

**NHS BLOOD AND TRANSPLANT
ORGAN DONATION AND TRANSPLANTATION DIRECTORATE
BOWEL ADVISORY GROUP**

Coronary angiography in high risk donors – Implementation Proposal

Background

At a previous CTAG meeting the issue of coronary artery disease and its diagnosis in donors was discussed. It was noted that (i) minor or single vessel CAD may not preclude successful donation even if bypass grafting is necessary and that (ii) manual examination of the donor heart is an unreliable method of determining whether flow-limiting CAD is present. The possibility of arranging coronary angiography was tabled and it was noted that the majority of hospitals in which donors arise have this facility. A pilot scheme was suggested in which specific high yield hospitals with coronary angiography facilities would begin to be requested to perform angiography in selected cases. A guideline to determine which donors would require angiography was requested. Importantly, it should be noted that a large fraction of donors in the USA, Canada, Italy and Germany are submitted to coronary angiography and it is expected that access to this investigation would increase heart yield.

As background, we examined the reasons for rejection of donor hearts subjected to inspection within the Heart Study. Of the first 891 donors within the study, we found that 348 hearts were subjected to retrieval team attendance and cardiac inspection. Of these, 211 hearts were retrieved for transplantation and 137 declined after inspection for a variety of reasons. Of those declined at inspection, palpable coronary artery disease was cited as the reason for non-retrieval in 46(33%). Thus, as a maximum, if donor coronary angiography revealed limited CAD, an additional 20 or more hearts per annum might be procured. These donors had a mean age(SD) of 48.6 ± 8.7 years and a median age(IQR) of 50(44,55) years. This age profile is compatible with the UNOS guidelines for coronary angiography and these were approved by CTAG at the last meeting.

We have persuaded NHSBT to fund coronary angiography in specific donors for the current financial year. However, there are a number of issues to be addressed including; indications, contra-indications, requesting, issues of nephrotoxicity, audit and perhaps most importantly data transfer and interpretation. The following represents a draft protocol proposal.

Indications for consideration of donor coronary angiography

Donor coronary angiography should be requested when a heart has been provisionally accepted for transplantation but there is an enhanced risk of donor coronary artery disease. The rationale for request is that (i) a finding of significant multivessel coronary artery disease would be a reason for declining the heart for transplantation to safeguard the potential recipient and (ii) that a

finding of no, minor multivessel or significant single vessel coronary artery disease would not preclude transplantation and the findings would override the detection of palpable atheroma at the time of retrieval (a common cause of heart rejection during the retrieval process).

The high risk cohort of donors potentially comprises the following:-

1. Male > 55 years of age or female > 60 years
2. Male > 40 years of age or female > 45 years in the presence of 2 risk factors (smoking, hypertension, diabetes, body mass index > 32, prior or family history of CAD disease)
3. Changes suggestive of ischaemia on electrocardiogram
4. Regional wall motion abnormalities on echocardiography or reduced ejection fraction($\leq 40\%$)
5. Presence of 3 or more risk factors at any age
6. History of cocaine use.

Numerically, review of existing NHSBT databases for all UK adult solid organ DBD (16-64 years) where consent exists for heart retrieval suggests the following possible numbers:-

		2008-2009	2009-2010	2010-2011	TOTAL
		N (%)	N (%)	N (%)	N (%)
1	No. potential heart donors	459 (100)	457 (100)	470 (100)	1386 (100)
2	No. potential heart donors in H with c/cath facility	-	-	-	-
3	No. males >55y	51 (11)	39 (9)	51 (11)	141 (10)
4	No. females >60y	21 (5)	22 (5)	22 (5)	65 (5)
5	No. males >40-55y with 2 risk factors	20 (4)	15 (3)	18 (4)	53 (4)
6	No. females >45-60y with 2 risk factors	22 (5)	20 (4)	17 (4)	59 (4)
7	No. donors with 3 or more risk factors (not yet included)	14 (3)	14 (3)	19 (4)	47 (3)
8	No. donors with a history of drug abuse	31 (7)	37 (8)	25 (5)	93 (7)
9	No. donors with abnormal ECG (not yet included)	62 (14)	92 (20)	99 (21)	253 (18)
10	No. donors with abnormal echo (Estimated EF<50)	16 (3)	17 (4)	18 (4)	51 (4)
11	Total donors meeting criteria (3-10)	237 (52)	256 (56)	269 (57)	762 (55)
12	Total transplanted (3-10)	30 (13)	32 (12)	38 (14)	100 (13)
13	Hearts rejected (3-10) for medical/organ reasons	145 (61)	155 (61)	156 (58)	456 (60)
14	Hearts rejected (3-10) for non-medical/non-organ/other reasons	62 (26)	69 (27)	75 (28)	206 (27)
15	Total donors outside criteria (11 minus 1)	222 (48)	201 (44)	201 (43)	624 (45)
16	Total transplanted	89 (40)	71 (35)	69 (34)	229 (37)
17	Hearts rejected for medical/organ reasons	85 (38)	87 (43)	71 (35)	243 (39)
18	Hearts rejected for non-medical/non-organ/other reasons	48 (22)	43 (22)	61 (31)	152 (24)

Contra-indications to donor coronary angiography

- The heart is not offered for donation.
- The heart is declined by the primary centre on the basis of the established guidelines issued by CTAG.

Reasons for non-offering of the donor heart

All potential hearts (donor age <65 years, consent to heart donation) should be offered to centres with URGENT category recipients regardless of clinical characteristics.

Reasons for not offering for non-URGENT recipients;

- a. Documented coronary artery disease with a confirmed prior history of myocardial infarction, coronary artery bypass surgery or percutaneous intervention. NB. Prior treatment for hypertension or non-investigated chest pain is not a contra-indication to offering.
 - b. Prior cardiac surgery of any type would not always be a contra-indication to offering unless this had been performed via a median sternotomy. e.g. Previous coarctation repair or ductus closure are not contra-indications to donation.
 - c. Documented evidence of a left ventricular ejection fraction of $\leq 30\%$ on more than one occasion prior to BSD.
 - d. Massive inotropic or pressor support, **but only** if adequate circulating volume has been confirmed by invasive monitoring.
- There has been no provisional acceptance of the donor heart for transplantation.
 - The donor hospital does not have facilities for coronary angiography at any time.
 - The donor hospital has limited facilities for coronary angiography and cannot accommodate coronary angiography within a time-scale commensurate with safe organ retrieval or in accordance with the permission of the relatives for any delays likely to be incurred.
 - The donor hospital has full 24 hour facilities for coronary angiography but after discussion cannot accommodate coronary angiography within a time-scale commensurate with safe organ retrieval or in accordance with the permission of the relatives for any delays likely to be incurred.
 - The donor, in the opinion of the Consultant Intensivists in attendance, is judged too unstable for transfer to the cardiac catheterisation laboratory (If stability is regained the query can be raised again).

Requesting donor coronary angiography at the donor hospital (Preliminary)

- The attending SN-OD should establish whether the donor hospital has full(24h) or limited facilities for the performance of coronary angiography.

Advising the donor family of possible coronary angiography

- The attending SN-OD should obtain consent for organ donation including heart donation.
- The attending SN-OD should establish whether the donor matches the indication criteria for donor coronary angiography (*vide supra*).
- The attending SN-OD should explain to the individuals providing consent that in order to maximise the possibility that the full gift of donation can be realised, additional tests may need to be performed. They should explain that standard tests include an electrocardiogram and echocardiogram and measurement of heart output (sometimes undertaken in the operating theatre at retrieval).

- The attending SN-OD should explain that one of the concerns regarding successful heart donation is the possible presence of coronary artery disease (blood vessel furring) which is very common within the population as they get older and may not have been causing symptoms in their relative.
- The attending SN-OD should explain that the donor has some risk of having had coronary artery disease by virtue of their age or medical history and that in some circumstances we would seek to undertake coronary angiography, a test in which the arteries or blood vessels that supply the heart with blood are injected with a dye or contrast to establish whether this coronary artery disease is present and to what extent.
- The attending SN-OD should emphasise that the test is very important and could make the difference in realising the full gift of donation and benefiting a recipient.
- The attending SN-OD should explain that the coronary angiography test would necessitate transferring the donor (for approximately 30-45 minutes) to a cardiac catheterisation laboratory for this test to be performed but that during this time the donor would continue to be attended by an ITU nurse and an ITU doctor.
- The attending SN-OD should explain that this test needs to be arranged and scheduled and this could inevitably cause some delay in the retrieval process. The need for this delay should be fully explained on the basis of full realisation of the gift of donation.
- The attending SN-OD should explain that this procedure should not affect the gift of other organs only the heart.
- Separate consent for this procedure should not be required as it is part of donor assessment which is already consented to.

Requesting donor coronary angiography at the donor hospital

- After the preliminary issues are addressed, the SN-OD should make formal contact with the Intensivist-in-charge and state that the donor falls into a high risk group and that coronary angiography, if this can be arranged is an important investigation. They should brief the intensive care that if coronary angiography can be arranged, that this will require the support of the ITU team for transfer and patient care during the procedure.
- The SN-OD should establish with the Intensivist-in-charge, that the donor is sufficiently stable for such transfer and that support during the transfer can be arranged.
- The attending SN-OD should directly communicate with the Consultant Cardiologist on-call for angiography and make a specific request for donor coronary angiography providing such explanations for such a request as necessary. Importantly, coronary angiography only should be requested. **Left ventriculography IS NOT REQUIRED OR REQUESTED.** Once agreed, the SN-OD should facilitate the liaison between ITU and the cardiac catheterisation laboratory to arrange the conduct of the angiography.

- The SN-OD should provide the Cardiologist with the current crib sheet for angiography analogous to the crib sheet for donor echocardiography.
- The SN-OD should provide the Cardiologist with contact telephone number of the retrieving centre Consultant Surgeon or the provisionally accepting centre Consultant Surgeon to deal with any queries.
- When the angiogram is performed, The SN-OD should request that the usual vessel closure methods relevant to that hospital are used and communicated to the ITU team
- At the end of the coronary angiography procedure the SN-OD should receive a report from the Cardiologist detailing their findings. This report may have varying detail but should include the following
 - Normal coronary arteries
 - Minimal coronary disease without flow limiting lesions
 - Coronary artery disease with flow limiting lesions affecting specific (named) vessels
 - The Cardiologist should be asked to telephone the retrieving centre Consultant Surgeon or the provisionally accepting centre Consultant Surgeon to discuss the findings of angiography

Aborting the efforts to obtain coronary angiography

- The attending SN-OD is empowered to make the necessary judgments as to whether the process of requesting and performing coronary angiography should be aborted. The considerations that impact upon this decision should include donor stability, the prevailing conditions at the donor hospital, unacceptable delays in the performance of the coronary angiography and the wishes of the donor family. However, where possible, all efforts should be made to undertake the procedure where conditions permit as this may increase the yield of donor hearts and successful heart transplantation.

Capturing and transferring angiographic data

We have explored different ways of transferring and acting upon donor coronary angiography data. The ideal arrangement is to have data transfer using secure inter-hospital NHS IEP systems such as PACS. The following text details how this method of data transfer might be achieved.

- Each cardiac transplant centre should establish how emergency angiography data can be accepted by their hospital from anywhere in the UK using secure NHS-information governance compliant data transfer.
- The usual national system is the PACS system which can be accessed by nearly all hospitals.
- To register the donor in PACS at the cardiac transplant centre, a minimal dataset including donor name and date of birth is required. This should be communicated to the transplant centre coordinator.
- The transplant centre coordinator should make contact with their local PACS team or on-call Radiographer to allow registration and uploading of images.

- The attending SN-OD should make the necessary arrangements that would allow the retrieving cardiothoracic team to review the angiogram on the donor hospital systems.
- Once angiography is complete and data uploaded onto PACS the attending SN-OD should notify the relevant recipient coordinator. If more than once centre has provisionally accepted, all such centres should be notified.
- Once notified, the recipient coordinator should contact their PACS team or on-call Radiographer to urgently accept and download the angiographic images.
- Once notified, the recipient coordinator(s) should contact their Consultant Transplant Surgeon to inform them that image downloading is imminent and that the films will soon be accessible and ready for inspection.
- The provisionally accepting centre(s) should notify the SN-OD as soon as possible and certainly within 40 minutes that the donor remains acceptable for heart retrieval and that retrieval planning should continue.

However, not all hospitals have PACS at all times and the ability to upload and download, particularly out-of-hours continues to be fraught with difficulty. Currently we have no coronary angiography in the UK at all and any improvement in this would be a boon. The following describes what we believe to be a more pragmatic approach:

- Descriptive communication between the Cardiologist and the retrieving centre Consultant Surgeon or the provisionally accepting centre Consultant Surgeon. Significant multi-vessel coronary artery disease would be a reason to decline the heart and not proceed with retrieval. No, minor or significant single vessel disease would be an indication to proceed with offering and the retrieval process.
- If the donor is attended by a retrieval team, the retrieving surgeon (who should be signed-off in coronary angiogram interpretation) should access the images and further communicate with the recipient centre. The recipient surgeon can make a judgement on this basis of whether conduit procurement and additional patient counselling is necessary in the recipient.
- A CD of the angiogram should be procured and sent with the heart to the recipient centre. Although this arrives after preparation of the recipient is advanced, there is the chance for implanting team scrutiny and action. In addition, there will already have been 2 independent reviews of the angiogram prior to recipient surgery.
- This more pragmatic approach is recommended.

Decision making and donor-recipient matching

- The Consultant Surgeon(s) has the final responsibility for deciding whether a heart should be utilised for transplantation.
- It is possible that a donor heart with some coronary artery disease may be acceptable for one recipient but judged unacceptable for another.

This includes within- and between-centre differences. Thus, there is an issue of re-offering to be discussed.

- The implanting Consultant surgeon(s) has the final responsibility of interpreting the angiogram and any reports and deciding whether to proceed.
- The Consultant surgeon(s) has the responsibility for communicating with intended recipient if additional planned procedures are necessary as part of the transplant procedure. It is advised that patients are informed that coronary artery bypass grafting may be contemplated and it is advised that this possibility is raised with recipients at waiting-list registration counselling.

The retrieval

- Regardless of whether angiography has been performed, the decision to proceed to retrieval and heart inspection is undertaken as per normal.
- The retrieving Cardiothoracic Surgeon will need to access and review the coronary angiogram on the donor hospital system and secure the copy CD for transit with the donor heart. This should be facilitated.
- Any and all additional planned procedures at the implanting hospital are entirely the responsibility of that hospital.

Effects on other solid organs

- Coronary angiography is a safe procedure with an estimated complication rate of <1 in 15000. Most complications relate to access site bleeding or vessel injury which should not affect organ retrieval.
- The procedure is safely conducted in patients with cardiogenic shock and recent myocardial infarction and should not destabilise the haemodynamic status of the donor.
- No percutaneous coronary interventions will be performed removing the necessity for any anti-platelet pre-treatment.
- In a stable donor it is an appropriate investigation and is used extensively in many Western countries.
- The contrast load for isolated coronary angiography is low and is not associated with nephrotoxicity, hepatic toxicity or pancreas toxicity.
- Allergic reactions to contrast are rare and usually slight and are easily treated with a small dose of steroid and anti-histamine.
- An immediate fatal or life-threatening complication of coronary angiography occurs in approximately 1 in 300,000 procedures. This rate of complication puts into context the risk to other solid organs compared to potential increased yield of donor hearts.

Monitoring of this service development

It is proposed that effectiveness of the intervention should be carefully monitored to assess whether the number of heart transplants increase particularly in those subsets of donors matching the criteria for donor coronary

angiography. This could be compared between donors undergoing angiography and those not.

The effect on other organs should also be noted. The primary graft dysfunction rate in kidneys of donors matching the criteria for donor coronary angiography and undergoing or not undergoing angiography should be compared.

The effect on the retrieval process should be monitored.

The effect on possible withdrawal of consent should be monitored.

This protocol is prepared for CTAG for comment and approval. Once finalised and approved it will process through other advisory groups and NHB&T for implementation.

R Bonser
CTAG Chair

Prepared in consultation with Dr J Townend, Dr S Lim, Mr M Mukadam, Ms. L Armstrong and Ms. S Beer