

UK National Protocol for direct procurement of cardiothoracic organs and *in situ* normothermic regional perfusion of the abdominal organs

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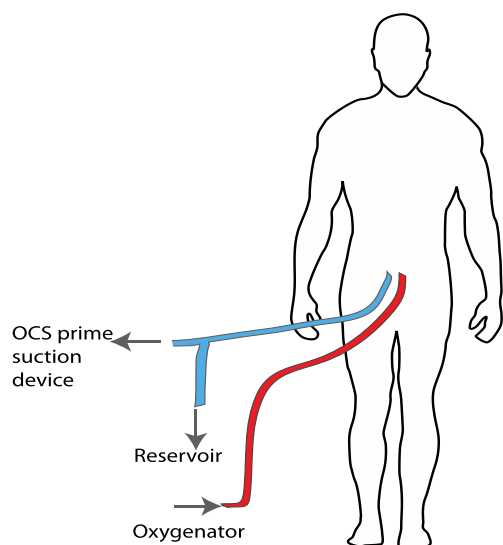
Preparation

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 35°C by circulating through the oxygenator/heat exchanger.

A pump sucker will be connected to the reservoir for blood loss recovery. 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 WOLST 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.

There are 2 protocol variations, which are detailed in appendix.

The variations result from current team practices and current team composition (i.e having a formal perfusionist in the team). With growing national experience, team changes and consumables availability, the protocol will be reviewed and re-assessed;

- 1. Timing of opening the OCS kit**
- 2. Timing and means of delivering antegrade pneumoplegia**

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 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.

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.

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 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.
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.



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.

5. The heart is assessed for any visible anomalies, palpable coronary artery disease, left ventricular hypertrophy, trauma, congenital disease etc. Once absence of heart anomalies has been assured and enough donor blood has been drained, the OCS module is opened and

primed in preparation for graft ex-situ perfusion. However, see **PROTOCOL VARIATION 1** in appendix.

6. 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.

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

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

9. 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.

10. 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**

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.

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.

Simultaneously to cardioplegia delivery, an additional cannula is inserted in the main pulmonary artery. 1-2 L of antegrade pneumoplegia supplemented with heparin as per UK National guidelines, are administered during cardiectomy. **Note PROTOCOL VARIATION 2** (see appendix) in relation to this.

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 ligaclipping 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
2. Placement of double lumen DLP cannula in the ascending aorta to ensure absence of brain perfusion
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.

Requirements to undertake DPP 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 DPP retrieval
- A cell saver, to enable blood to be washed plus disposables
- 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

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

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

<i>TO BE COMPLETED AT HANDOVER</i>	<i>CTH SURGEON</i>	<i>ABDO SURGEON</i>
<i>1 Protocol reviewed prior to WOLST</i>	<input type="checkbox"/>	<input type="checkbox"/>
<i>2 Debrief completed prior to WOLST</i>	<input type="checkbox"/>	<input type="checkbox"/>
<i>3 CTh team equipment ready</i> <i>(Cell saver, Clamps, OCS, Fluids for perfusion)</i>	<input type="checkbox"/>	
<i>4 Abdominal team equipment ready</i>		<input type="checkbox"/>

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

Appendices

Protocol variation 1 – Time to open the OCS rig

Harefield and Papworth have a slight variation in protocol regarding timing.

Harefield will open the kit only after the heart was inspected for coronary disease, congenital malformation or any other anatomy variance which will make the organ un-transplantable.

Papworth opens the kit when patient meets criteria. This is due to current team configuration (NO PERFUSIONIST) and the agreement Papworth has with Transmedics that they will replace every kit opened for which the organ not used based on clinical ground.

Protocol variation 2 - delivering antegrade pneumoplegia

Harefield delivers 1-2 L of pneumoplegia simultaneously during cardiectomy. The CTh assistant holds PA cannula while cardiectomy takes place and in this way we reduce the risk of the blood clotting inside the lung vessels.

Papworth

Similar to TANRP protocol, the cardiothoracic plegia administration and retrieval is done sequentially. The heart will receive 500cc of cardioplegia and full cardiectomy will be performed. Next step will be to administer antegrade the full pneumoplegia, via Foley catheters into the right and left pulmonary arteries.

Both teams agree to back-table retrograde perfusion of the lungs.