DCD heart donor management and transplantation – the Australian ex-vivo program

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NUMBER OF TRANSPLANTS BY YEAR
1984 - 2015

ANZCOTR 2016 Annual Report
NUMBER OF TRANSPLANTS BY YEAR
1984 - 2015

ANZCOTR 2016 Annual Report
Legal Definition of Death in Australia

- The legal definition of death in the States and Territories of Australia... .... is that a person is dead when there is:

  - **irreversible cessation of all functions of the brain** of the person
  - **irreversible cessation of circulation** of blood in the body of the person,

**Brain Death** - Brain death is established by the documentation of irreversible coma and irreversible loss of brain stem reflex responses and respiratory centre function or by the demonstration of the cessation of intracranial blood flow.

- all organs harvested post determination of brain death

**Donations after CIRCULATORY (NOT cardiac) death (DCD)** - established by permanent cessation of respiration and circulation (regardless of ECG) – (2 -5 minutes)

- Until 2014 used for lung, kidney and liver organ procurement
DCD ≠ donation after cardiac death!

To confuse health professionals

To confuse the general public
Clinical experience with DCD hearts

1967  First heart Tx was technically a DCD donor heart (donor & recipient co-located)

2008  3 DCD hearts used in paediatric heart transplants with good outcomes, all alive at 6 months; Denver, USA (donor & recipient co-located)

2009  Human DCD heart successfully resuscitated ‘in situ’ using extracorporeal perfusion (NRP)

**CASE REPORTS**

Cardiac Recovery in a Human Non-Heart-beating Donor After Extracorporeal Perfusion: Source for Human Heart Donation?

Ayyaz Ali, MBChB, FRCPS; Paul White, PhD; Nisamud Din, FRCS; Marian Ryan, RCN; Steven Tait, FRCS; and Stephen Large, FRCS
# DBD vs DCD Organ Donation

<table>
<thead>
<tr>
<th>DBD</th>
<th>DCD (NHBD)</th>
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<tbody>
<tr>
<td>• Severe brain injury</td>
<td>• Severe brain injury</td>
</tr>
<tr>
<td>• Loss of all brain functions</td>
<td>• Some brain function</td>
</tr>
<tr>
<td>• Brain death sequelae</td>
<td>• No brain death sequelae</td>
</tr>
<tr>
<td>– Autonomic storm</td>
<td>– Withdrawal of life-support</td>
</tr>
<tr>
<td>– Loss of neurohormonal vasc control</td>
<td>– Ventilation</td>
</tr>
<tr>
<td>– Pro-inflam upregulation</td>
<td>– Inotropics support</td>
</tr>
<tr>
<td>• Heart beating</td>
<td>• Non-heart beating</td>
</tr>
<tr>
<td>– Donor heart assess - echo</td>
<td>– Obligatory warm ischaemia</td>
</tr>
<tr>
<td>• Cold preservation</td>
<td>– Uncertain duration</td>
</tr>
<tr>
<td></td>
<td>– Post-arrest assessment</td>
</tr>
<tr>
<td></td>
<td>• Optimal preservation?</td>
</tr>
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</table>
Myocardial injury during withdrawal of life-support

- Normothermic ischaemia
  - Both ventricles
- Hypoxic pulmonary vasoconstriction$^{1,2}$
  - RV distension
  - LV unloading

Implications for clinical translation disproportionate injury to RV

The Steps to Clinical Heart Transplantation from DCD Donors

1. Minimise damage during withdrawal of life support

2. Optimisation of organ preservation during transport

3. Allow organ viability assessment prior to Tx
The Steps to Clinical Heart Transplantation from DCD Donors

1. Minimise damage during withdrawal of life support

   **Hypothesis:** Pharmacological post-conditioning will reduce myocardial ischaemic injury and prolong the tolerable WIT

2. Optimisation of organ preservation during transport

   **Hypothesis:** Ex vivo myocardial perfusion will provide superior preservation to static cold storage

3. Allow organ viability assessment prior to Tx

   **Hypothesis:** Ex vivo normothermic perfusion will allow the surgeon to assess the viability of the DCD heart prior to implantation
Increasing the Tolerance of DCD Hearts to Warm Ischemia by Pharmacological Postconditioning

A. Iyer1,2,3, L. Gao1, A. Doyle1, P. Rao1, D. Jayewardene4, B. Wan4, G. Kumarasinghe1,2,5, A. Jabbour1,2,5, M. Hicks1,6,7, P. C. Jansz2,3,4, M. P. Feneley1,2,4,5, R. P. Harvey1,4,8, R. M. Graham1,4,5, K. K. Dhital1,2,3,4 and P. S. Macdonald1,2,4,5,*

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2Heart and Lung Transplant Unit, St. Vincent’s Hospital, Darlinghurst, Australia
3Department of Cardiothoracic Surgery, St. Vincent’s Hospital, Darlinghurst, Australia
4St. Vincent’s Clinical School, Faculty of Medicine, University of New South Wales, Kensington, Australia
5Department of Cardiology, St. Vincent’s Hospital, Darlinghurst, Australia
6Department of Clinical Pharmacology, St. Vincent’s Hospital, Sydney, Australia

≤30-min WIT may be suitable for transplantation and warrant assessment in a transplant model.

Keywords: Donation after circulatory death (DCD), ex vivo perfusion, ischemia reperfusion injury (IRI), ischemic postconditioning, warm ischemic time (WIT)

Abbreviations: AF, aortic flow; C, Celsior preservation solution; Cs, supplemented Celsior solution; DCD, donation after circulatory death; EVP, ex vivo perfusion; IRI, ischemia reperfusion injury; LAP, left atrial pressure; NDD, neurological determination of death; OCS, Organ Care System; WIT, warm ischemic time; WM, working mode

Received 11 November 2013, revised 10 March 2014 and accepted for publication 30 March 2014
Porcine DCD Hearts flushed with Celsior solution recovered fully during normothermic machine perfusion if retrieved within 20 minutes of WLST but recovered poorly with longer warm ischaemic times (no recovery after 40 min WLST)

Porcine DCD Hearts flushed with Celsior supplemented with erythropoietin, glyceryl trinitrate and zoniporide recovered fully after 30 minutes of WLST (partial recovery at 40 min)

It is possible to intervene after circulatory death to protect the heart from warm ischaemic injury
Normothermic Ex Vivo Perfusion Provides Superior Organ Preservation and Enables Viability Assessment of Hearts From DCD Donors

A. Iyer¹, ², ³, L. Gao¹, A. Doyle¹, P. Rao¹, J. R. Cropper², C. Soto², A. Dinale², G. Kumarasinghe¹, ², ⁴, A. Jabbour¹, ², ⁴, M. Hicks¹, ⁵, ⁶, P. C. Jansz², ³, ⁷, M. P. Feneley¹, ², ⁴, ⁷, R. P. Harvey¹, ⁷, ⁸, R. M. Graham¹, ⁴, ⁷, K. K. Dhital¹, ², ³, ⁷ and P. S. MacDonald¹, ², ⁴, ⁷, *

transplantation. Viability studies of human DCD hearts using NEVP are warranted.

Abbreviations: CPB, cardiopulmonary bypass; CS, cold storage; DCD, donation after circulatory death; IPC, ischemic postconditioning; IRI, ischemia reperfusion injury; NEVP, normothermic ex vivo perfusion; WIT, warm ischemic time
Porcine DCD hearts retrieved after 30 min warm ischaemia with supplemented Celsior solution then stored on ice for 4 hours failed to recover post heart transplant.

The combination of pharmacological post-conditioning with normothermic machine perfusion was required to achieve successful transplantation of DCD hearts.
Normothermic *Ex Vivo* Heart Perfusion (Transmedics OCS)
Lactate profiles of 30 minute WIT hearts on Transmedics OCS

Hamed A TS, Huber J, Lin R, Pogglo EC, Ardehalt A Serum lactate is a highly sensitive and specific predictor of post cardiac transplant outcomes using the organ care system. J Heart Lung Transplant 2009; 28 (2): S71
DCD Experimental Program – Study 3

- Human DCD heart recovery
  - Optimal preservation solution
  - Ex vivo transport (Transmedics)
  - Ex vivo evaluation
Translating laboratory findings into Human Heart Transplantation from DCD donors

• Engagement of key stakeholders
  – Intensive Care Specialists
  – Abdominal transplant retrieval surgeons
    • Need to drain up to 1.5 l of donor blood before infusion of any abdominal preservation solution (1.5 min)
  – SVH Human Research & Ethics Committee
  – NSW Department of Health
    • Revision of existing DCD Guidelines (Debbie Verran)
  – National Organ Tissue Authority
    • NSW DonateLife Organ Donation Service
Translating laboratory findings into Human Heart Transplantation from DCD donors

• Additional Considerations
  – Zoniporide not approved for human administration
  – Celsior not recommended for cardioplegia/flush prior to normothermic perfusion

• Flush solution for human DCD HTx
  – St Thomas’s No 2 Solution
  – EPO 5000U/L + GTN 100 mg/L
St Vincent’s DCD Heart Procurement Technique

• No ante-mortem Heparin given to donors

• Circulation is not re-established in the donor after death

• Rapid venous decompression – with blood drained for OCS
  – 1.5l donor blood drained for priming TransMedics OCS ex-vivo perfusion system

• Administration of supplemented St Thomas’ cardioplegia
  – Erythropoietin 5000 Units/L and Glyceryl trinitrate 100 mg/L
  – Topical cooling

• Heart explanted first
HUMAN DCD HEART STUDY

10 ICU Specialists Across NSW

- Suhel Al-Soufi – St Vincent’s Hospital
- Anders Aneman – Liverpool Hospital
- Michael O’Leary – Royal Prince Alfred Hospital
- Arvind Rajamani – Nepean Hospital
- Matthew MacPartlin – Wollongong Hospital
- Peter Saul – John Hunter Hospital
- Gordon Flynn – Prince of Wales Hospital
- Andrew Cheng – St George Hospital
- Dani Goh – Westmead Hospital
- Ray Raper – Royal North Shore Hospital
DCD donors – inclusion criteria

- **Age** ≤ 60 years
- **No known history** of significant structural cardiac disease
- **Stable haemodynamics** prior to withdrawal of life support (CVP < 10 mmHg with MAP > 60 mmHg)
- **Maintenance inotrope/vasopressor equivalent to noradrenaline** ≤ 0.2 mcg/kg/min
- **Warm ischaemic time (WIT)** ≤ 60 min following withdrawal of life support.
First human DCD donor – July 2013

- 62 y.o donor; No heparin
- Time To Arrest 16 min;
- Blood collected by 31 min
- Cardioplegic flush 32 min;
- Ex Vivo Perfusion 45 min
- Kidneys retrieved & transplanted
- Perfused on OCS for t=9 hours
- Working mode 3 hours
At 3 hours of EVP –
no dobutamine

4 hours of EVP –
Dobutamine 5mcg/kg/min
First three patients

Cardiac Output vs LA Pressure

- DCD 1: 62 yo Male
- DCD 2: 39 yo Male IVDU + BD
- DCD 3: 27 yo Male Dense Pericard adhesions

Serial Lactates

- Time (hours)
- Working mode

- 0:30 to 7:30
What do we do if we retrieve a DCD heart that meets OCS viability criteria? (lactate < 5; Cor Art > Cor Sinus)

- Marginal Heart Study
  - For extended criteria NDD hearts
  - Amended
    - Study Protocol
      - DCD donors ≤ 40 years of age
      - Warm Ischaemic Time ≤ 30 min
      - Viable lactate profile on OCS
    - PICF (with help from Julie Letts)
• 26 year old male (height 183 cm; weight 92 kg) DCD donor after hypoxic cerebral injury.
• Echocardiography 2 days prior to withdrawal: hyperdynamic LV function
• Time to Circulatory Arrest 16 minutes post withdrawal
• 2 min stand-off time
• 1500 ml drained via RA cannula
• Time to cardioplegia 28 minutes
• Heart, lungs, liver & both kidneys retrieved
Serial Lactates

<table>
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<tr>
<th>Time on OCS (minutes)</th>
<th>Lactate Level (mmol/L)</th>
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<td>60 min</td>
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<td>220 min</td>
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<td>240 min</td>
<td>2</td>
</tr>
<tr>
<td>260 min</td>
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Transplant Recipient

- 58 year old woman
- Familial DCM
  - Son has already undergone HTx
- Intractable NYHA Class IV HF
  - Recurrent admissions with ADHF over 2014
  - No previous cardiac surgery
  - Transpulmonary Gradient 6 mmHg
DCD Heart Transplant Recipient: Echo at Day 1 and Day 7
Endomyocardial Biopsy – Day 8

Normal histology
Adult heart transplantation with distant procurement and ex-vivo preservation of donor hearts after circulatory death: a case series

Kumud K Dhital, FRCS-CTh, Arjun Iyer, MBBS, Mark Connellan, FC Cardio (SA), Hong C Chew, MS, Ling Gao, PhD, Aoife Doyle, MEngSc, Mark Hicks, PhD, Gayathri Kumarasinghe, FRACP, Claude Soto, MSc, Andrew Dinale, BAppSc, Bruce Cartwright, MBBS, Priya Nair, FCICM, Emily Granger, MBBS, Paul Jansz, PhD, Andrew Jabbour, PhD, Eugene Kotlyar, MD, Prof Anne Keogh, MBBS, Prof Christopher Hayward, MD, Prof Robert Graham, MD, Phillip Spratt, FRACS, Prof Peter Macdonald, MD

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**DCD Heart Procurement**

**June 2013 - Current**

- **22 Clinical**
  - 16 Transplanted
    - 6 NSW (2 ‘in house’)
    - 10 Interstate > 1000 km
  - 6 Not used
    - 2 OCS Malfunction
    - 4 Unsatisfactory lactate profile
    - 3 Research
    - 12 Did not progress
- **25 DCD Hearts Procured**
Donor locations of the transplanted DCD hearts

- Darwin (1)
- Brisbane (1)
- Sydney (6)
- Gold Coast (2)
- Adelaide (1)
- Melbourne (4)
- Canberra (1)
- Canberra (1)
Donor locations of the transplanted DCD hearts
<table>
<thead>
<tr>
<th>No.</th>
<th>Age</th>
<th>Sex</th>
<th>Wt  (Kg)</th>
<th>Mechanism of death</th>
<th>Noreadrenaline (ug/kg/min)</th>
<th>Echocardiography</th>
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<td>26</td>
<td>Male</td>
<td>92</td>
<td>Hanging</td>
<td>0.07</td>
<td>Normal</td>
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<tr>
<td>2</td>
<td>26</td>
<td>Male</td>
<td>80</td>
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<td>3</td>
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<td>85</td>
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<tr>
<td>4</td>
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<td>Stroke</td>
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<td>LVEF 60%</td>
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<td>31</td>
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<td>85</td>
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</tr>
<tr>
<td>6</td>
<td>30</td>
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<td>65</td>
<td>Head Trauma</td>
<td>0.03</td>
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<td>7</td>
<td>28</td>
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<td>90</td>
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<td>0.07</td>
<td>LVEF 50%</td>
</tr>
<tr>
<td>8</td>
<td>38</td>
<td>Female</td>
<td>63</td>
<td>Stroke</td>
<td>0.03</td>
<td>LVEF 60%</td>
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<tr>
<td>9</td>
<td>37</td>
<td>Male</td>
<td>85</td>
<td>Aspiration</td>
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<td>LVEF 60%</td>
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<td>15</td>
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DCD Heart Transplant Pathway

Withdrawal

Cessation of Circulation

Observation Period

Transfer to Operating Table

Knife-to-skin to cardioplegia

Mean time (minutes)

10 min (4 – 16)

4 min (2 – 8)

5 min (1 – 8)

4 min (3 – 6)

Includes 2 min for blood collection
<table>
<thead>
<tr>
<th>No</th>
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<th>Gender</th>
<th>Diagnosis</th>
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<td>44</td>
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<td><strong>24</strong></td>
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</table>
Time from circulatory arrest to cardioplegia – a key determinant of Delayed Graft Function?

![Graph showing time from circulatory arrest to cardioplegia and its impact on Delayed Graft Function (DGF) compared to no DGF. The graph indicates a statistically significant difference with p < 0.005.]

- DGF
- No DGF

Time (min)

- p < 0.005

DCD (n = 16)

BD Cold storage (n = 143)

Extended Criteria BD OCS (n = 11)
DCD (Donation after Circulatory Death) is now practiced clinically in Australia and UK.

- 58 DCD cases have been performed.
  - 16 in Australia
  - 42 in UK
    - 32 Papworth (14 NRP; 14 DPP)
    - 7 Harefield (DPP)
    - 3 Wythenshawe (DPP)
Transplantation of the heart after circulatory death of the donor: time for a change in law?


The Melbourne Age, Sydney Morning Herald 21/9/2015
NUMBER OF TRANSPLANTS BY YEAR
1984 - 2016
Conclusions

- Hearts from selected DCD donors can be successfully transplanted with outcomes comparable to those seen with hearts transplanted from DBD donors.

- Traditional static cold storage of DCD hearts retrieved by ‘direct procurement” is unsafe

- Post-conditioning strategy combined with ex vivo normothermic perfusion of DCD hearts retrieved by ‘direct procurement” has allowed the successful utilisation of DCD donors

- There is an urgent need for better prediction algorithms for estimating the time from WLST to circulatory arrest
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1984 - 2016
HTx 2714
LTx 2830
HLTx 196
Australia & New Zealand
Combined population 29 million
Total 5740
Post-Heart Transplant Survival: Oct 2012 – Oct 2016 (n = 120)

Kaplan-Meier Cumulative Survival Plot
Censor Variable: Censor
Stratification Variable: donor_DCD
Grouping Variable: Preservation

DCD (n = 11)
BD Cold storage (n = 100)
Extended Criteria BD OCS (n = 9)