MHIF FEATURED STUDY:

Heart EXPAND CAP

OPEN AND ENROLLING:

EPIC message to *Research MHIF Patient Referral*

CONDITION:	PI:	RESEARCH CONTACTS:	SPONSOR:
Heart Failure/Transplant	Karl Mudy, MD	Kari Thomas - Kari.M.Thomas@allina.com | 612-863-7493 Kari Williams - Kari.Williams@allina.com | 612-863-0027	TransMedics, Inc.

DESCRIPTION: a single-arm study evaluating the OCS™ Heart System and extended criteria donor hearts (those that are currently not transplanted or are seldom transplanted in the US)

CRITERIA LIST/ QUALIFICATIONS:

Donor Heart Inclusion

- Expected total cross-clamp time of ≥4 hours; **OR** expected total cross-clamp time of ≥2 hours PLUS one of the following risk factors:
  - Donor age 45-55 years, inclusive, with no coronary catheterization data
  - Donor age ≥55 years
  - Left ventricular septal or posterior wall thickness of >12 mm, but ≤16 mm
  - Reported down time of ≥20 min, with stable hemodynamics at time of final assessment
  - Left heart ejection fraction (EF) ≥40%, but ≤50% at time of acceptance of offer
  - Donor angiogram with luminal irregularities with no significant CAD (≤50%)
  - History of carbon monoxide poisoning with good cardiac function at time of donor assessment
  - Social history of alcoholism with good cardiac function at time of donor assessment
  - History of diabetes without significant CAD on angiogram (≤50%)

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

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MHIF FEATURED STUDY:

Heart DCD

PENDING APPROVAL:

EPIC message to *Research MHIF Patient Referral*

CONDITION:	PI:	RESEARCH CONTACTS:	SPONSOR:
Heart Failure/Transplant	Karl Mudy, MD	Kari Thomas - Kari.M.Thomas@allina.com | 612-863-7493 Kari Williams - Kari.Williams@allina.com | 612-863-0027	TransMedics, Inc.

DESCRIPTION: To evaluate the effectiveness 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, 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.

CRITERIA LIST/ QUALIFICATIONS:

Donor Heart Inclusion

- Maastricht Category III DCD donor, defined as expected death after the withdrawal of lifesupportive 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 four successful uses of the TransMedics Organ Care System (OCS™), aka "Heart in the Box"

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Heart in a Box

Bassam Shukrallah, MD Karol Mudy, MD

February , 3rd , 2020

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Disclosures

- Shukrallah's original accent is not really southern
- Mudy's accent is real- he doesn't speak English much

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Content

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

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Organ Shortage

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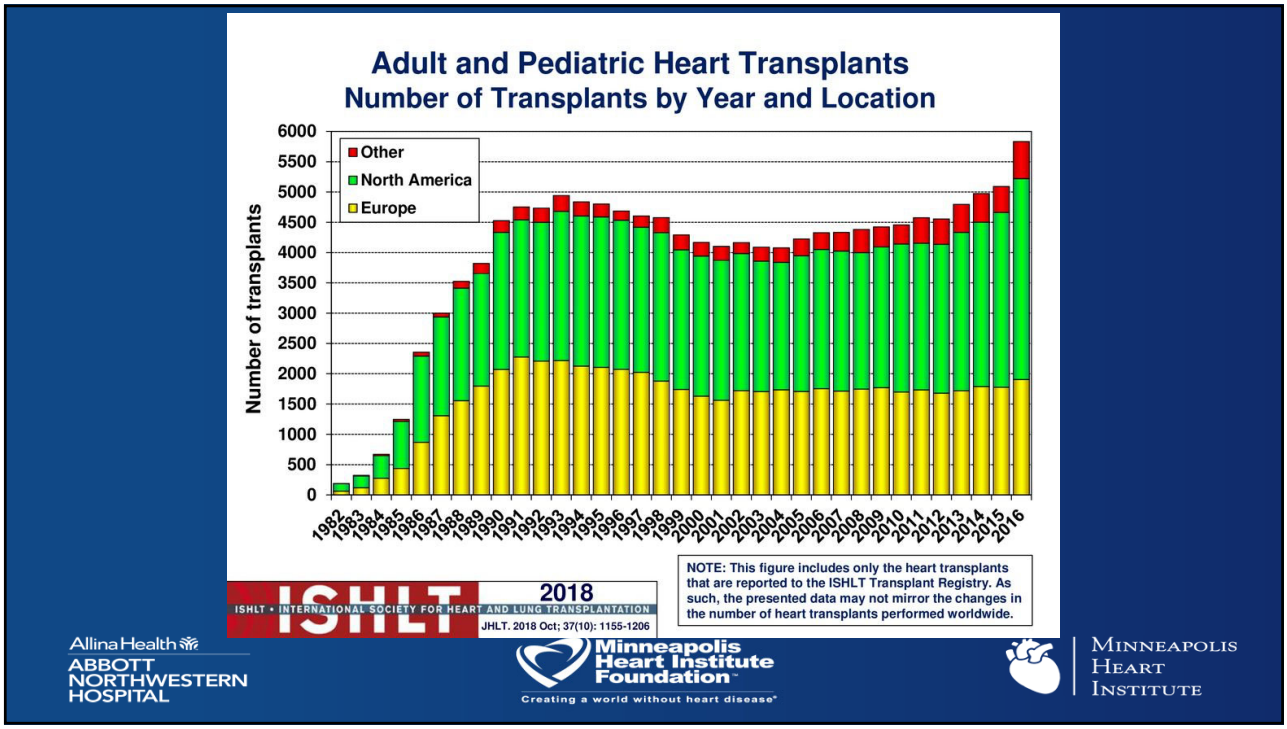
Adult and Pediatric Heart Transplants
Number of Transplants by Year and Location
Number of transplants
Other
North America
Europe
6000
5500
5000
4500
4000
3500
3000
2500
2000
1500
1000
500
0
1982 1983 1984 1985 1986 1987 1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016
ISHLT • INTERNATIONAL SOCIETY FOR HEART AND LUNG TRANSPLANTATION
2018
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.
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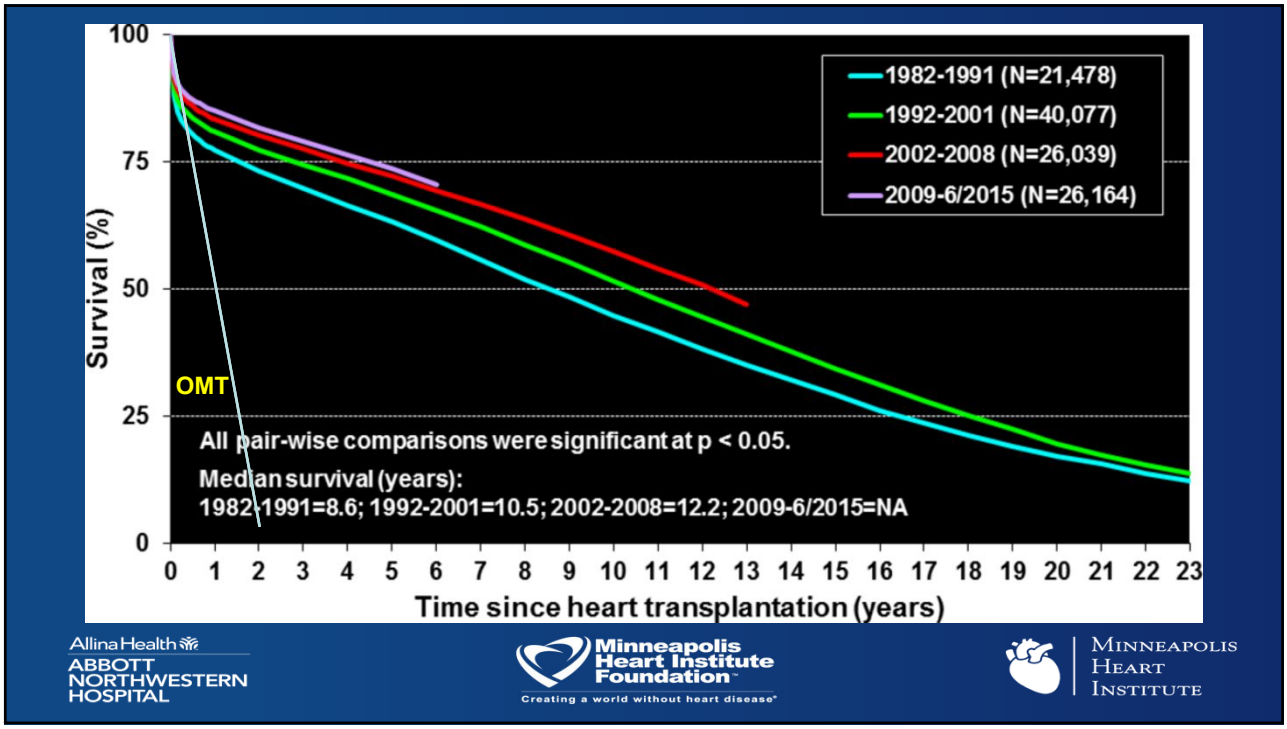
Survival (%)
100
75
50
25
0
1982-1991 (N=21,478)
1992-2001 (N=40,077)
2002-2008 (N=26,039)
2009-6/2015 (N=26,164)
OMT
All pair-wise comparisons were significant at p < 0.05.
Median survival (years):
1982-1991=8.6; 1992-2001=10.5; 2002-2008=12.2; 2009-6/2015=NA
0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23
Time since heart transplantation (years)
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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

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1. Distance

2. Imperfect organ

…Hawaii

Ex-vivo perfusion

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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

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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

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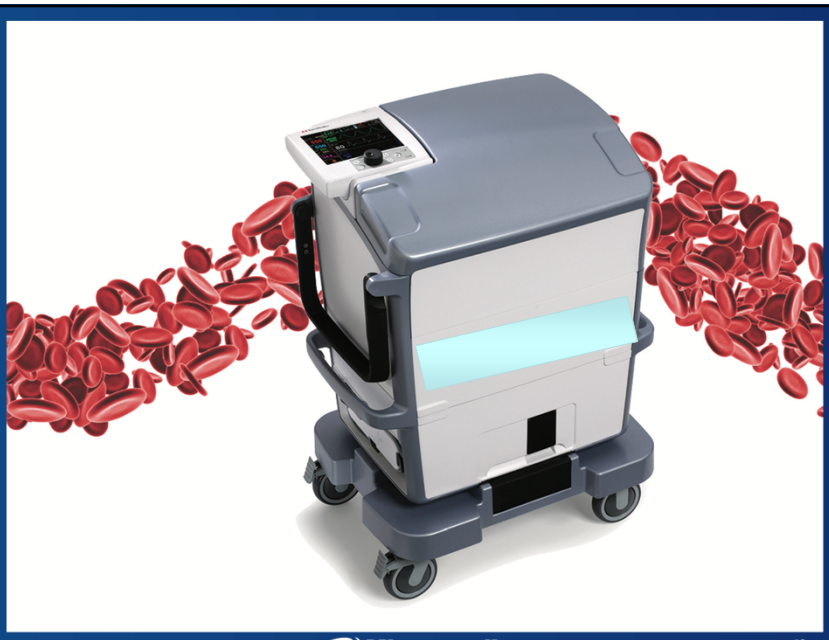

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- **The ********® Organ Care System (OCS) is a portable ex-vivo organ perfusion system, intended to preserve a donor heart in a near-normothermic and beating state from retrieval until the eventual transplantation.**

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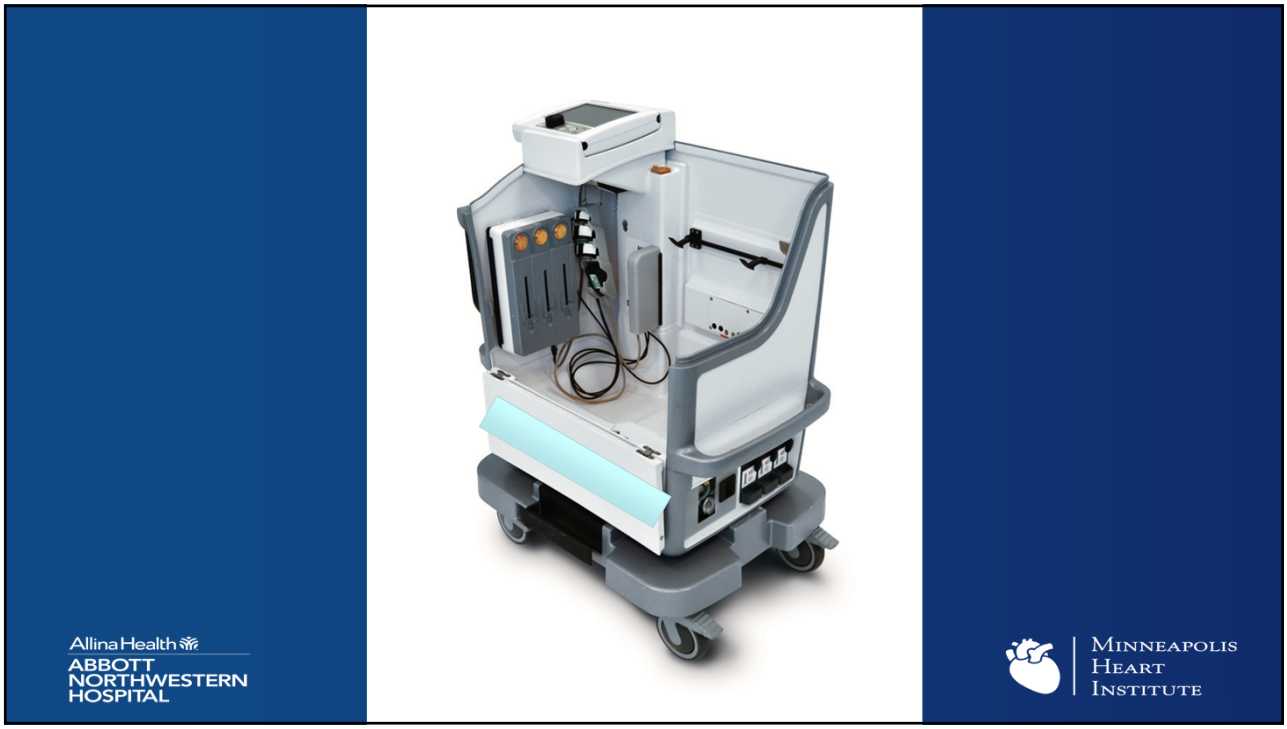
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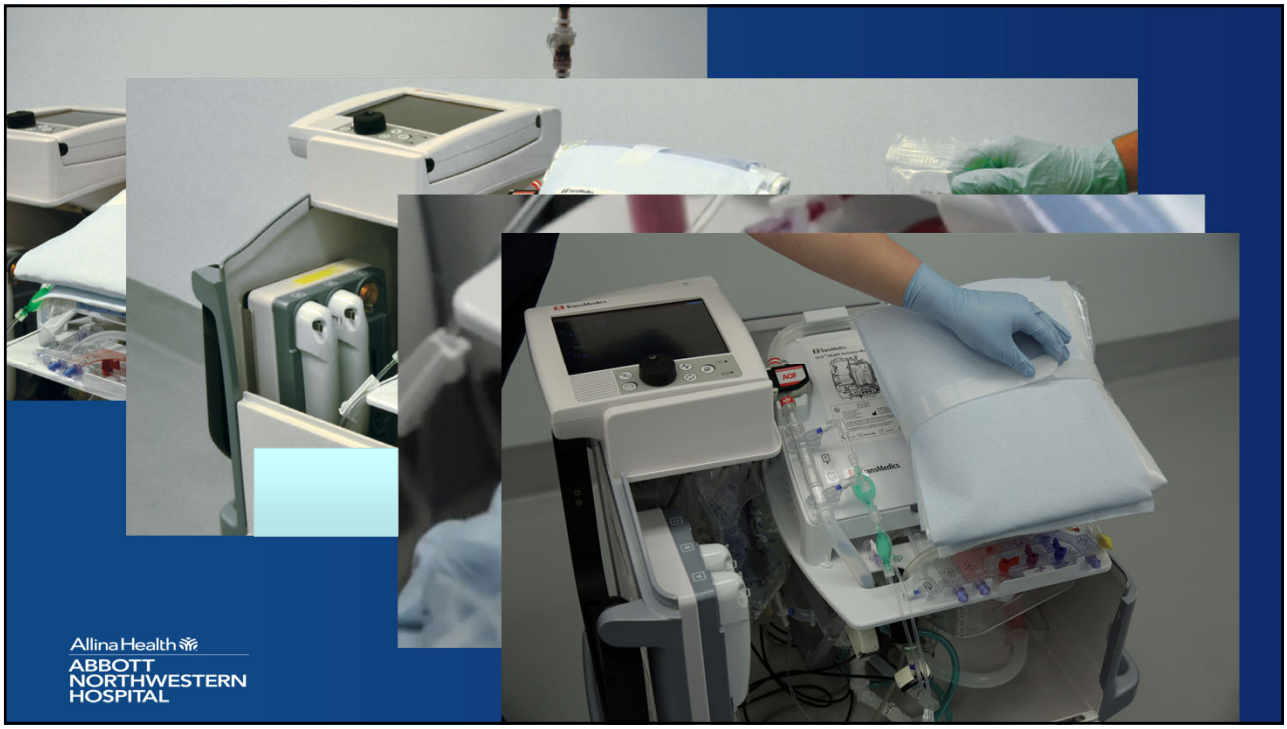
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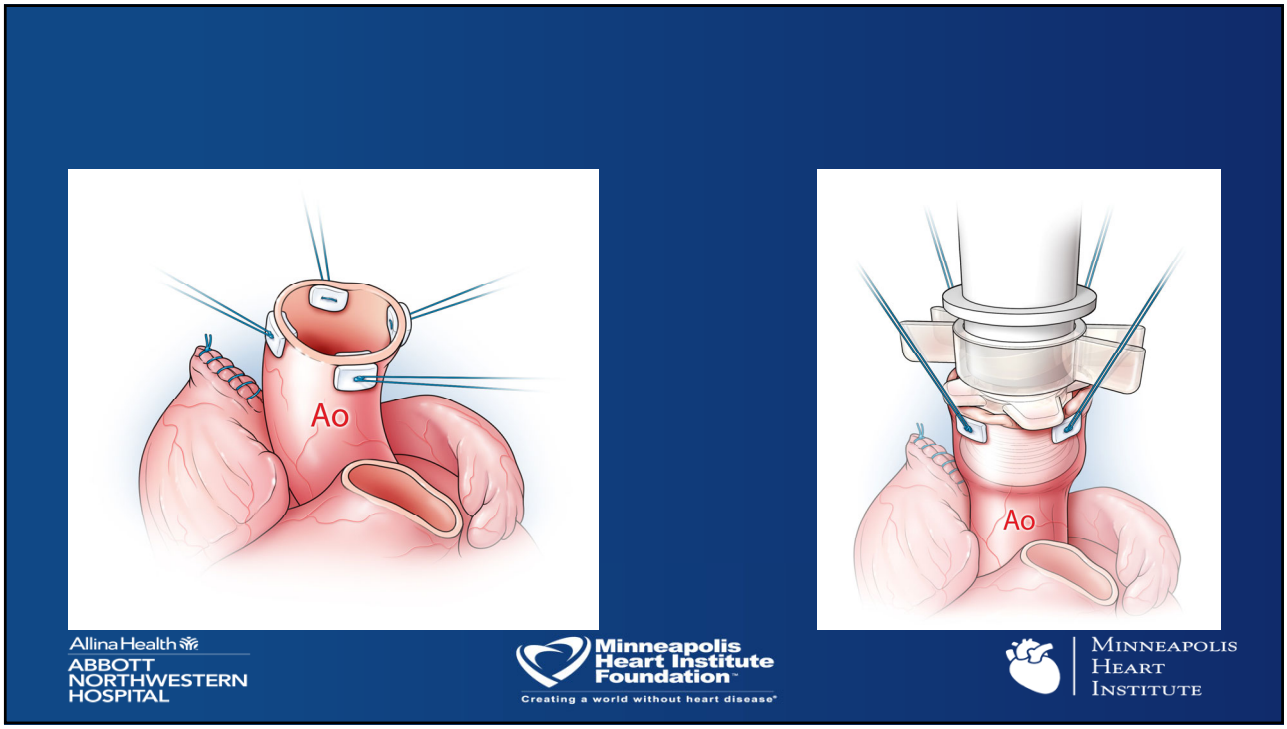
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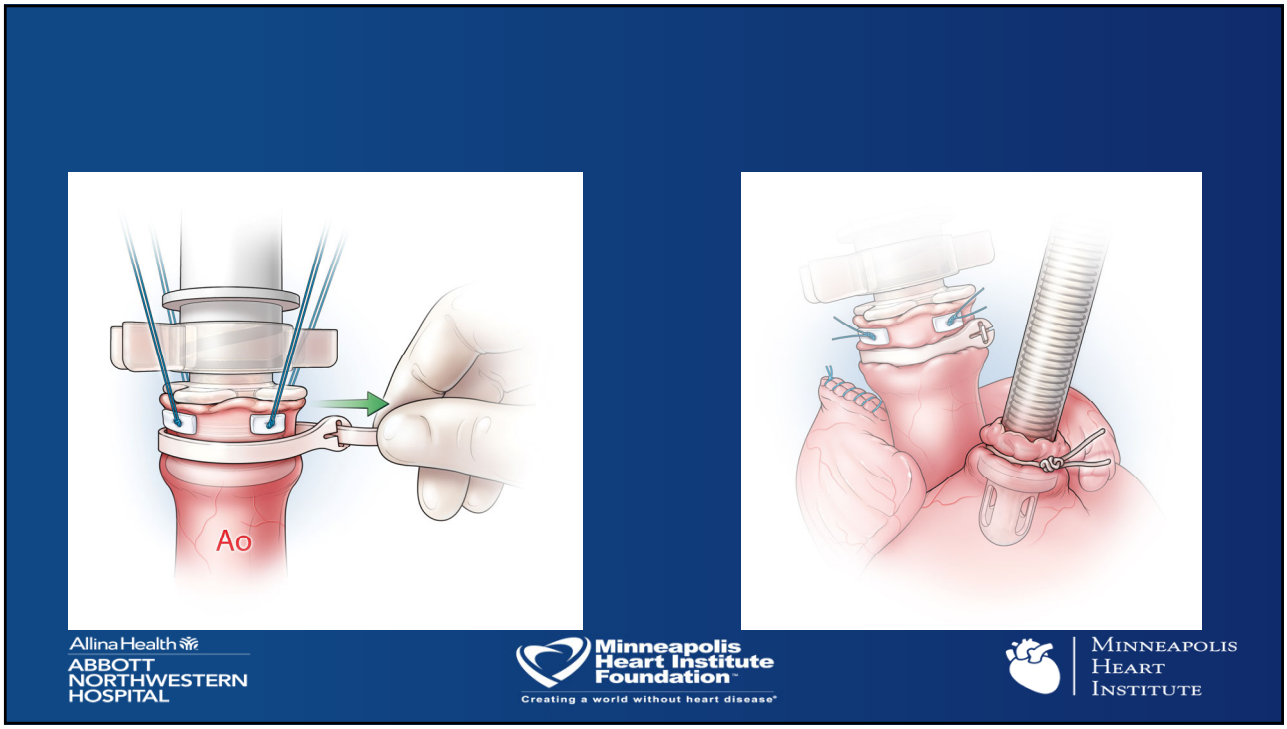
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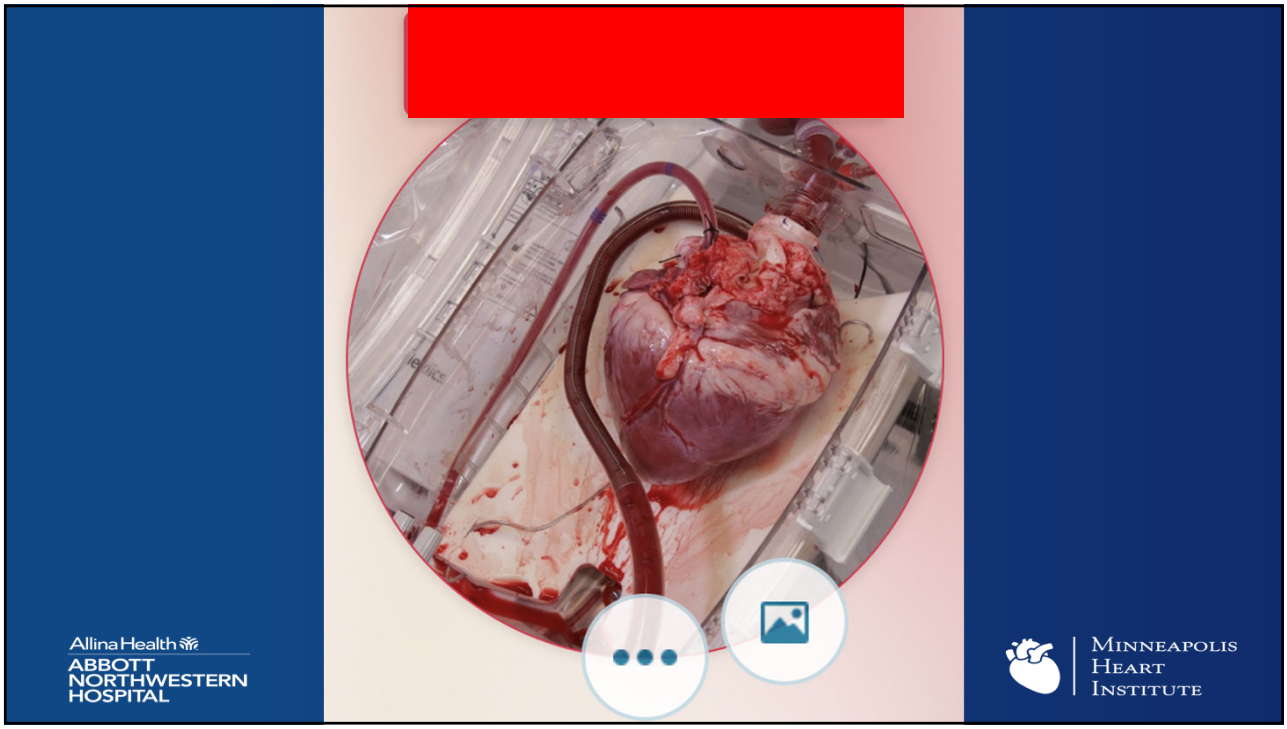
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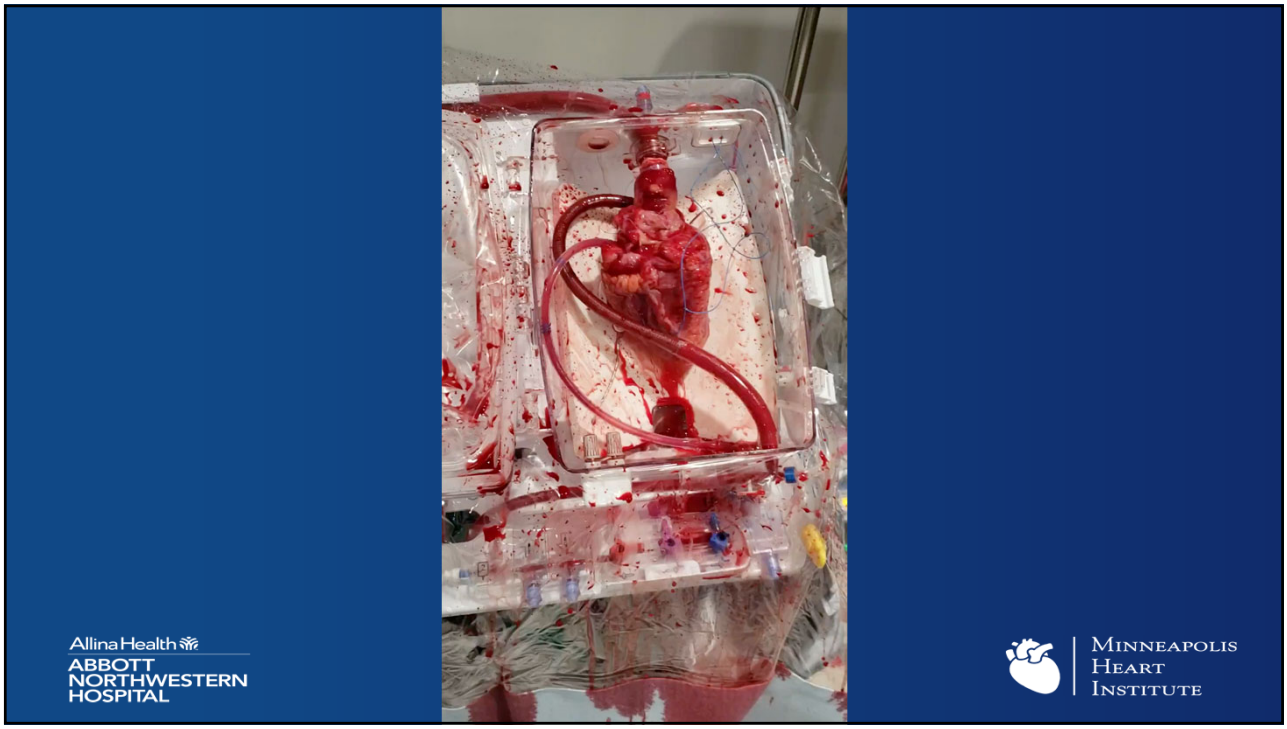
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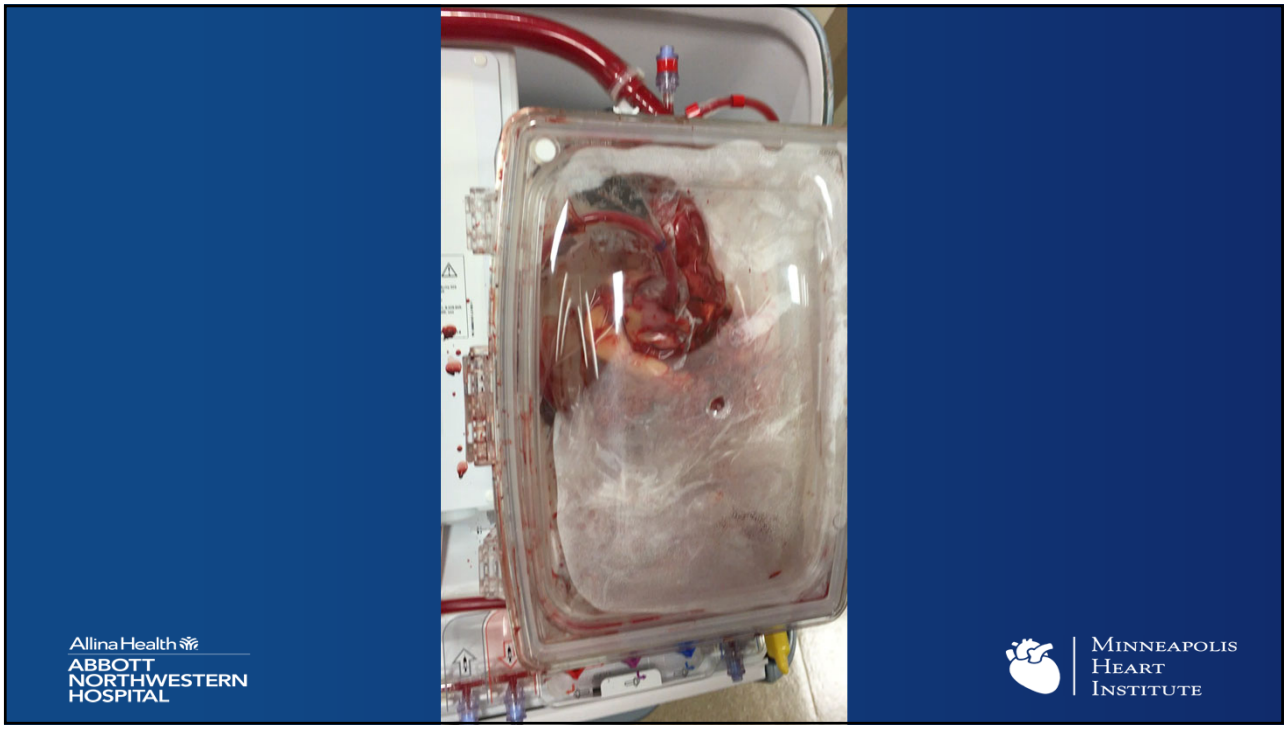
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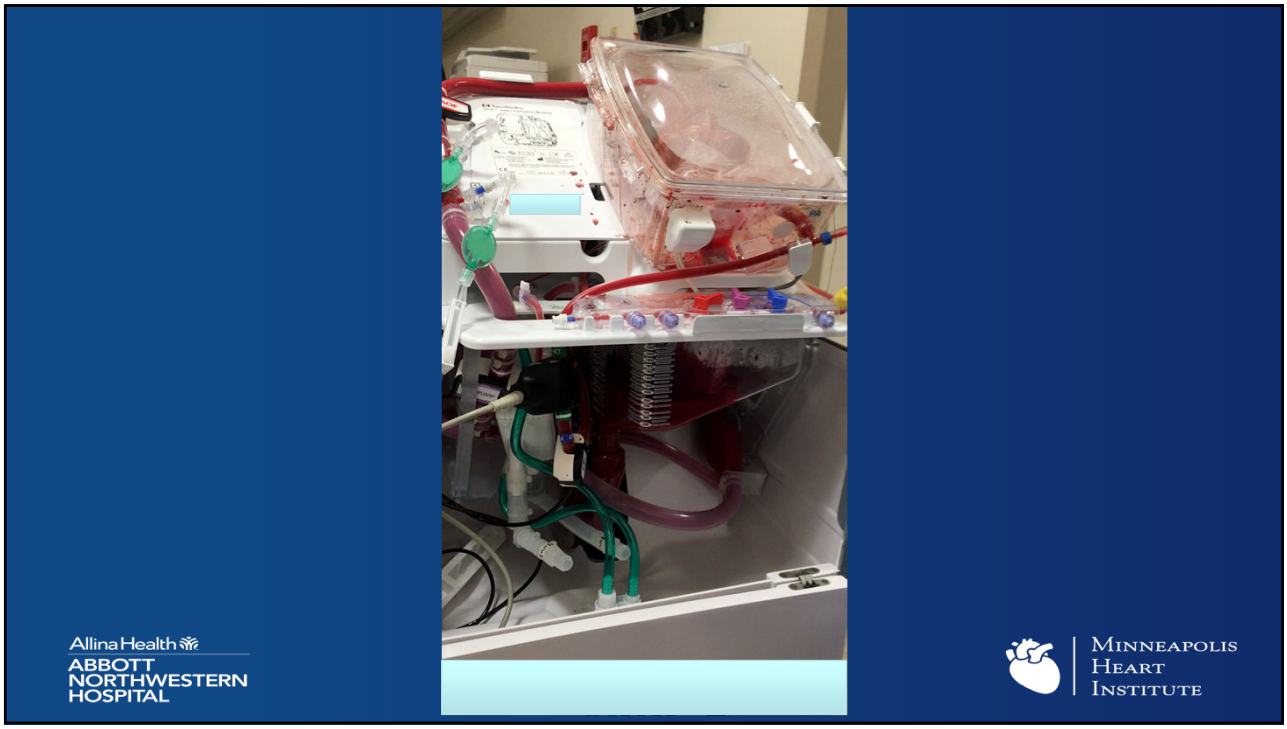
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TransMedics
2019-09-04 01:49:16
02:52
CF L/min
0.73
AOP mmHg
118/52
(80)
AOF L/min
1.11
HR BPM
82
SvO2
98%
HCT
15%
Temp °C
34.0
PAP mmHg
6
Lactate mmol/L
80
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OR2
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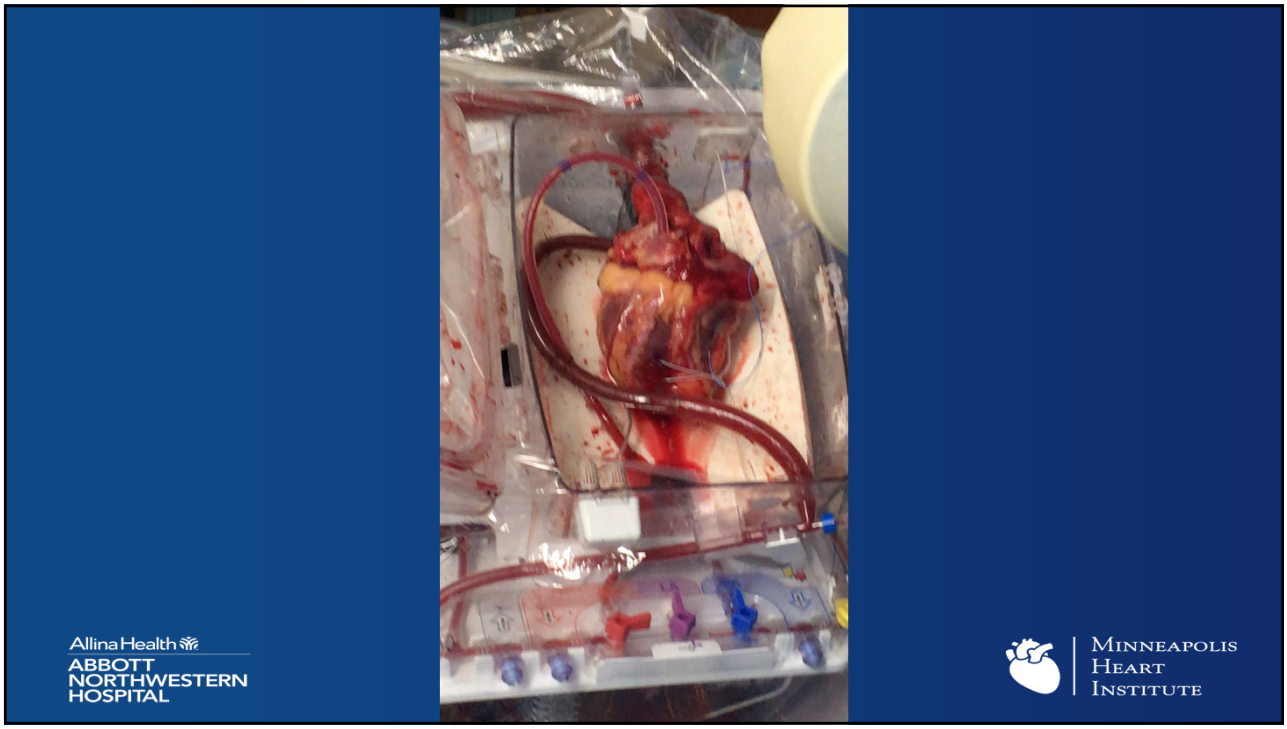
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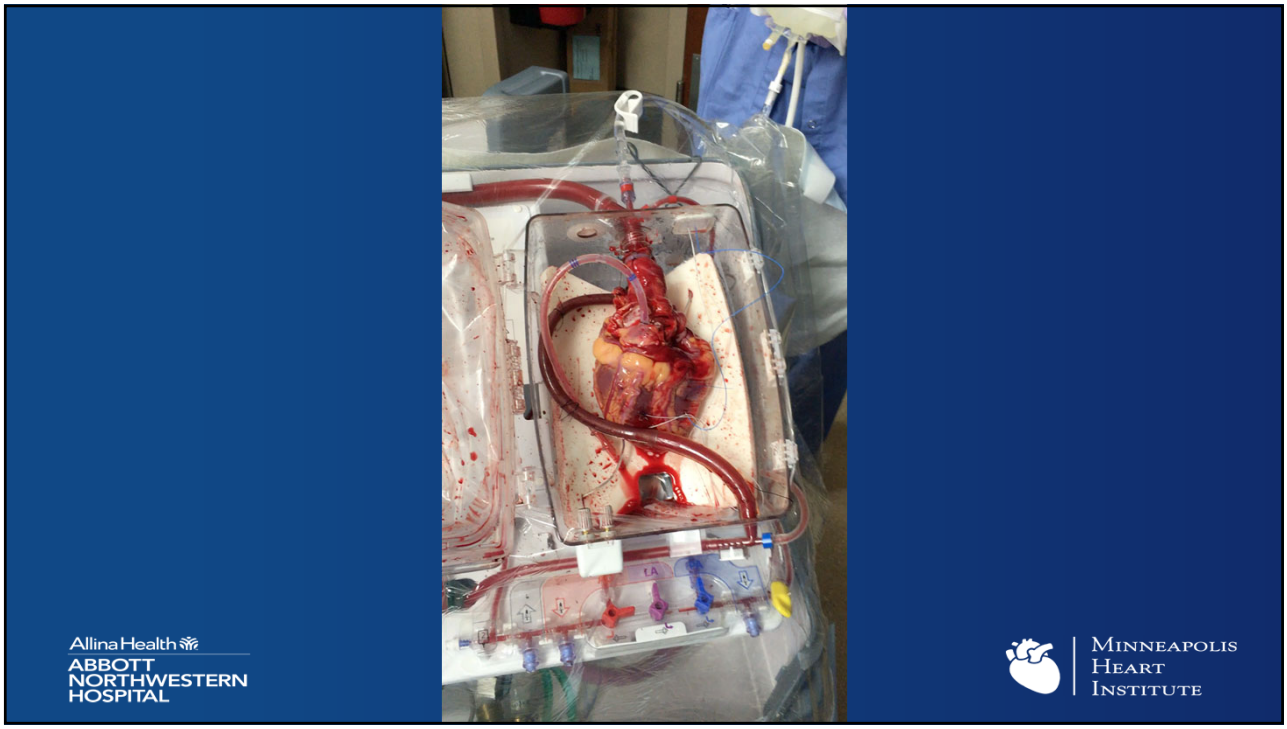
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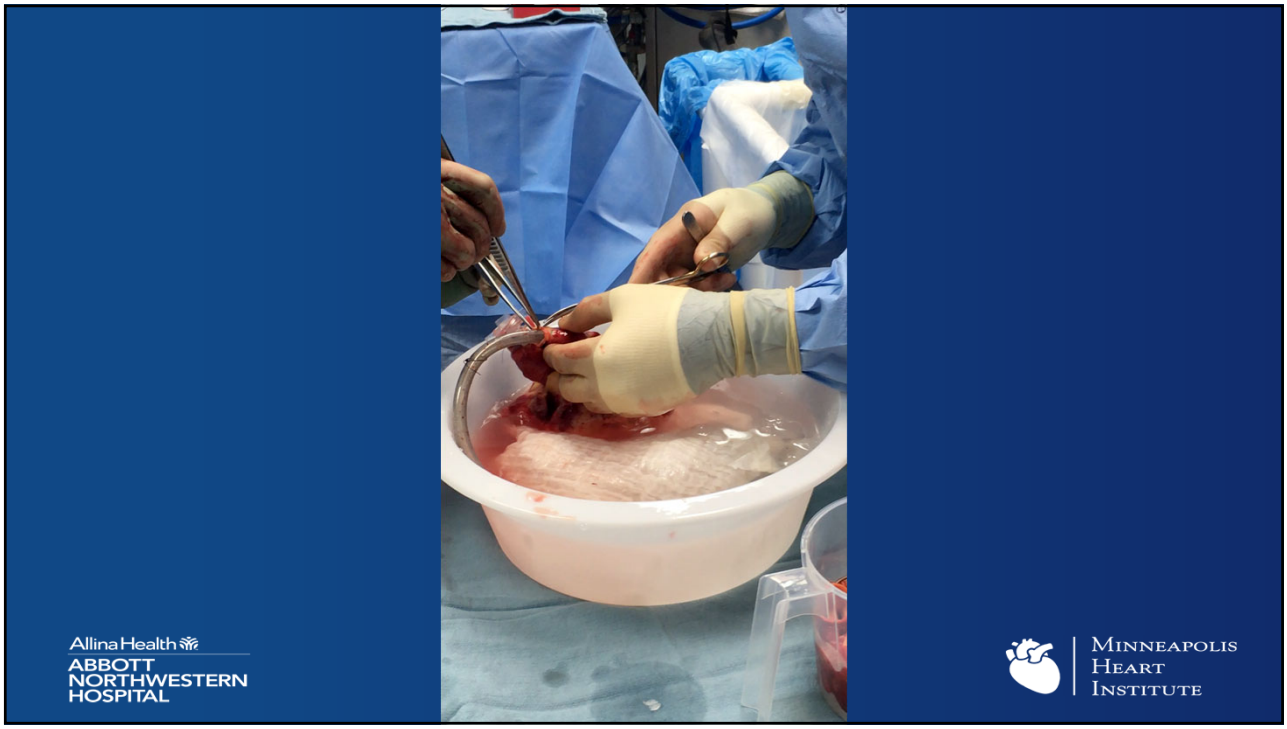
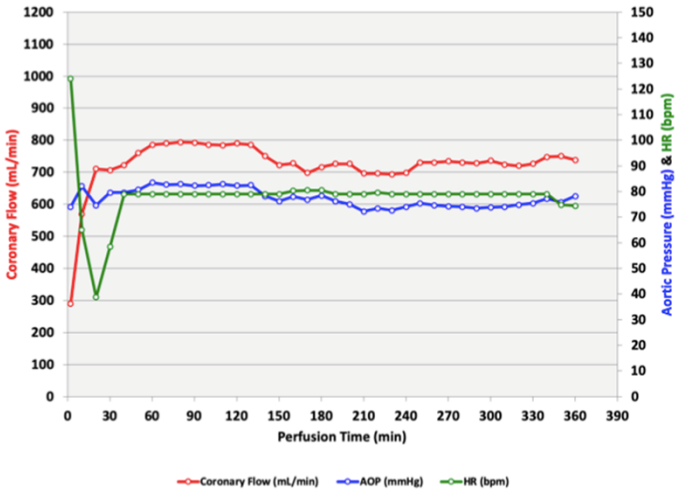


Donor Characteristics

- 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

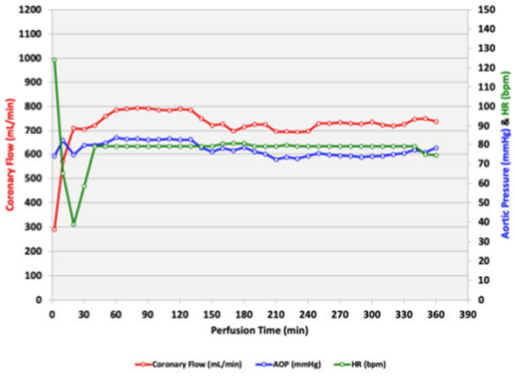
Perfusion Parameters

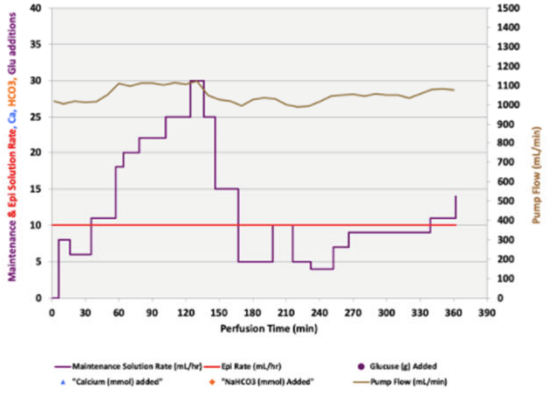


MHIF/04September2019/Transplant

3

Perfusion Parameters and Controls



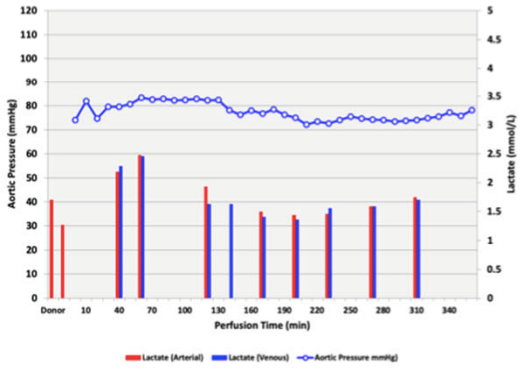


MHIF/04September2019/Transplant

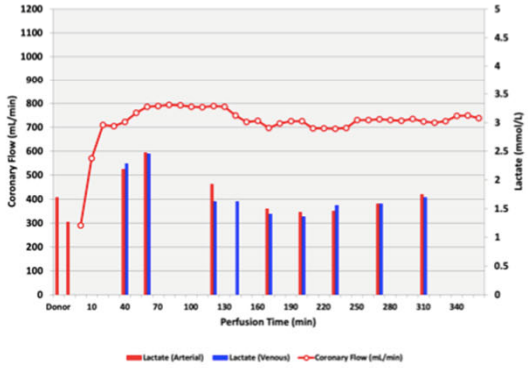
5

Lactate Profile

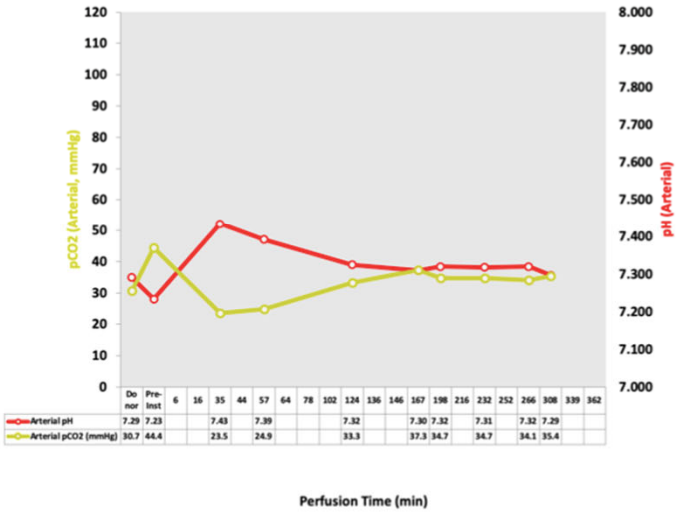
AOP



CF



pH and Arterial pCO_2



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

Recipient Characteristics

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

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

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

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

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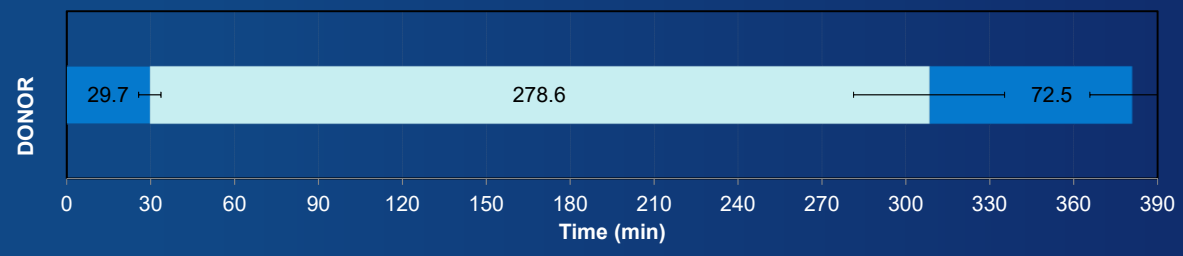
OCS Reduced Ischemic Time on Donor Hearts

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)

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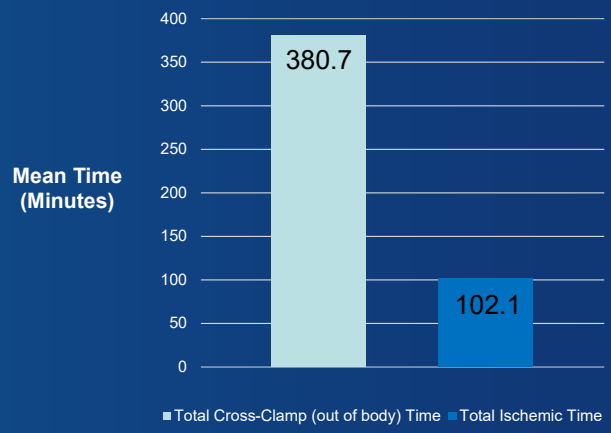
OCS Heart EXPAND – Total Out of Body Time vs. Ischemic Time



TA11

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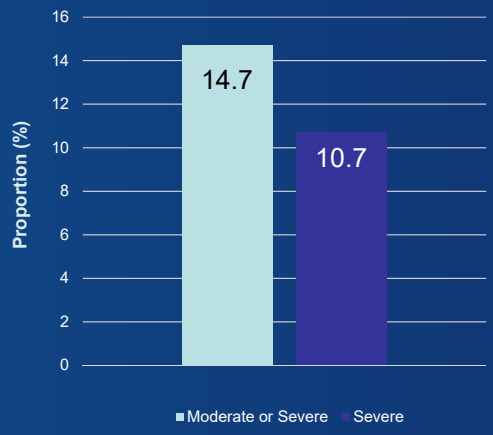
OCS Heart EXPAND – Incidence of PGD



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Slide 47

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

OCS Heart EXPAND

30 day survival- 94.7%

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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

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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

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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

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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

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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

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

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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.

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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.

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DPP vs NRP

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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.

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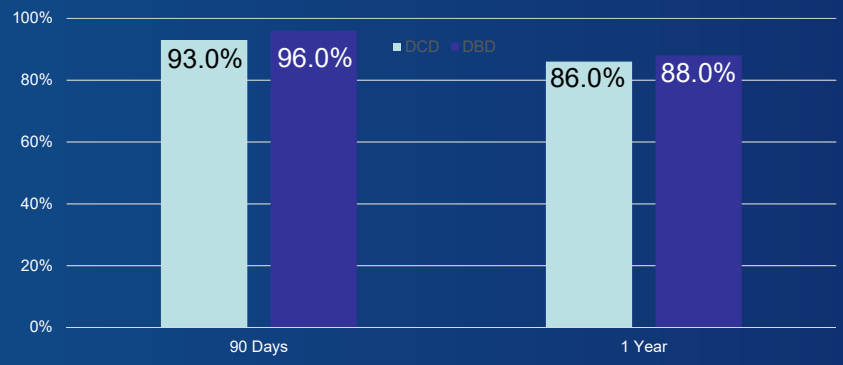

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U.S. DCD Trial

- **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.

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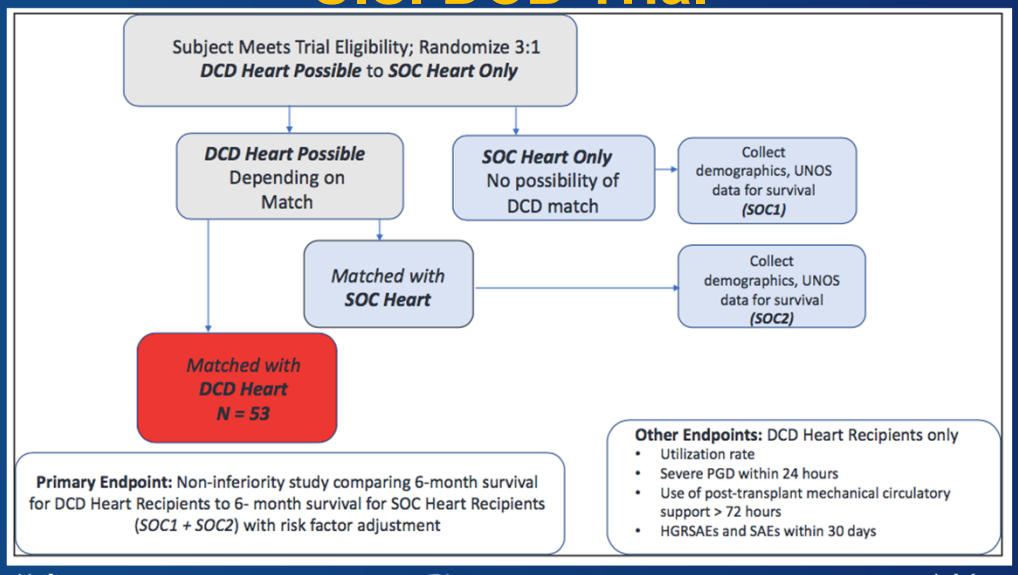

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Trial Size and Subject Follow-up

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.

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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.

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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.

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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.

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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**

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Special Thanks

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

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Very Special Thanks

Dr. Bassam Shukrallah

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Surgeon waking up for a morning transplant

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