the hospital (24 for DCD vs 25 for DBD days, p = 0.84).
CONCLUSIONS: DCD heart donation increased overall heart transplant activity at RPH by 48%, with no difference in 30-day or 1-year survival in comparison with conventional DBD heart transplantations.
Allina Health
ABBOTT NORTHWESTERN HOSPITAL
Minneapolis Heart Institute Foundation
Creating a world without heart disease
Minneapolis Heart Institute

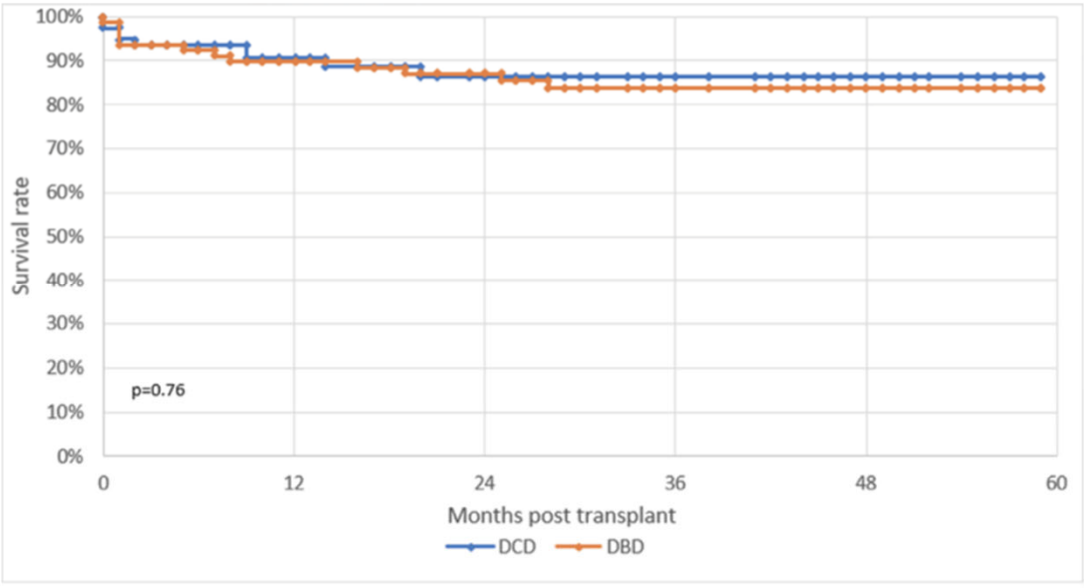
30



DBD, donation after brain death; DCD, donation after circulatory-determined death

Figure 2 The annual proportion of DBD/DCD heart transplantations. DBD, donation after brain death; DCD, donation after circulatory-determined death.

31



32

JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY
© 2019 PUBLISHED BY ELSEVIER ON BEHALF OF THE
AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION

VOL. 73, NO. 12, 2019

Outcomes of Donation After Circulatory Death Heart Transplantation in Australia

Hong Chee Chew, MS,[a,b,c] Arjun Iyer, PhD,[a] Mark Connellan, FC Cardio SA,[a] Sarah Scheuer, MD,[b] Jeanette Villanueva, PhD,[b] Ling Gao, PhD,[b] Mark Hicks, PhD,[b] Michelle Harkness, RN, MCN,[b] Claudio Soto, MSc,[a] Andrew Dinale, BAppSc,[a] Priya Nair, MD,[a] Alasdair Watson, PhD,[a] Emily Granger, MBBS,[a] Paul Jansz, PhD,[a] Kavitha Muthiah, PhD,[a] Andrew Jabbour, PhD,[a] Eugene Kotlyar, MD,[a] Anne Keogh, MBBS,[a] Chris Hayward, MD,[a] Robert Graham, MD,[b] Phillip Spratt, MD,[a] Peter Macdonald, MD,[a,b,c] Kumud Dhital, PhD[a,b,c]

Allina Health ABBOTT NORTHWESTERN HOSPITAL

Minneapolis Heart Institute Foundation
Creating a world without heart disease

Minneapolis Heart Institute

33

BACKGROUND Transplantation of hearts retrieved from donation after circulatory death (DCD) donors is an evolving clinical practice.

OBJECTIVES The purpose of this study is to provide an update on the authors' Australian clinical program and discuss lessons learned since performing the world's first series of distantly procured DCD heart transplants.

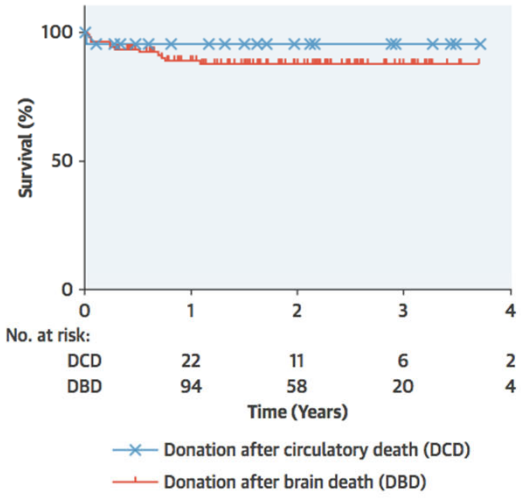
METHODS The authors report their experience of 23 DCD heart transplants from 45 DCD donor referrals since 2014. Donor details were collected using electronic donor records (Donate Life, Australia) and all recipient details were collected from clinical notes and electronic databases at St. Vincent's Hospital.

RESULTS Hearts were retrieved from 33 of 45 DCD donors. A total of 12 donors did not progress to circulatory arrest within the pre-specified timeframe. Eight hearts failed to meet viability criteria during normothermic machine perfusion, and 2 hearts were declined due to machine malfunction. A total of 23 hearts were transplanted between July 2014 and April 2018. All recipients had successful implantation, with mechanical circulatory support utilized in 9 cases. One case requiring extracorporeal membrane oxygenation subsequently died on the sixth post-operative day, representing a mortality of 4.4% over 4 years with a total follow-up period of 15,500 days for the entire cohort. All surviving recipients had normal cardiac function on echocardiogram and no evidence of acute rejection on discharge. All surviving patients remain in New York Heart Association functional class I with normal biventricular function.

CONCLUSIONS DCD heart transplant outcomes are excellent. Despite a higher requirement for mechanical circulatory support for delayed graft function, primarily in recipients with ventricular assist device support, overall survival and rejection episodes are comparable to outcomes from contemporary brain-dead donors. (J Am Coll Cardiol 2019;73:1447-59)

34

CENTRAL ILLUSTRATION Recipient Survival After Cardiac Transplantation Using Donation After Circulatory Death Versus Donation After Brain Death



Chew, H.C. et al. J Am Coll Cardiol. 2019;73(12):1447-59.

This survival curve illustrates the excellent survival of donation after circulatory death (DCD) hearts at up to 4 years post transplantation when compared to the institutional donation after brain death (DBD) cohort over the same time period.

Allina Health ABBOTT NORTHWEST HOSPITAL

Minneapolis Heart Institute

35

U.S. DCD Trial

- **Study design**

  A prospective, randomized and concurrent controlled, non-inferiority pivotal trial in which subjects who receive a DCD donor heart transplant will be compared to subjects who receive a standard criteria donor heart transplant (SOC1 and SOC2 - from both randomized and concurrent control groups), adjusting for differences in risk factors.

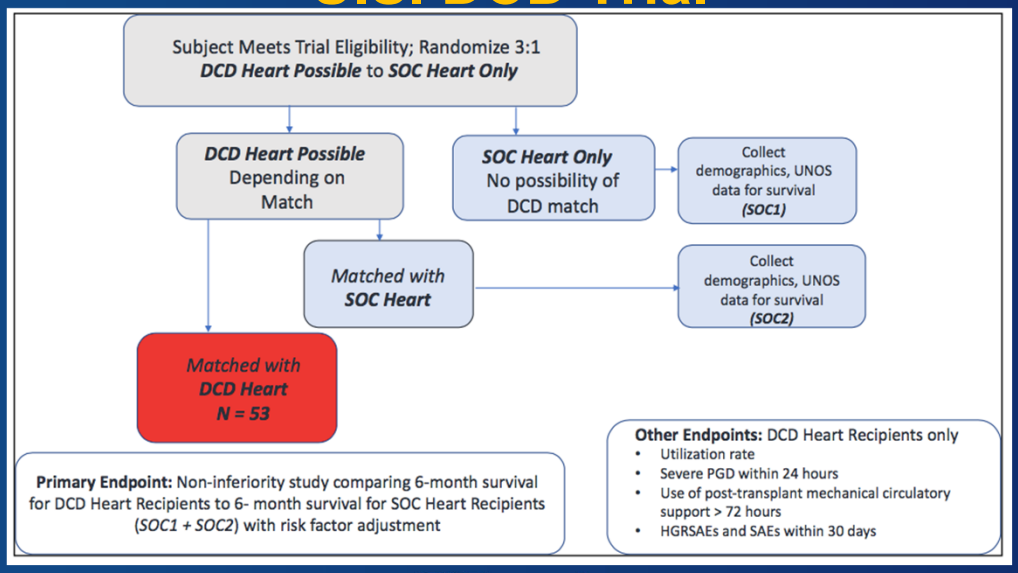
Allina Health ABBOTT NORTHWESTERN HOSPITAL

Minneapolis Heart Institute Foundation™ Creating a world without heart disease®

Minneapolis Heart Institute

36

U.S. DCD Trial



Allina Health ABBOTT NORTHWESTERN HOSPITAL | Minneapolis Heart Institute Foundation™ Creating a world without heart disease® | Minneapolis Heart Institute

37

Trial Size and Subject Follow-up

A maximum of **15** participating sites with a minimum of **53** transplanted DCD heart recipients and at least **159** standard of care heart transplant recipients. Follow-up data for the SOC recipients will be obtained from UNOS/OPTN standard database for transplant recipients.

Allina Health ABBOTT NORTHWESTERN HOSPITAL | Minneapolis Heart Institute Foundation™ Creating a world without heart disease® | Minneapolis Heart Institute

38

Donor Inclusion Criteria

- Maastricht Category III DCD donor, defined as expected death after the withdrawal of life- supportive therapy (WLST)
- Donor age 18-49 years old inclusive
- Warm ischemic time (WIT) ≤ 30 mins, with warm ischemic time defined as: Time from when mean systolic blood pressure (SBP) is < 50 mmHg or peripheral saturation < 70% to aortic cross-clamp and administration of cold cardioplegia in the donor.

Allina Health ABBOTT NORTHWESTERN HOSPITAL | Minneapolis Heart Institute Foundation™ Creating a world without heart disease® | Minneapolis Heart Institute

39

U.S. DCD Trial

Primary Endpoint

A non-inferiority comparison of patient survival at 6 months post-transplant between recipients of DCD donor hearts preserved on the OCS Heart System (***DCD Heart Transplanted Recipient Population)*** and recipients of standard criteria donor hearts preserved using cold storage (***SOC1 + SOC2, SOC Heart Transplanted Recipient Population***), adjusting for risk factors.

Allina Health ABBOTT NORTHWESTERN HOSPITAL | Minneapolis Heart Institute Foundation™ Creating a world without heart disease® | Minneapolis Heart Institute

40

U.S. DCD Trial

Secondary Endpoint

Utilization Rate is defined as the number of eligible DCD donor hearts that met the warm ischemic time limit and were instrumented on the OCS Heart System that meet the acceptance criteria for transplantation after OCS Heart preservation divided by the total number of eligible DCD donor hearts that met the warm ischemic time limit above and were instrumented on the OCS Heart System.

Allina Health ABBOTT NORTHWESTERN HOSPITAL

Minneapolis Heart Institute Foundation™ Creating a world without heart disease®

Minneapolis Heart Institute

41

U.S. DCD Trial

- **90 (initially 53) DCD hearts were transplanted across 9 sites.**
- **90 (initially 159) Cold static-preserved hearts were enrolled as well**
- **There were 11 hearts declined after OCS assessment resulting in an overall utilization of 89%**
- **Similar recipient MCS support as in EXPAND CAP**

Allina Health ABBOTT NORTHWESTERN HOSPITAL

Minneapolis Heart Institute Foundation™ Creating a world without heart disease®

Minneapolis Heart Institute

42

U.S. DCD Trial

- Mean AOP has been in the range of 72 mmHg
- Mean CF has been in the range of 730 mL/min
- Mean perfusion time has been in the range of 4.5 hours with the longest in this study being 472 minutes
- PGD and survival can not be reported at this time but are very favorable

Allina Health ABBOTT NORTHWESTERN HOSPITAL
Minneapolis Heart Institute Foundation™ Creating a world without heart disease®
Minneapolis Heart Institute

43

U.S. DCD Trial- CAP

- 37 patients enrolled out of a possible (90)
- All results similar to the U.S. DCD Trial

Allina Health ABBOTT NORTHWESTERN HOSPITAL
Minneapolis Heart Institute Foundation™ Creating a world without heart disease®
Minneapolis Heart Institute

44

U.S. DCD Trial- CAP- MHI

- 5 runs
- 3 patients enrolled
- 75% utilization rate- 4 runs with recovery of the organ/ 3 transplants (1 heart declined after arrival at ANW)
- 1 "dry run"- patient didn't expire
- 2 of 3 required postoperative MCS (grade 3 PGD- 16-72 hours to full recovery)

Allina Health ABBOTT NORTHWESTERN HOSPITAL

Minneapolis Heart Institute Foundation™ Creating a world without heart disease®

Minneapolis Heart Institute

45

Conclusions

- Organ shortage still a limiting factor
- Deaths on waitlists despite changes in allocation strategies
- Distance- major obstacle to allocate all organs
- Ex-vivo perfusion- future direction
- OPOs and centers working together

Allina Health ABBOTT NORTHWESTERN HOSPITAL

Minneapolis Heart Institute Foundation™ Creating a world without heart disease®

Minneapolis Heart Institute

46

Special Thanks- MHIF!

- Ben Sun and Peter Eckman
- OPOs
- Transplant Coordinators
- Perfusionists
- Research Coordinators
- The whole Advanced Heart Failure Team

Allina Health ABBOTT NORTHWESTERN HOSPITAL

Minneapolis Heart Institute Foundation
Creating a world without heart disease

Minneapolis Heart Institute

47

48

Surgeon waking up for a SCHEDULED morning transplant

Allina Health ABBOTT NORTHWESTERN HOSPITAL

Minneapolis Heart Institute Foundation
Creating a world without heart disease

Minneapolis Heart Institute

49

Thank You

Allina Health ABBOTT NORTHWESTERN HOSPITAL

Minneapolis Heart Institute Foundation
Creating a world without heart disease

Minneapolis Heart Institute

50

Content

- Demand- Supply mismatch
- Ex-vivo perfusion with DBD- Donation after brain death
- Ex- vivo perfusion with DCD- Donation after circulatory determined death

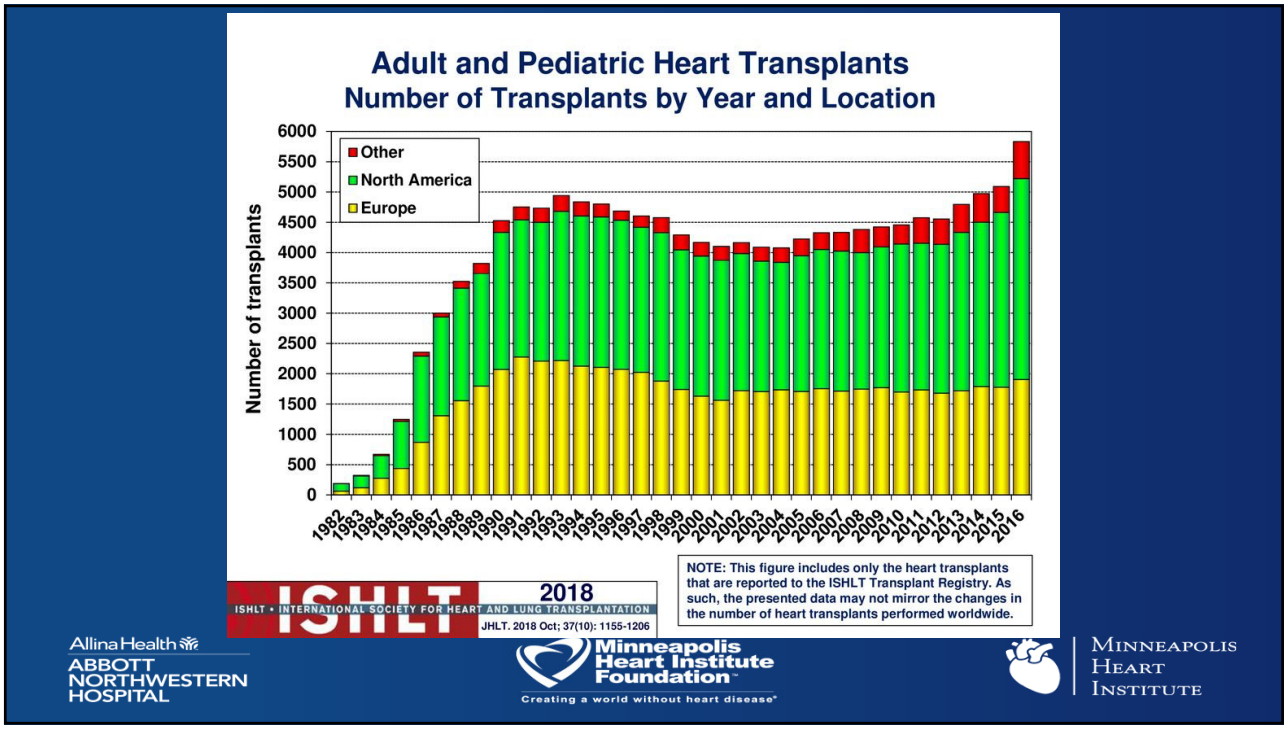
Allina Health ABBOTT NORTHWESTERN HOSPITAL
Minneapolis Heart Institute Foundation™ Creating a world without heart disease®
Minneapolis Heart Institute

51

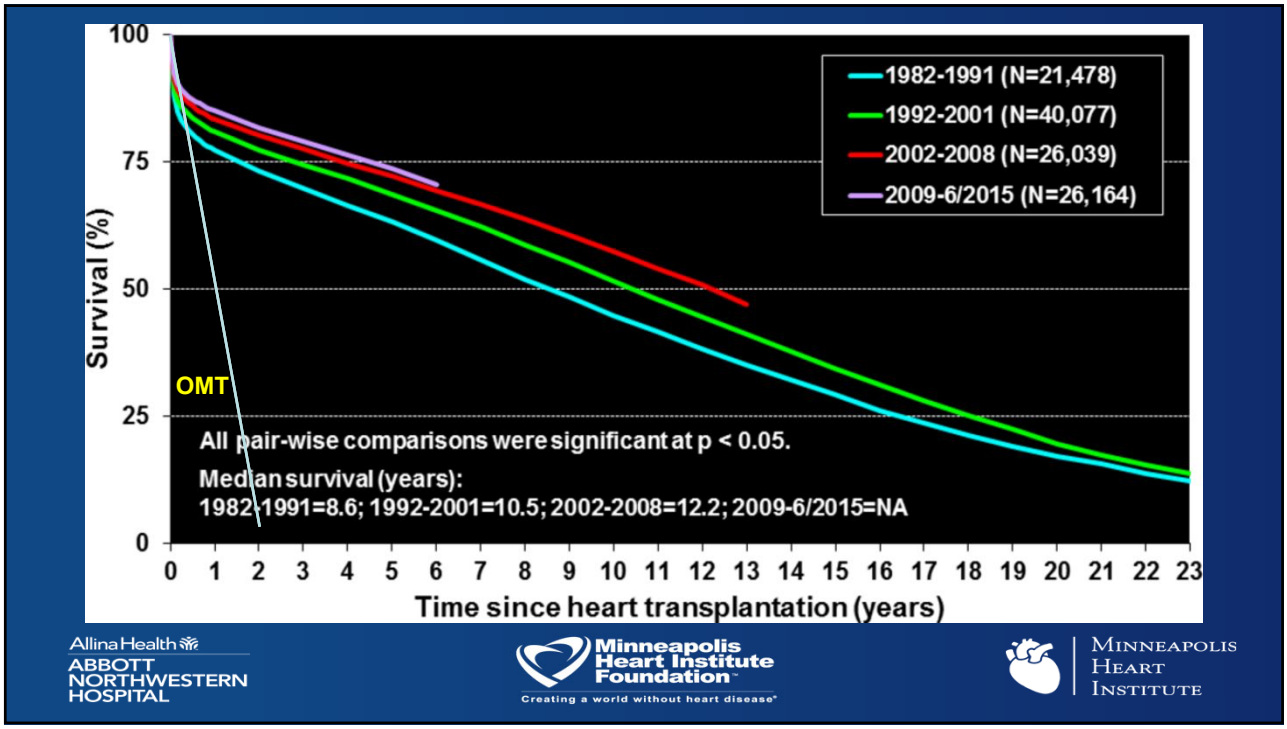
Organ Shortage

Allina Health ABBOTT NORTHWESTERN HOSPITAL
Minneapolis Heart Institute Foundation™ Creating a world without heart disease®
Minneapolis Heart Institute

52


Adult and Pediatric Heart Transplants
Number of Transplants by Year and Location
Number of transplants
Other
North America
Europe
6000
5500
5000
4500
4000
3500
3000
2500
2000
1500
1000
500
0
1982 1983 1984 1985 1986 1987 1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016
ISHLT
2018
ISHLT • INTERNATIONAL SOCIETY FOR HEART AND LUNG TRANSPLANTATION
JHLT. 2018 Oct; 37(10): 1155-1206
NOTE: This figure includes only the heart transplants that are reported to the ISHLT Transplant Registry. As such, the presented data may not mirror the changes in the number of heart transplants performed worldwide.
Allina Health
ABBOTT NORTHWESTERN HOSPITAL
Minneapolis Heart Institute Foundation
Creating a world without heart disease
Minneapolis Heart Institute

53


Survival (%)
100
75
50
25
0
1982-1991 (N=21,478)
1992-2001 (N=40,077)
2002-2008 (N=26,039)
2009-6/2015 (N=26,164)
OMT
All pair-wise comparisons were significant at p < 0.05.
Median survival (years):
1982-1991=8.6; 1992-2001=10.5; 2002-2008=12.2; 2009-6/2015=NA
0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23
Time since heart transplantation (years)
Allina Health
ABBOTT NORTHWESTERN HOSPITAL
Minneapolis Heart Institute Foundation
Creating a world without heart disease
Minneapolis Heart Institute

54

Reason of removal from the list

Removal reason	2015	2016	2017
Deceased donor transplant	2331	2734	2811
Patient died	395	324	290
Patient refused transplant	24	25	27
Improved, transplant not needed	161	187	176
Too sick for transplant	297	261	290
Other	246	251	273

OPTN/SRTR 2017 Annual Data Report: Heart

Allina Health ABBOTT NORTHWESTERN HOSPITAL

Minneapolis Heart Institute Foundation™ Creating a world without heart disease®

Minneapolis Heart Institute

55

1. Distance

2. Imperfect organ

…Hawaii

Ex-vivo perfusion

Allina Health ABBOTT NORTHWESTERN HOSPITAL

Minneapolis Heart Institute Foundation™ Creating a world without heart disease®

Minneapolis Heart Institute

56

Allina Health ABBOTT NORTHWESTERN HOSPITAL
Minneapolis Heart Institute Foundation
Creating a world without heart disease
Minneapolis Heart Institute

57

- **The TransMedics® Organ Care System (OCS) is a portable ex-vivo organ perfusion system, intended to preserve a donor heart in a near-normothermic and beating state from retrieval until the eventual transplantation.**

Allina Health ABBOTT NORTHWESTERN HOSPITAL
Minneapolis Heart Institute Foundation
Creating a world without heart disease
Minneapolis Heart Institute

58


TransMedics
Allina Health
ABBOTT NORTHWESTERN HOSPITAL
Minneapolis Heart Institute

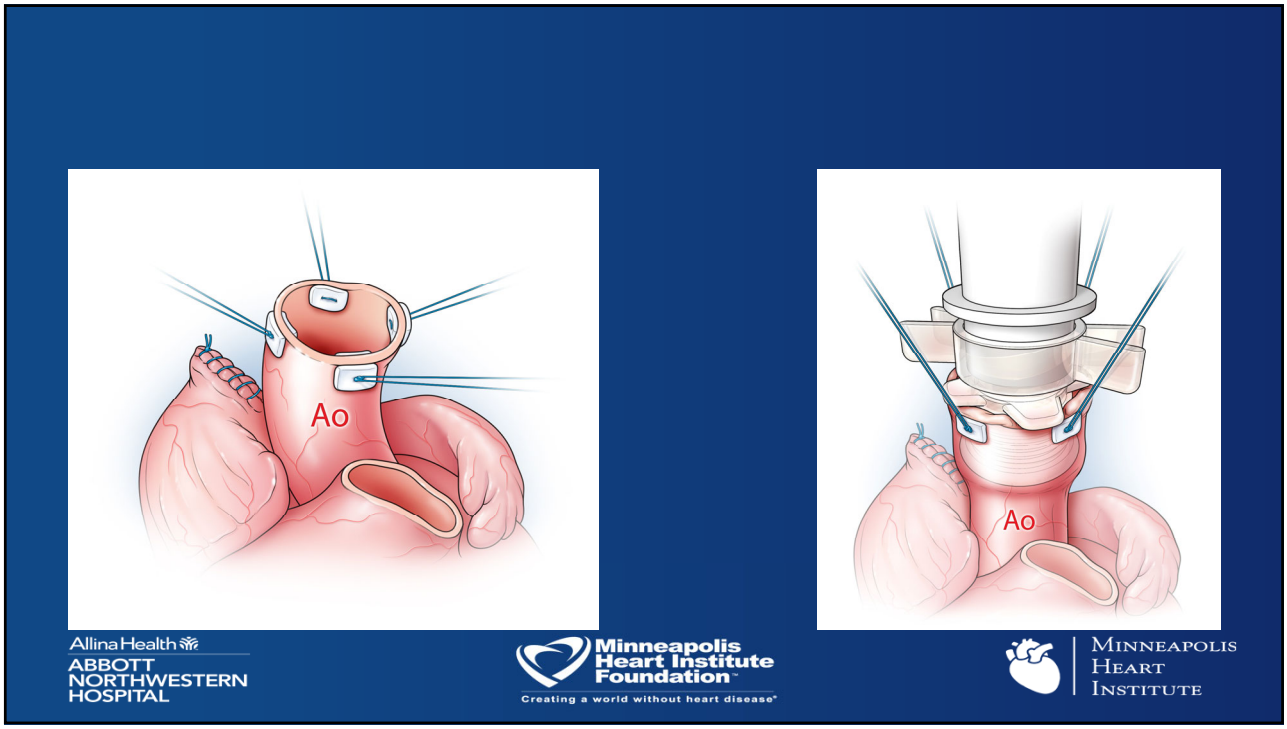
59


TransMedics
PA
Allina Health
ABBOTT NORTHWESTERN HOSPITAL
Minneapolis Heart Institute

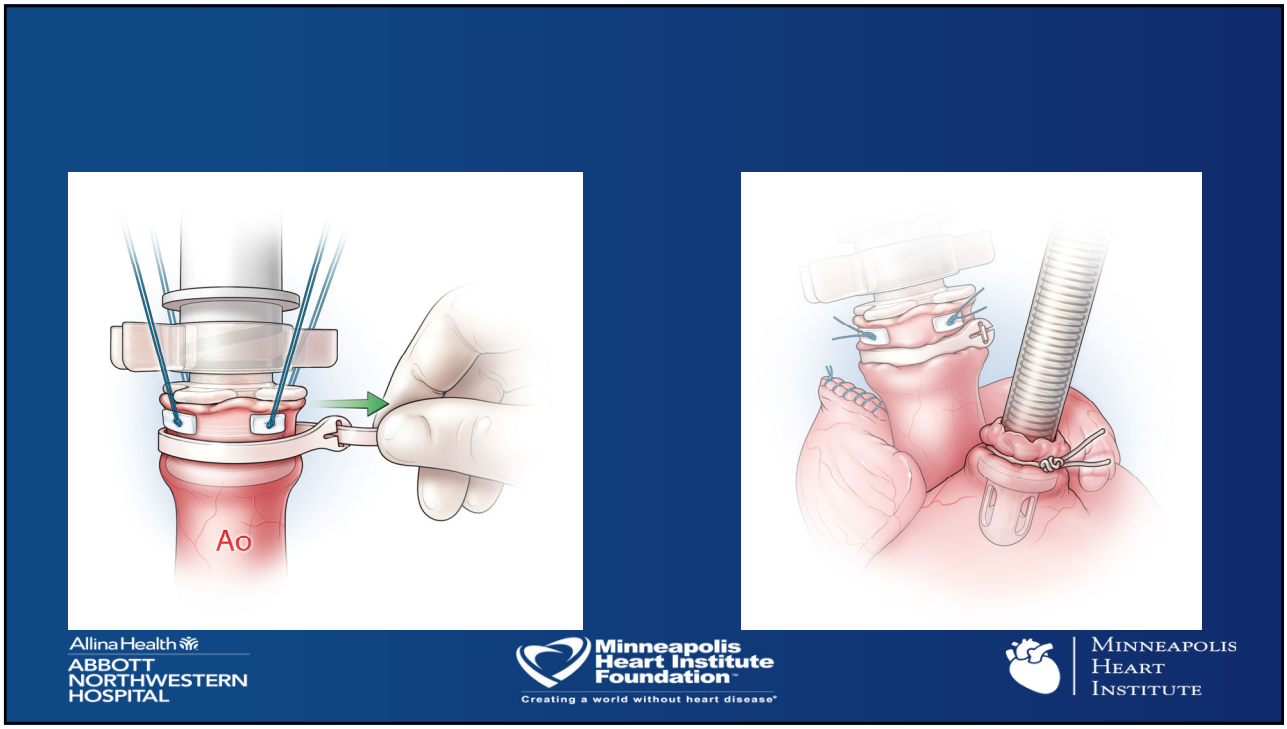
60


Allina Health
ABBOTT
NORTHWESTERN
HOSPITAL

61


Ao
Ao
Allina Health
ABBOTT
NORTHWESTERN
HOSPITAL
Minneapolis
Heart Institute
Foundation
Creating a world without heart disease
Minneapolis
Heart
Institute

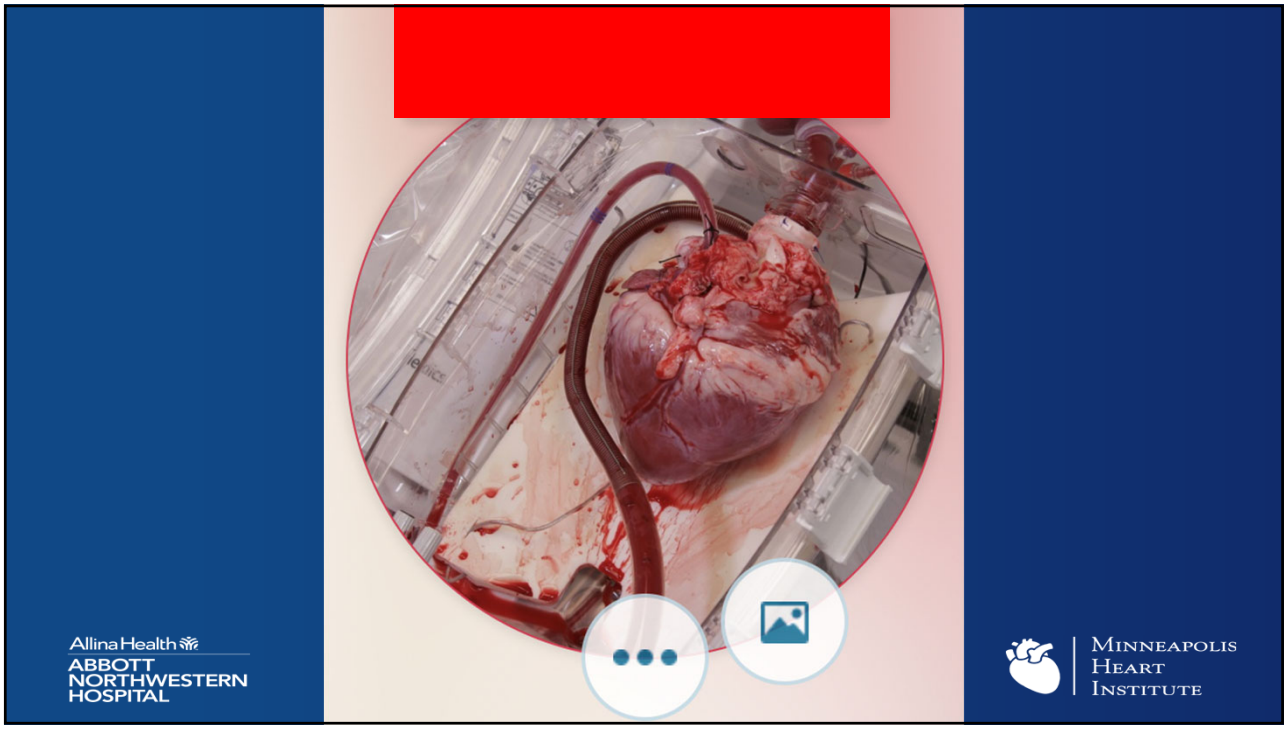
62


Ao
Allina Health
ABBOTT NORTHWESTERN HOSPITAL
Minneapolis Heart Institute Foundation
Creating a world without heart disease
Minneapolis Heart Institute

63


Allina Health
ABBOTT NORTHWESTERN HOSPITAL
Minneapolis Heart Institute Foundation
Creating a world without heart disease
Minneapolis Heart Institute

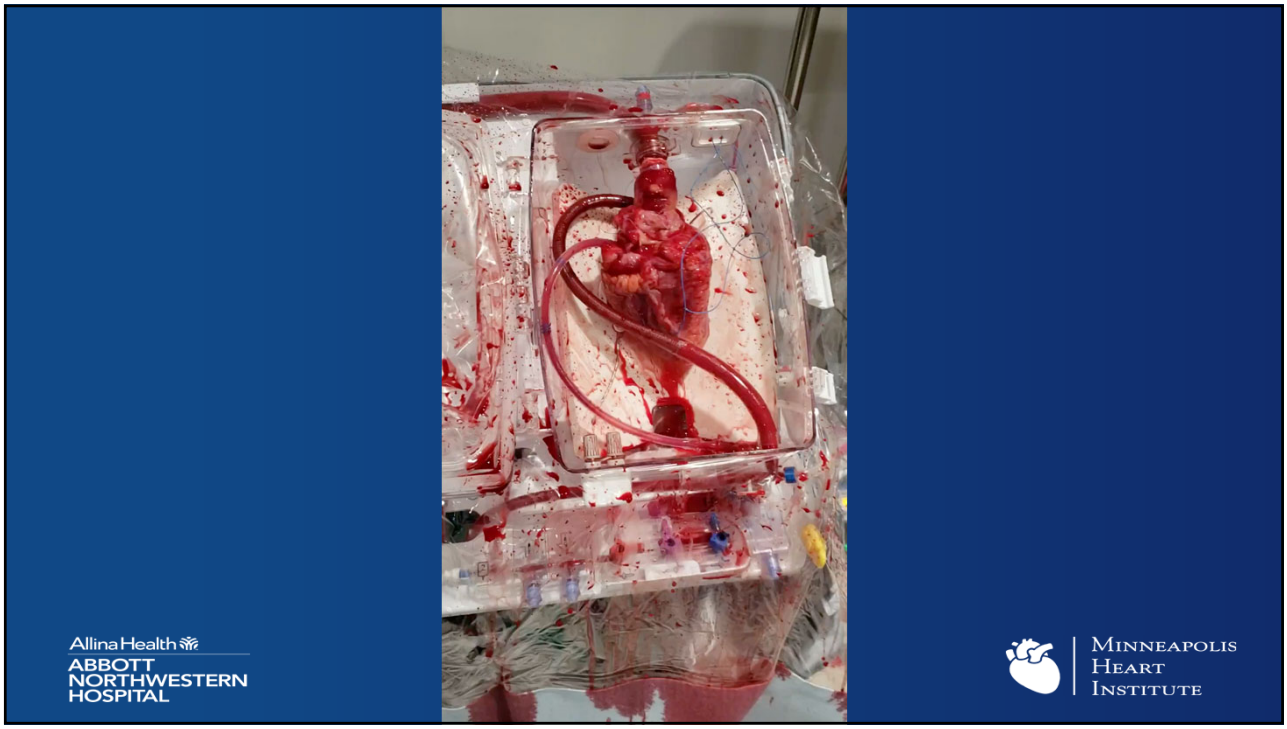
64


Allina Health
ABBOTT NORTHWESTERN HOSPITAL
Minneapolis Heart Institute

65


Allina Health
ABBOTT NORTHWESTERN HOSPITAL
Minneapolis Heart Institute

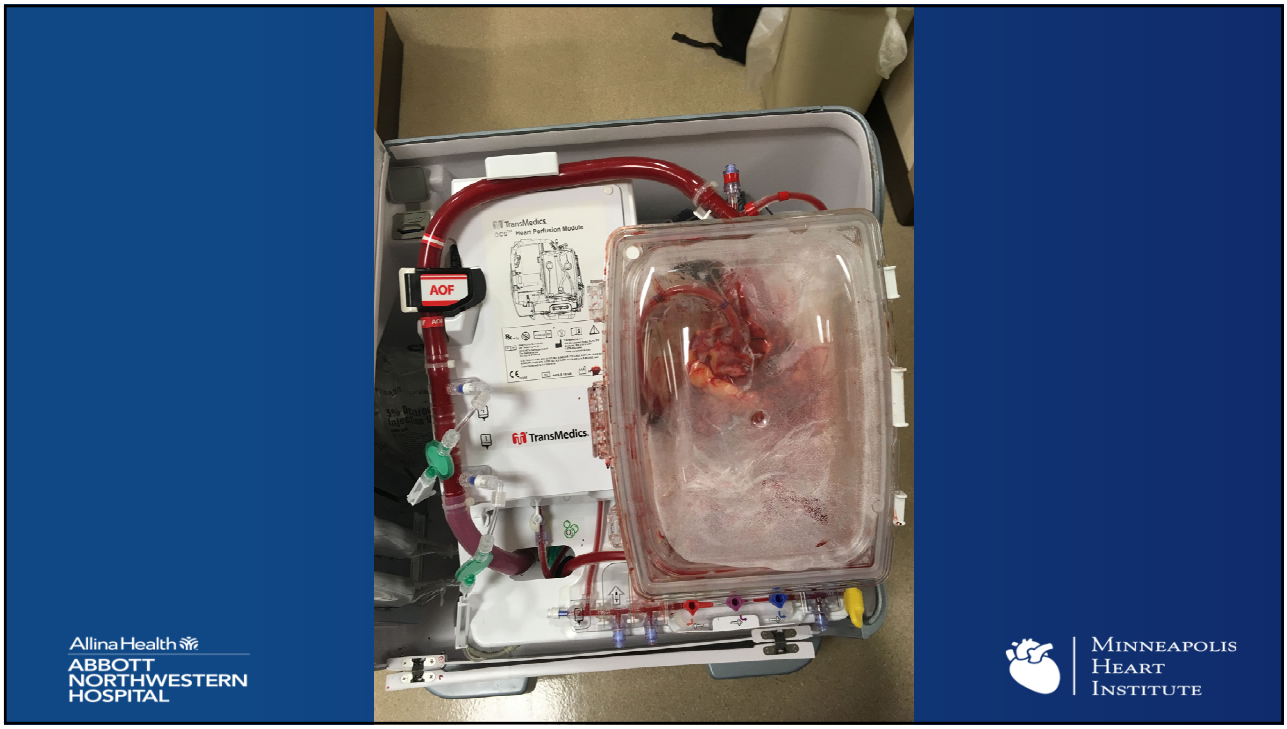
66


Allina Health
ABBOTT NORTHWESTERN HOSPITAL
Minneapolis Heart Institute

67


Allina Health
ABBOTT NORTHWESTERN HOSPITAL
Minneapolis Heart Institute

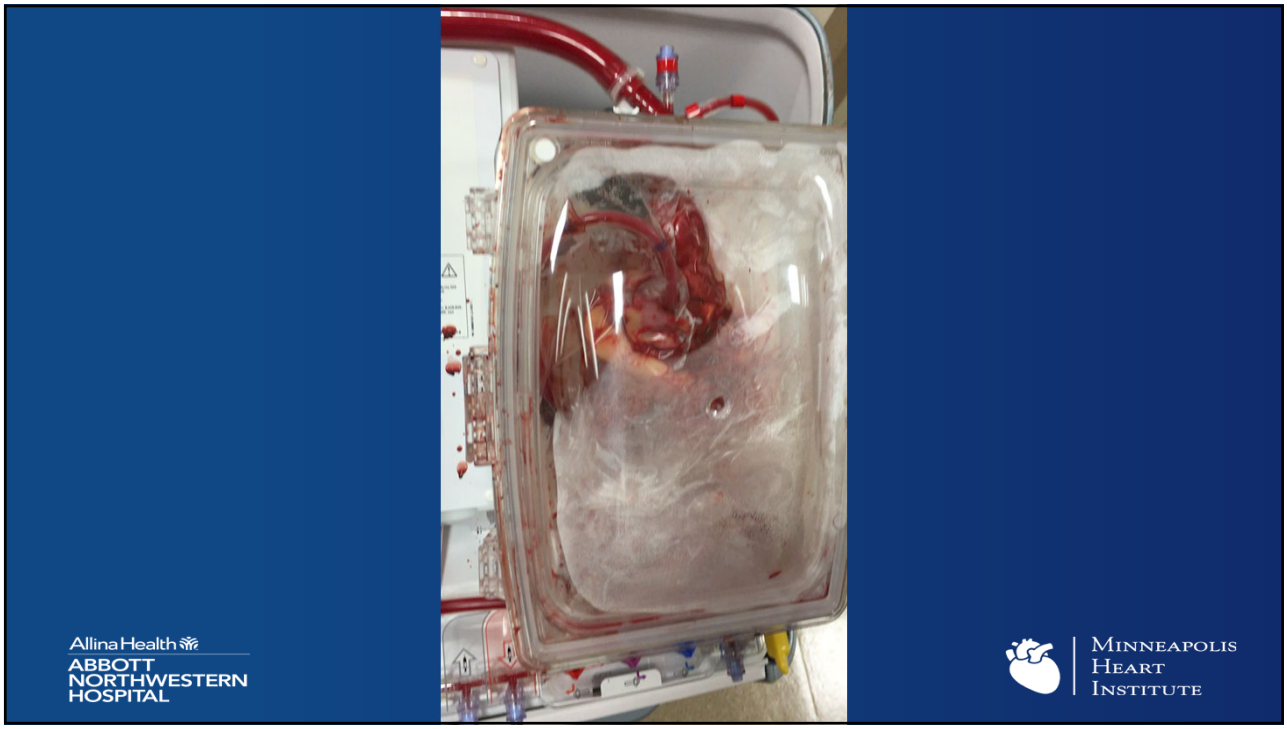
68


AOF
TransMedics
Allina Health
ABBOTT NORTHWESTERN HOSPITAL
Minneapolis Heart Institute

69


Allina Health
ABBOTT NORTHWESTERN HOSPITAL
Minneapolis Heart Institute

70


Allina Health
ABBOTT NORTHWESTERN HOSPITAL
Minneapolis Heart Institute

71


Allina Health
ABBOTT NORTHWESTERN HOSPITAL
Medics
Minneapolis Heart Institute

72


Allina Health
ABBOTT NORTHWESTERN HOSPITAL
Minneapolis Heart Institute

73


Allina Health
ABBOTT NORTHWESTERN HOSPITAL
Minneapolis Heart Institute

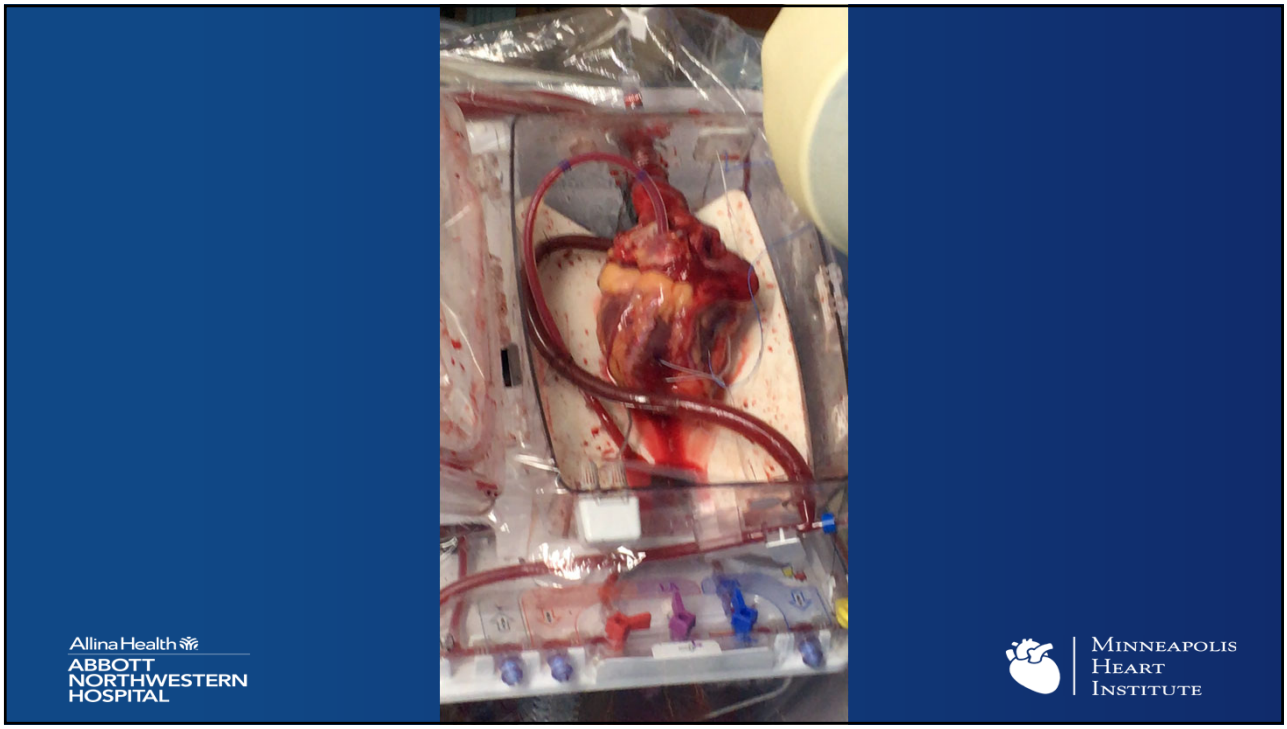
74


TransMedics
2019-09-04 01:49:16
02:52
CF L/min
0.73
AOP mmHg
118/52
(80)
AOF L/min
1.11
HR BPM
82
SvO2
98%
HCT
15%
Temp °C
34.0
CF L/min
0.73
AOP mmHg
80
PAP mmHg
6
Lactate mmol/L
24:59
10:23
09:28
Allina Health
ABBOTT NORTHWESTERN HOSPITAL
Minneapolis Heart Institute

75


OR2
Allina Health
ABBOTT NORTHWESTERN HOSPITAL
Minneapolis Heart Institute

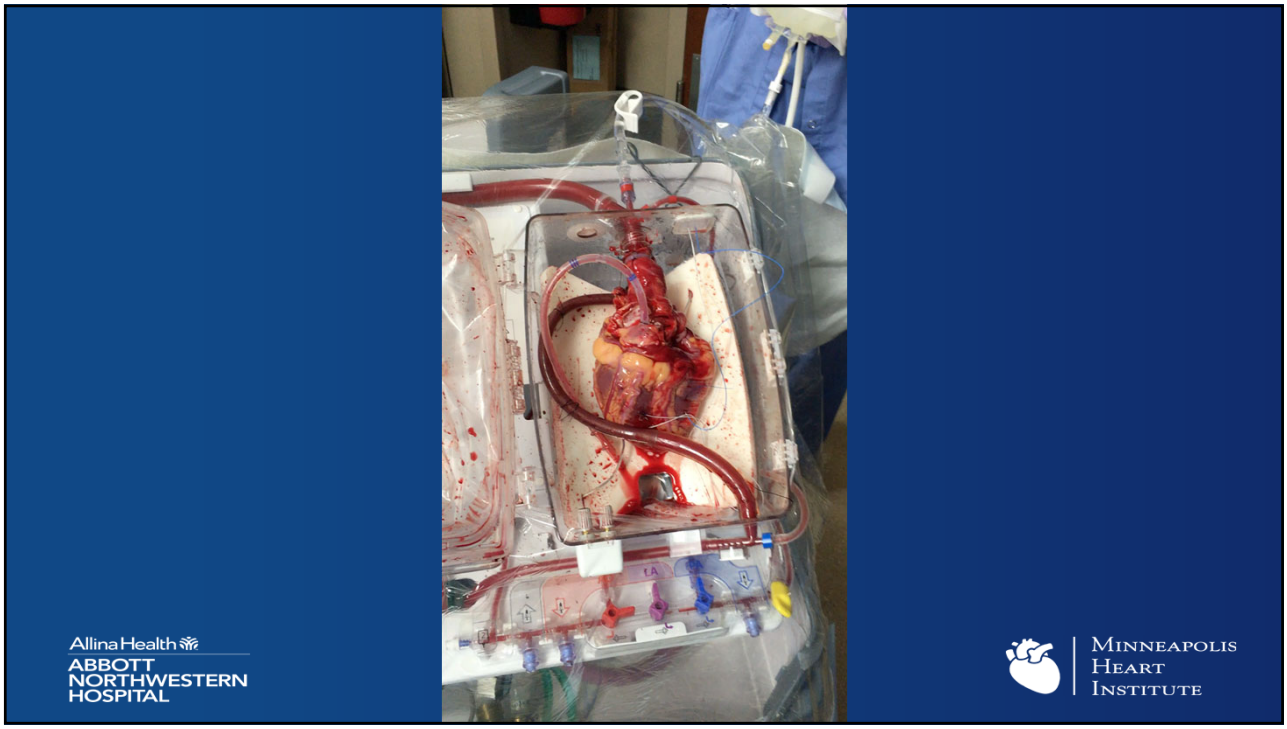
76


Allina Health
ABBOTT NORTHWESTERN HOSPITAL
Minneapolis Heart Institute

77


Allina Health
ABBOTT NORTHWESTERN HOSPITAL
Minneapolis Heart Institute

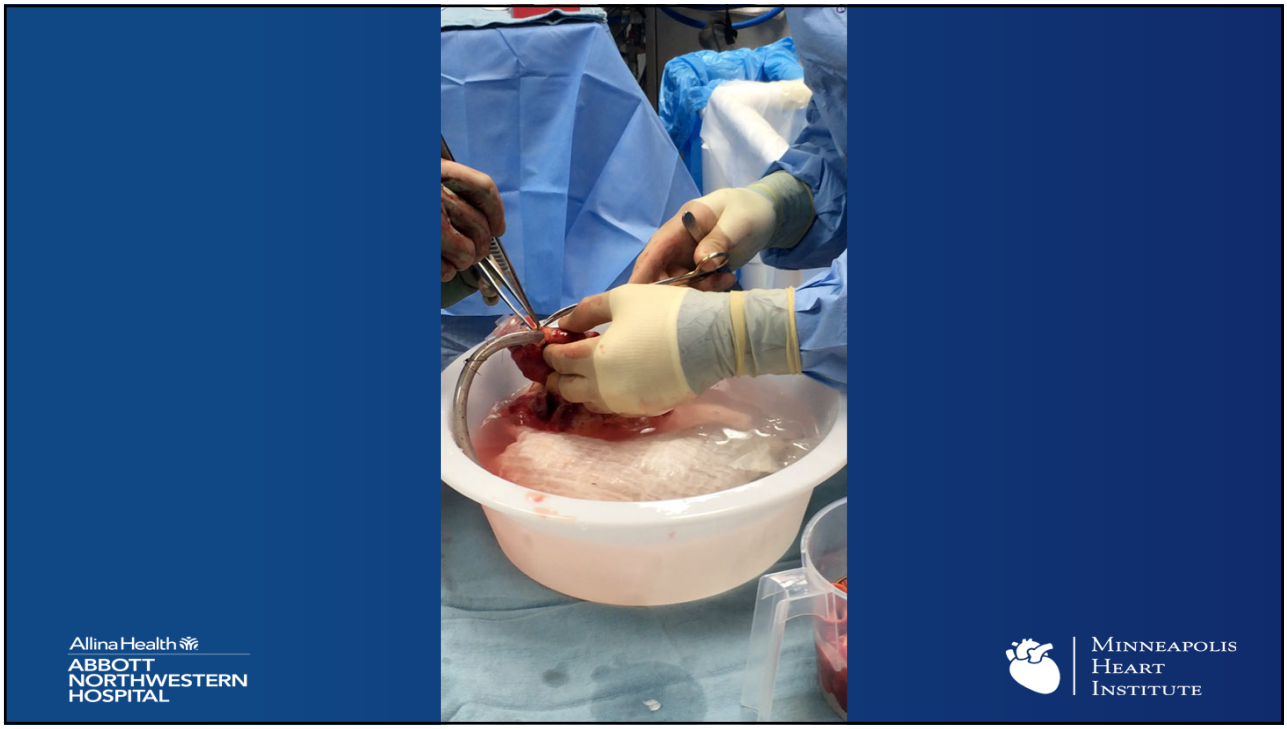
78


Allina Health
ABBOTT NORTHWESTERN HOSPITAL
Minneapolis Heart Institute

79


Allina Health
ABBOTT NORTHWESTERN HOSPITAL
Minneapolis Heart Institute

80



81

TransMedics

Donor Characteristics

- 45 yr Female
- 162 cm, 54.4 kg
- Cause of brain death: Cerebrovascular hemorrhage
- Inclusion criteria:
  - Anticipated cross clamp time ≥4 hrs plus
- Additional risk factors:
  - Hypertension

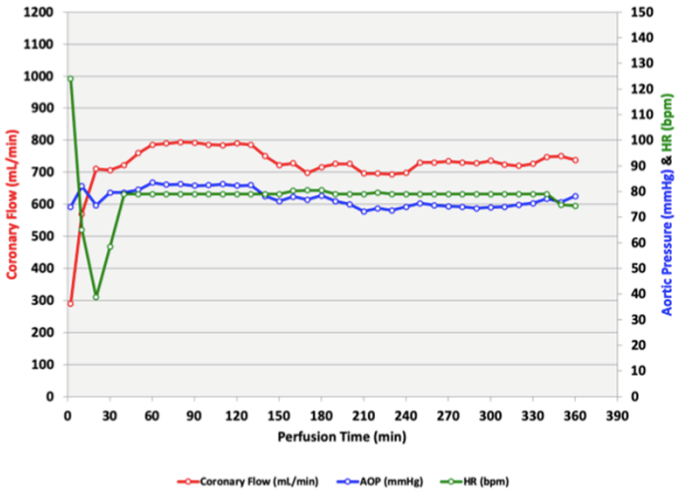
MHIF/04September2019/Transplant

2

82

TransMedics

Perfusion Parameters



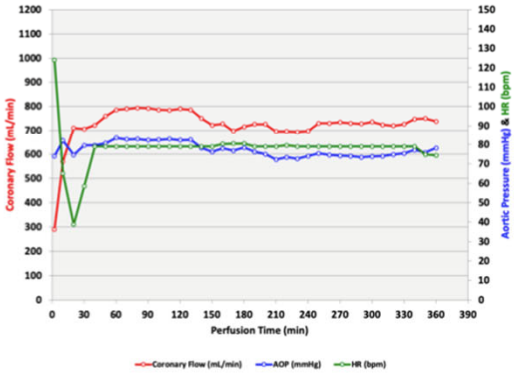
MHIF/04September2019/Transplant

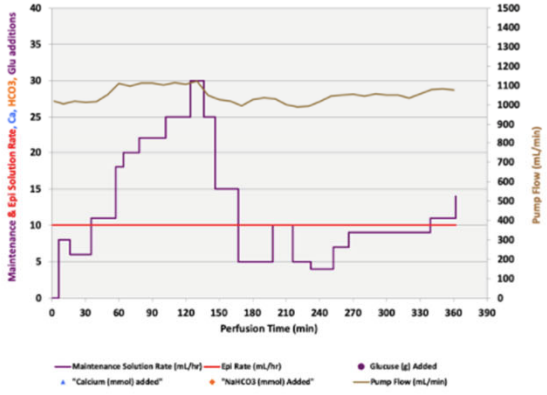
3

83

TransMedics

Perfusion Parameters and Controls





MHIF/04September2019/Transplant

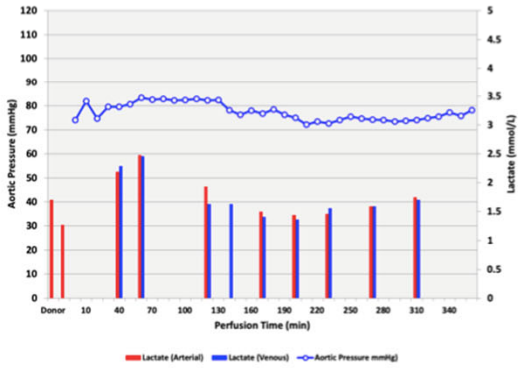
5

84

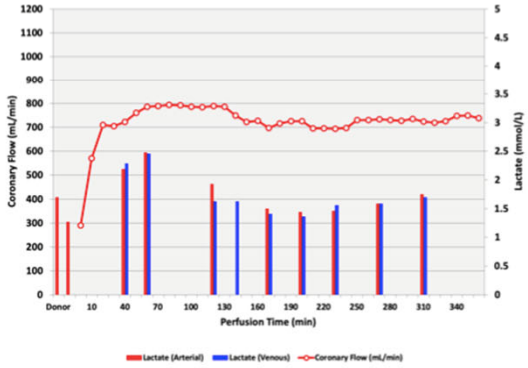
TransMedics

Lactate Profile

AOP



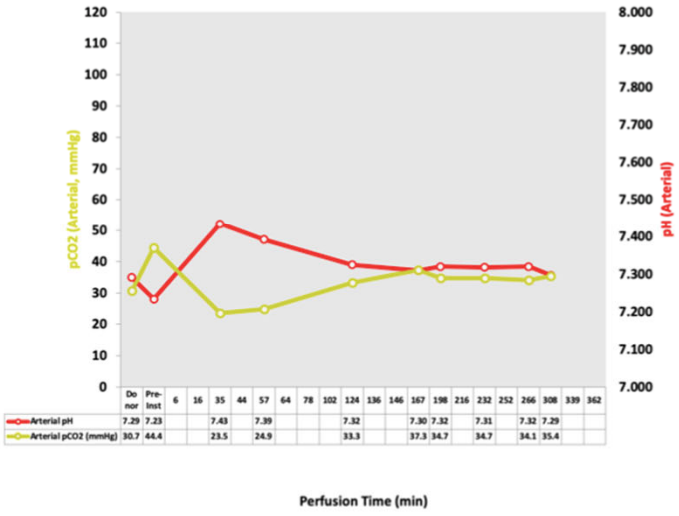
CF



85

TransMedics

pH and Arterial pCO_2



86

TransMedics

Critical Times

- Donor Cross-clamp to start of OCS perfusion: 29 minutes
- Warm Perfusion Time: 362 minutes
- Cooling Time: 6 minutes
- End of OCS perfusion/cooling to release of recipient cross-clamp: 59 minutes

87

TransMedics

Recipient Characteristics

- 67 yr Female
- 157 cm, 76.2 kg
- Diagnosis: Ischemic cardiomyopathy

88

TransMedics

Discussion

- Early perfusion characterized by rapid achievement of target mean AOP. Initial Use Model range for CF (700-800 mL/min) achieved within 10 minutes, however, TMDX recommends achieving 750 mL/min as early as possible
- Lactate transitioned from secreting to absorbing between the first and second sample sets with mean AOP 82 mmHg and CF 790 mL/min. Parameters were maintained at these values prior to third lactate samples
- There was a 1 hour interval between the second and third lactate samples. A 10-15 minute interval would have been appropriate as there had been ab increase in lactate between the first and second sample sets despite transitioning from secreting to absorbing

MHIF/04September2019/Transplant 14

89

TransMedics

Discussion

- Based on the rapid decrease in lactate between the second and third sample sets, a decrease in pump flow would have been possible to avoid hyper-perfusion
- There was raoid trend of respiratory acidosis. An increase in gas flow rate from 150 mL/min to 200 mL/min at two hours of perfusion would have been appropriate
- Mean AOP and CF for the case were 77.5 mmHg and 734 mL/min, respectively

MHIF/04September2019/Transplant 15

90

Conclusions

- Organ shortage still a limiting factor
- Deaths on waitlists despite changes in allocation strategies
- Distance- major obstacle to allocate all organs
- Ex-vivo perfusion- viable option to mitigate it
- Future- DCD!!!
- Future- OPOs and centers working together

Allina Health ABBOTT NORTHWESTERN HOSPITAL
Minneapolis Heart Institute Foundation™ Creating a world without heart disease®
Minneapolis Heart Institute

91

Special Thanks

- OPOs
- Transplant Coordinators
- Perfusionists
- Research Coordinators
- The whole Advanced Heart Failure Team

Allina Health ABBOTT NORTHWESTERN HOSPITAL
Minneapolis Heart Institute Foundation™ Creating a world without heart disease®
Minneapolis Heart Institute

92

Very Special Thanks

Dr. Bassam Shukrallah

Allina Health ABBOTT NORTHWESTERN HOSPITAL

Minneapolis Heart Institute Foundation™ Creating a world without heart disease®

Minneapolis Heart Institute

93

Surgeon waking up for a morning transplant

Allina Health ABBOTT NORTHWESTERN HOSPITAL

Minneapolis Heart Institute Foundation™ Creating a world without heart disease®

Minneapolis Heart Institute

94