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**UK National Protocol for direct retrieval and perfusion
(DRP) of DCD Hearts and Lungs with or without abdominal
NRP (A-NRP) to Ex-situ Normothermic perfusion**

This protocol is an agreed guidance between NORS and transplant team. It is the responsibility of lead retrieval and implanting surgeons to agree final details.

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DCD HEART DONOR SELECTION

Donor Inclusion Criteria

- Controlled DCD (Maastricht Category 3 and 4)
- Age \leq 50 years
- Weight \geq 50 Kg.
- Weight \geq 30 kg – if suitable paediatric recipient at GOSH or Newcastle, discuss directly with Papworth on call retrieval consultant. Refer to DCD paediatric protocol. Protocol will be updated in future once perfusion technology available for $<$ 30kg donors.
- Consent/authorisation obtained from next of kin/ organ donor register

Donor Exclusion Criteria

- Previous cardiac surgery
- Previous midline sternotomy
- Valvular heart disease
- Congenital heart disease
- Significant coronary artery disease
- Chronic atrial fibrillation
- Insulin dependent diabetes
- Virology: HIV+
- Current IV drug abuse.
- Tumour with high risk of transmission according to NHSBT SABTO guidelines

NORS team Mobilisation

- Cardiac NORS team to arrive 2 hours before the planned withdrawal of treatment time
- Abdominal team to arrive 1 hour before withdrawal of treatment time, if NRP being used the team must arrive at the same time as the Cardiac team (2 hours before planned withdrawal time)

DCD HEART ASSESSMENT

- A transthoracic Echocardiogram (TTE) will be performed for all donors and be available at the time of the offer. All efforts should be made to transfer the images for review by the implanting team prior to mobilization of the NORS DCD Heart team. If that is not possible, the retrieval team will review the images and communicate with the implanting team prior to withdrawal of life sustaining treatment (WLST).
- If an echocardiogram has not been performed prior to offering, there should be no more than 3h delay in performing and conveying the results.
- If no formal echo available, explore if the ICU team will be willing to perform a Focused Cardiac Ultrasound (FCU – previously known as FICE) though this is not mandatory for the ICU. This will serve as a screening step.
- Formal TTE will be performed by donor hospital, or, trained member of the retrieval team. NO TOE (transoesophageal) echocardiography will be performed at any stage!
- If no FCU or TTE is available, heart should still be offered for transplantation. It is the responsibility of the lead transplanting surgeon to discuss with the lead retrieval surgeon regarding the offer without an ECHO. The decision to accept or decline must be made within the standard offering timeframe.
- Echo main criteria: EF > 50%, no valvular pathology, PW and/ or IVS < 15mm

DCD HEART Withdrawal of life sustaining treatments

- Withdrawal of life sustaining treatments should ideally be undertaken in the anaesthetic room / theatre complex by the local hospital intensive care team.
- If it is not local practice to withdraw in the anaesthetic room / theatre complex then it may need further discussion between retrieval and donor hospital teams, aiming to withdraw support as close to theatre as possible, in order to minimize the ischaemic time during transfer to theatre. The place of withdrawal should be agreed before the NORS team is mobilised to avoid disagreement at the point of retrieval.
- SNOD – If Heart is not suitable for transplantation, please explore pathway for research approved project or valves.

- **It is recommended that the donor is transfused to Hb of ≥ 100 g/L.** Timing of transfusion - once CT NORS team is mobile.
- **SNOD – prepare units of packed red blood cells (cross matched to donor) :**
 - 4 units – no NRP
 - 8 units - abdominal NRP

DCD HEART Functional Warm ischaemia and Stand Down Criteria

- After withdrawal of treatment, regular contact will be maintained with the SNOD regarding blood pressure and arterial saturations on the donor.
 - When Harefield is implanting team and the ICU team in the donor hospital are agreeable; once arterial saturation is $<80\%$ an arterial blood gas should be taken to confirm donor hypoxia, according with local hospital policy.
 - Functional warm ischaemia begins when systolic blood pressure falls below 50mmHg.
 - 30 minutes from beginning of functional warm ischaemia until cold cardioplegia is delivered will be tolerated before standing down.
 - Essential for the team diagnosing death to be familiar with the Academy of Medical Royal Colleges 2008 Code of Practice for the Diagnosis and Confirmation of Death.
 - If cardiac arrest does not occur within 120 minutes from withdrawal of treatment, consider standing down DCD heart retrieval at this stage, unless death is likely to be imminent
 - We recommend having a discussion between retrieval and recipient centers after 60 min from withdrawal.

If the donor meets criteria the OCS module should be opened at that point and the priming process started

Transfer to operating theatre

- When the donor is brought into the operating room, the SNOD shows the patient name band to confirm donor identity.

- **ONLY IF LUNG RETRIEVAL IS TAKING PLACE AS WELL.** Once the donor is transferred to the operating table, an endotracheal tube size above 8 is inserted. At a point no earlier than 10 minutes after the onset of mechanical asystole, the lungs are re-inflated with a single breath of oxygen-enriched air. Lung ventilation will commence once ascending aorta is clamped, as per described in the National Standards for Organ Retrieval.
- The thoracic and abdominal surgeons will prepare the skin with an alcohol-based skin preparation solution and apply 4 drapes.
- A midline sternotomy is performed with a retractor to spread the sternal tables placed upside down. The abdominal surgeon will open the abdomen simultaneously.

1.Surgical protocol – NO ABDOMINAL NRP

Preparation

- Prepare St Thomas cardioplegia - Add the following medication to 500ml bag of Ringers:
 - 2,500iu of Epoetin Alfa
 - 50mgs GTN
 - 3mls Sodium bicarbonate 8.4% (840mgs in 10ml amp)
 - 10mls cardioplegia concentrate

(Solution to be put back into the ice box but easily accessible for use when donor arrives in theatre)

- Prepare St Thomas cardioplegia for back at implant site – Add the following medication to 1L bag of Ringers:
 - 5000iu of Epoetin Alfa
 - 100mgs GTN
 - 6mls Sodium bicarbonate 8.4% (840mgs in 10ml amp)
 - 20mls cardioplegia concentrate

(Solution to be put back into the ice box for use when heart is at implant site))

- Blood collection: Minimum of 1.2-1.5L to be collected with a raised table in head down position. It is crucial to ensure that no preservation solution is given until donor blood is drained, and no vasoconstrictor bolus is given at this stage. This should take no more than 60secs.

There are several variations across units;

- Insertion of a 2-stage venous cannula connected to a blood collection bag with Heparin 25,000 IU. If this is the case, 25,000 IU of heparin are injected into the right atrium and 25,000 IU of heparin into the pulmonary trunk prior to blood drainage.
- Insertion of a drainage cannula connected to a sucking device or sterile reservoir. Blood is drained under suction and simultaneously mixed with the OCS priming solution containing 60000 IU of heparin

- During donor blood collection the cardiothoracic surgeon will clamp the descending aorta above the diaphragm, as low as possible. The cardiothoracic surgeon will announce this clamp is in place and the time will be recorded on the National DCD Heart Passport.
- A clamp is placed across the ascending aorta and a DLP cannula inserted into the ascending aorta for cardioplegia delivery and the heart excised in the standard fashion for heart retrieval.
- If the lungs are to be retrieved, the local hospital anaesthetist or the NORS team donor care practitioner will reintubate the donor during sternotomy as per DCD Lung retrieval.
 - Care must be taken to leave the posterior wall of PA carina when removing the heart. As soon as the heart is removed, ante-grade pneumo- plegia is delivered through these cannulae followed by retrograde pneumo-plegia via the pulmonary veins. Fibre optic bronchoscopy is performed and lungs are retrieved in standard fashion for DCD lung retrieval.

Preparation of the DRP-DCD heart prior to Ex-Situ perfusion

- The heart is immediately placed into a basin of ice cold sterile saline solution.
- Dissection made to free the aorta from the pulmonary artery placing and securing the appropriately sized perfusion connector for the Organ Care System (OCS) with the supplied cable tie. Teflon pledgeted aortic stitches are used to further

secure the aorta to the OCS so reducing the risk of disconnection during travel to the recipient hospital.
- The heart is placed and de-aired onto the primed OCS.
- Insert and secure LV vent through the left atrium into organ chamber.

Place ventricular pacing wires in case pacing is required at a later stage.

PA cannula (Protocol difference)

Harefield implanting or retrieval – PA cannula secured and connected. (SVC and IVC - sutured) and connect blue flow probe – follow Transmedics protocol.

Manchester/Papworth retrieval – PA cannula NOT connected, allowing free drainage.

Three teams agreed cross over protocol at JiF DCD meeting on 28/1/2020

OCS perfusion parameters during transport:

Commence OCS perfusion of donor heart aiming for:

- Mean AOP 55-70 mmHg
- Aortic flow of 900-1100 mL/min-
- Heart rate 70-90 BPM with V-pacing
- Once heart rhythm and perfusion are stable consider to synchronise perfusion depending on discussion with implanting team.

Acquire simultaneous AV blood samples. Perfusate targets are:

- Hct >15%
- Calcium 1.0-1.3 mmol/l
- Bicarbonate 22-29 mmol/l
- Ph – 7.3-7.45

Video clip to be transferred to implanting center at 30min reperfusion on the rig

Transport

Ensure to travel with a safety ice box and roadside bag which will include;

- Ice, cardioplegia, giving set + pressure bag, 8 liters of cold saline

Roadside bag – sterile instruments, sterile gloves different size, sterile gowns, 3 packing bags for heart.

Cardioplegia at recipient site (agreed telecom 2.9.20)

Once implanting team are happy to receive the heart,

- The retrieval team have set up to administer cardioplegia.
- All 3 teams will administer St. Thomas at retrieval and implant site when retrieving for any 6/7 UK centers.
- Harefield will carry both Custadiol and St. Thomas and will have a choice of Custadiol or St. Thomas when retrieving for Harefield.

(Refer to St. Thomas preparation on page 7)

2-Surgical protocol – WITH ABDOMINAL NRP

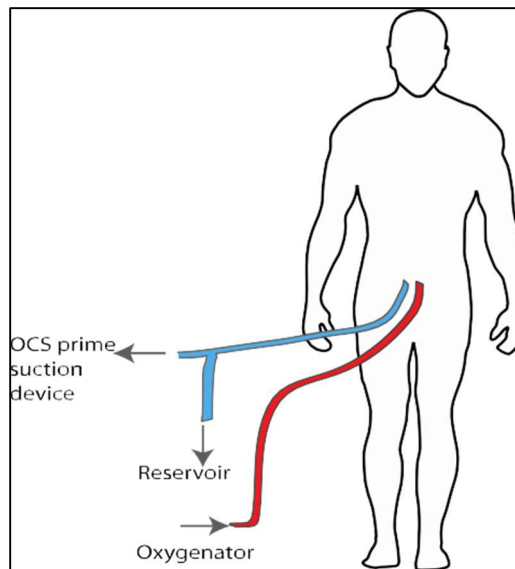
Preparation

Circuit

The NRP circuit needs to have a Y attachment on the venous return limb just above the reservoir, and needs to be fitted prior to arrest. This needs to be connected to the cell saver to allow for donor blood drainage needed for *ex situ* heart perfusion, but clamped initially.

Prime solution

- 4 units packed red cells (approx. 1200mls)
- 1.5 litre Hartmann's solution 50000 units heparin
- 1gm Methyl prednisolone 500mg Meropenem 200mg Fluconazole
- 1ml/kg 8.4% sodium bicarbonate (=1mmol/kg)



The NRP circuit is primed with 1.5 litres of Hartmann's, to which are added 4 units of red cells. The circuit needs to be set up before withdrawal of treatment, and warmed to 37°C by circulating through the oxygenator/heat exchanger.

A pump sucker will be connected to the reservoir for blood loss recovery. (This is the preferred standard with teams working towards this, until then existing practice will prevail). This will only be used to recover blood from the pericardium if heart retrieval only, or to recover blood from pericardium and pleural space if combined heart-lung retrieval. Blood should not be recovered from the pleural space in the presence of chest sepsis. Additional care must be taken to avoid any perfusion fluid/saline being recovered using this sucker.

THIS ADDITIONAL SUCKER WILL NOT BE USED IN CASES OF PERICARDIAL, MEDIASTINAL OR SYSTEMIC INFECTION. CAREFUL HAEMOSTASIS SHOULD BE PERFORMED IN THE CHEST EVEN IN THE EVENT OF HAVING A PUMP SUCKER AVAILABLE.

Two long DeBakey vascular clamps will be ready to use by the cardiothoracic team prior to WLST to clamp descending aorta and IVC. Two Roberts clamps will also be ready to clamp SVC and ascending aorta. It has been agreed that clamps will be provided by the abdominal team as they need to stay in place once the CTh team has left the operating theatre.

Due to the complexity of the technique all cardiothoracic organs will be perfused and retrieved only for transplantation or valve donation purposes.

Operative procedure

Following verification of death 5 minutes after circulatory arrest, the patient is transferred to the operating table.

IT IS MANDATORY TO FOLLOW THIS STEP SEQUENCE

Abdominal procedure

1 The circulating pump is stopped, and the sash is clamped and divided, and the arterial cannula attached and primed.

2 Once the donor is in theatre, the abdomen is opened through a midline incision.

3 The venous cannula is placed in the right common iliac vein (or IVC) and connected to the venous limb of the sash, with care to exclude air. Care should be taken not to place too much cannula in the IVC to prevent it going into the right atrium.

Clamps are removed and 1.5L venous blood drained out and diverted into the collecting receptacle for the OCS (such as the cell saver system used by Harefield).

The Y-connector is clamped and venous return blood now diverted to drain back into the reservoir (see figure)

4 The arterial cannula is placed in the right common iliac artery or aorta while the venous drainage occurs.

5 Once the cardiac team have clamped the descending thoracic aorta and stated that clearly for both teams to hear, and the 1.5L venous OCS prime has drained, the NRP pump is started aiming for flows over 2.5L/min. The time that the descending thoracic aorta is clamped will be recorded on the National DCD Heart Passport.

Abdominal NRP must not start until both teams have confirmed for all to hear that the descending aorta is clamped.

6 Once the heart is removed it is important to check the security of the supra-hepatic IVC clamp – this may need to be sutured in place to avoid inadvertent unclamping or slipping from the cut IVC. The cut ends of the pulmonary vessels and SVC may be oversewn with 3/0 Prolene at this stage also. While the cardiac surgeons should ensure haemostasis in the chest, in reality it is the abdominal surgeons who are usually free at this stage and can stop large vessel bleeding. There should be no major bleeding.

Cardiac procedure

The chest is opened in the midline and sternum split while the abdomen is being opened.

Pericardiotomy

Heart retrieval only

1. The left pleural space is opened and DESCENDING THORACIC AORTA IS CLAMPED above the diaphragm to isolate abdominal NRP. Priority will be given to ensure absence of brain reperfusion via NRP system. The act of clamping the descending aorta should be announced loud enough for all to hear and the time will be recorded on the National DCD Heart Passport
2. PLACEMENT OF DOUBLE LUMEN DLP CANNULA IN THE ASCENDING AORTA, as high as possible. Initially, used to drain the ascending aorta blood. Later in the sequence, it can be used for cardioplegia delivery.

Once the DLP cannula is in place and open to air, the cardiothoracic surgeon announces that the aortic arch is vented. The time will be recorded on the National DCD Heart Passport. If there is copious arterial bleeding from the DLP cannula, the NRP pump must stop and the clamp on the descending aorta must be re-positioned to occlude the aorta. Only then can the NRP pump re-start.



3. The SVC and azygous vein are dissected to ensure enough length.
4. The IVC is dissected around. If the tip of the cannula is inside the right atrium, the abdominal team should be asked to pull the cannula back below diaphragm to allow for IVC clamping at a later stage. Check to ensure the venous cannula does not encroach into the right atrium.

The heart is assessed for any visible anomalies, palpable coronary artery disease, left ventricular hypertrophy, trauma, congenital disease etc.

5. Once 1.3-1.5L of donor blood has been received into the receptacle / cell saver for the OCS prime, CLAMPS ARE PLACED ACROSS THE IVC ABOVE THE DIAPHRAGM, AND THE SVC CAUDAL TO THE AZYGOS. The SVC is transected caudal to clamp, placed below azygos vein.

6. The ascending aorta is clamped, initially distal to DLP cannula, only during cardioplegia delivery. This is in addition to the descending thoracic aortic clamp.

7. IVC is opened just cranial to the clamp for venting and left atrium is opened at level of pulmonary veins for pulmonary return.

8. Cardioplegia supplemented with 20000 IU heparin, EPO and 50 mg of GTN is administered **The clamp previously placed on ascending aorta, needs to be repositioned proximal to DLP cannula which will stay in place, open to air, to ensure there is no brain perfusion.**

The heart is then excised leaving all previously placed clamps in situ to minimize blood loss.

9. The heart graft is prepared at the back table and re-perfused with ex situ normothermic perfusion technology in the usual manner.

Heart and Lung retrieval

Once the donor is transferred to the operating table, an endotracheal tube size above 8 is inserted. At a point no earlier than 10 minutes after the onset of irreversible asystole, the lungs are re-inflated with a single breath of oxygen-enriched air. Lung ventilation will commence once ascending aorta is clamped, as per described in the National Standards for Organ Retrieval. Bronchoscopy performed usually at this point if an additional surgeon is available, or later after pneumoplegia completion.

1. The left pleural space is opened and DESCENDING THORACIC AORTA IS CLAMPED. The act of clamping the descending aorta should be announced loud enough for all to hear and the time will be recorded on the National DCD Heart Passport.

2. Placement of double lumen DLP cannula in the ascending aorta, and cannula opened to air; This cannula is used initially to ensure absence of brain perfusion and later used for cardioplegia delivery.

Once the DLP cannula is in place and open to air, the cardiothoracic surgeon announces that the aortic arch is vented. The time will be recorded on the National DCD Heart Passport. If there is copious arterial bleeding from the DLP cannula, the NRP pump must stop and the clamp on the descending aorta must be re-positioned to occlude the aorta. Only then can the NRP pump re-start.

3. SVC, IVC dissection and donor blood drainage, as per heart only retrieval technique, is performed.

4. Clamps are placed across the IVC above the diaphragm and the SVC caudal to the Azygos. The IVC is opened just proximal to the clamp for venting and the left atrial appendage is vented widely.

5. The ascending aorta is clamped, initially distal to DLP cannula, only during cardioplegia delivery.

Once cardioplegia delivery is completed, the clamp previously placed on ascending aorta, needs to be repositioned proximal to DLP cannula which will stay in place, open to air, to ensure there is no brain perfusion.

6. After cardiectomy, antegrade pneumoplegia is completed according to National protocol. Simultaneously, the pleurae are opened widely and lungs inspected and palpated, ensuring adequate delivery of flush and topical cooling with copious volumes of 4°C saline.

7. If the lungs are suitable and accepted for transplantation a competent lung retrieval surgeon will complete rest of dissection while abdominal NRP continues, by dividing the descending thoracic aorta and taking this along with the lung bloc. This would involve ligacclipping all the intercostal arteries (L and R) up to the arch, being careful to avoid bleeding.

8. The azygos vein must be ligated twice and cut in between. This can be done easily in the right pleural space.

The rest of the lung dissection can be completed with diathermy and by using surgical Liga-clips aiming to minimize blood loss.

9. The trachea is stapled and cut leaving a clamp or staple line on the top end.

10. Retrograde pulmonary venous flush of the lungs is performed on the back-table at the donor site and Lungs are packed as per National protocol.

Lung retrieval only

Once the donor is transferred to the operating table, an endotracheal tube size above 8 is inserted. At a point no earlier than 10 minutes after the onset of irreversible asystole, the lungs are re-inflated with a single breath of oxygen-enriched air. Lung ventilation will commence once ascending aorta is clamped, following all steps as per the National Standards for Organ Retrieval.

Bronchoscopy performed usually at this point if an additional surgeon is available, or later after pneumoplegia completion.

1. The left pleural space is opened and DESCENDING THORACIC AORTA IS CLAMPED.
The act of clamping the descending aorta should be announced loud enough for all to hear and the time will be recorded on the National DCD Heart Passport.
2. Placement of double lumen DLP cannula in the ascending aorta to ensure absence of brain perfusion
Once the DLP cannula is in place and open to air, the cardiothoracic surgeon announces that the aortic arch is vented. The time will be recorded on the National DCD Heart Passport. If there is copious arterial bleeding from the DLP cannula, the NRP pump must stop and the clamp on the descending aorta must be re-positioned to occlude the aorta. Only then can the NRP pump re-start.

3. Ascending aorta is clamped proximal to DLP cannula, and cannula should be open to air to ensure absence of brain perfusion.
4. SVC, IVC dissection is performed. Clamps are placed across the IVC above the diaphragm and the SVC caudal to the Azygos. The IVC is opened just proximal to the clamp for venting and the left atrial appendage is vented widely.
5. Antegrade pneumoplegia as per UK National guidelines is administered. Simultaneously, the pleurae are opened widely and lungs inspected and palpated, ensuring adequate delivery of flush and topical cooling with copious volumes of 4°C saline.
6. Cardiectomy performed leaving **a long IVC cuff above previously placed IVC clamp**. Ascending aorta and SVC are both cut caudal to clamps, which stay in place to avoid bleeding.
7. If the lungs are suitable and accepted for transplantation the rest of dissection will be completed while abdominal NRP continues, being careful to avoid bleeding.
8. **The azygos vein must be ligated twice and cut in between.** This can be done easily in the right pleural space.
9. The rest of the lung dissection can be completed with diathermy and by using surgical Liga-clips aiming to minimize blood loss.
10. The trachea is stapled and cut leaving a clamp or staple line on the top end
11. Retrograde pulmonary venous flush of the lungs is performed on the back-table at the donor site and Lungs are packed as per National protocol.

The cardio-thoracic surgeon should ensure haemostasis in the chest during and at the end of retrieval, before leaving the donor hospital. Excess bleeding may result in an unusable liver, pancreas and kidneys.

Requirements to undertake DRP and NRP

The following are required for the successful removal of the heart during NRP

From the cardiac team

- Senior surgeon who is experienced in DRP retrieval
- The *ex situ* normothermic heart perfusion machine. Technician to operate the *ex situ* perfusion machine and the cell saver
- The necessary sterile tubing and adapters to connect to the NRP circuit (3/8 and ½ inch tubing). An appropriately staffed and equipped lung retrieval team if the lungs are also being retrieved

From the abdominal team

- Senior surgeon who is experienced in NRP
- The NRP disposable circuit
- NRP heater/cooler and pump (e.g. Cardiohelp)
- Experienced NRP perfusion practitioner
- 2 x long vascular clamps for descending aorta and IVC clamping

From the SNOD

8 units of bank blood, 4 to be added to prime

**SAFETY CHECKLIST FOR DIRECT RETRIEVAL OF THE HEART/ HEART AND LUNGS
AND *IN SITU* NORMOTHERMIC REGIONAL PERFUSION OF THE ABDOMINAL
ORGANS**

TO BE COMPLETED AT HANDOVER

CTH SURGEON

ABDO SURGEON

1 Protocol reviewed prior to WLST

☐☐

2 Debrief completed prior to WLST

☐☐

3 CTh team equipment ready

☐

(Cell saver, Clamps, OCS, Fluids for perfusion)

4 Abdominal team equipment ready

☐

Leading surgeon; Full name and signature

TO BE COMPLETED PRIOR TO START ABDOMINAL NRP

(Time to be noted and signed by Abdominal team Perfusionist)

1 Descending Aorta x clamp time