

NHS BLOOD AND TRANSPLANT
CARDIOTHORACIC ADVISORY GROUP
CLINICAL AUDIT GROUP CHAIRMAN'S REPORT

SUMMARY

- 1 This paper provides a summary of the work of the CTAG Clinical Audit Group since the last CTAG meeting. As always, I would like to acknowledge the work carried out by, and contributions of, the Audit Group members and our colleagues in NHSBT statistics.

INTRODUCTION

- 2 The Clinical Audit Group held teleconferences on 6 January 2016 and 10 March 2016 (the latter instead of a full meeting because of the BMA industrial action).

CLINICAL AUDIT FELLOWS

- 3 Progress reports for the work carried out by Aravinda Page (NHS England Clinical Fellow) and Sanjeet Singh (NHS Scotland Clinical Fellow) are provided in the **Appendix A**.

ACTIVE PROJECTS

- 4 **Long-term VAD outcomes**
The last phase of data analysis is currently being run with a plan for the results to be presented to the group in April and then to prepare a manuscript.
- 5 **Outcomes from listing for lung transplantation**
A telecon was held in January to discuss results from the survival from listing modelling and post-transplant survival modelling. Amendments were suggested and further work is being carried out on the death on the list and the time to transplant models.
- 6 **Effect of ischemia time upon post lung transplant survival**
Secondary end points are currently being considered and a paper is to be drafted on the final results.
- 7 **Congenital heart disease project**
A poster is being presented at the ISHLT meeting in April based on the results from the adult analysis. A paper is being drafted and will then be followed by a second paper on results from the paediatric analysis.

- 8 **Interval between Brain Stem Death to organ retrieval**
A poster is being presented at the ISHLT meeting in April on the results from the heart utilisation analysis. A paper is being drafted which present results on the effect of this interval upon both heart utilisation and post heart transplant survival.
Equivalent work is being done for lungs and a separate paper will then be drafted.
- 9 **A second LVAD outcome project** was proposed but it has been delayed for several reasons, most recently a lack of statistical resources. We hope to reactivate this project later in the year.

DATA APPLICATIONS

- 10 **Prof Sian Harding, National Heart and Lung Institute, Imperial College London: 'Cellular and tissue level characterisation of structure and function of human myocardium? '**
This data application was approved by the Audit Group. The aim of the project is to analyse samples from failing hearts that were explanted from Harefield patients prior to their heart transplant. The research group wish to compare these samples with a control group. The control group will be donor hearts that were retrieved but not transplanted (with consent for research) from donors within the London area. These donor hearts are a proxy for 'healthy' hearts as this is the nearest they can get to taking samples from healthy hearts. The data application related to obtaining data on these unused hearts within the London area.

UPDATED RISK ADJUSTED SURVIVAL MODELS

- 11 In Autumn 2015, the Clinical Audit Group worked with NHSBT Statistics and Clinical Studies in order to produce new 30-day, 1-year and 5-year post heart transplant survivals models and 90-day, 1-year and 5-year post lung transplant survival models. The final models will presented in the CTAG Heart and CTAG Lung meetings. The major limitation is that ischaemia time is not included in the heart models due to lack of information collected on the NHSBT database regarding OCS use and other perfusion techniques.

ISCHAEMIA TIME DATA COLLECTION

- 12 Proposed data collection fields regarding components of ischaemia time (and capture of OCS usage) for heart transplantation were discussed at the Autumn 2015 CTAG meeting and signed off by CTAG shortly after the meeting. Equivalent data collection fields have been proposed by Mo Al-Aloul and will be presented at the CTAG Lung meeting for discussion. Once these data fields are agreed and implemented, we will be able to able model the effect of ischaemia time on post-transplant survival more accurately.

As part of his work as NHS Scotland Clinical Audit Fellow Sanjeet Singh is implementing prospective data collection to determine the incidence of PGD after heart transplantation, using the ISHLT definition.

NHSBT ORGAN SPECIFIC REPORTS

- 13 The published Interim Cardiothoracic Organ Specific Report has been included in the *For Information Only* section of the CTAG Shared Issues agenda. The new risk adjusted survival models have been used in this report to produce risk-adjusted survival estimates by centre.
- 14 As part of his work as NHS England Clinical Audit Fellow, Aravinda Page is designing a survey on the use of the NHSBT Cardiothoracic Annual Reports. He will be contacting centres and CTAG Patient Group members shortly asking them to disseminate the survey to anyone who uses this report.

EUROMACS DATA SHARING

- 15 The CTAG Chair and Unit Directors have agreed an approach to encourage IMACS and EUROMACS to implement our previous data sharing agreement for UK data.

FUTURE MEMBERSHIP OF THE CLINICAL AUDIT GROUP

- 16 An approach to refreshing the membership of CTAG Audit Group has been discussed with the current CTAG Chair. This will be pursued once the re/appointment of the CTAG Chair has taken place.

Nick Banner

March 2016

Appendix A

Aravinda Page – NHS England Clinical Fellow

Date of commencement of full-time post: 01/08/2015

Stream One: Scout Project Phase II

I have been involved with the Scout Project Working Group in refining the data collection for the second phase of the scout project. One of the big challenges we have faced in Phase II is incomplete data. In an attempt to ensure as complete a dataset I have been assisting the group with auditing of the data collection forms through the respective scout champions. Alongside this I have worked together with the Working Group in addressing the research questions as best the data allows.

From the data collected, it was decided to continue with scouting, however, the decision was made to stop collecting a complete set of data for Phase II of the Scout Project. The plan has been to audit scout activity to aid in the preparation of a business plan to incorporate scouting into the standard retrieval protocols. I am currently in the process of creating a new data collection form which will be followed up with a weekly audit of scouting activity.

Stream Two: Advanced optimisation of poorly functioning donor hearts

Together with my supervisors we have designed an experimental protocol to Investigate the effect of circulatory support in optimising poorly functioning donor hearts. This research protocol investigates two aspects, firstly, the use of extra corporeal membrane oxygenation (ECMO) in the brain dead donor in an attempt to offload the donor heart and allow for a period of recovery while limiting the use of deleterious pharmacological support. Secondly, the protocol investigates the effect of normothermic machine perfusion compared to cold storage. The novel strategy we propose will combine these two circulatory support technologies to allow poorly functioning donor hearts a chance to recover, as well as minimize the ischaemic insult sustained as a result of the retrieval process.

We hope to prove this concept in an animal model followed by further validation in poorly functioning human hearts that are turned down for transplantation.

We have currently applied to charitable funds including the Evelyn Trust and Heart Research UK for the necessary funds to proceed with these experiments. In addition to application for funding, I am preparing the necessary ethical approval applications and related documents to allow for us to carry out our work involving unused human hearts as well successfully transplanted patients.

General

Over the period of the last 7 months I have attended heart and lung retrievals from both DBD and DCD donors. This has given me the opportunity to gain insight into

the retrieval process as well as learn how to perform this operation. This has benefitted me both personally and professionally. It has been a privilege to be a part of the retrieval team and has contributed significantly to my training towards my aspiration of becoming a transplant surgeon. Furthermore, it has educated me about the retrieval process and put the research and audit element that I am undertaking into a clinical context.

The second cardiothoracic organ specific report was published in September 2015 and I have designed a survey to help NHSBT review the content of the report and to understand its audience.

Courses and Conferences

During the last 7 months I have attended the EACTS courses on heart and lung failure as well as the NHSBT Retrieval Masterclass.

I have had the privilege to attend the 16th International Victor Chang Symposium in Sydney, Australia and had the opportunity to deliver a presentation on DCD heart transplantation which was well received.

I have also attended the Transplant Academy Event hosted by Novartis Pharmaceuticals UK and Sandoz Limited.

Future Work

1. Scout project – I plan to write-up the Scout Project once the data has been analysed completely for peer review publication
Expected Date of completion – April 2016
2. Experimental protocol – we are currently in the process of applying for funding to carry out this project. I have provided below a timeline for the expected progress provided we are awarded the grants. I am also planning to prepare grant applications to BHF and the Wellcome Trust, however in order to submit to these larger bodies we need to raise resources to fund the preliminary pilot work.

Sanjeet Singh – NHS Scotland Clinical Fellow**i) National Primary Graft Dysfunction Audit**

Sanjeet has visited 4 of the 6 cardiac transplant centres as part of his national audit project. He has collected data from Papworth, Harefield, Birmingham and Glasgow. He will be visiting Manchester and Newcastle next. His data set is looking at the incidence of primary graft dysfunction across the centres according to the ISHLT 2014 consensus statement, whereby Inotrope scores, Pulmonary Artery Catheter readings, LVEF%, use of mechanical support and outcomes are recorded. He will also be introducing a spread sheet for prospective data collection to the centres.

ii) Pulmonary Vascular Resistance Mismatch

He is currently looking at pulmonary vascular mismatch from a retrospective dataset as a potential risk factor for primary graft dysfunction. He is looking at data for all patients who underwent heart transplants in Glasgow from 2008-2015 (75 patients in total). He is also looking at RVSWI mismatch as a potential risk factor. He is supervised by Prof Nawwar Al-Attar and colleagues.

iii) He is currently writing up a protocol for a prospective study on the role of troponins and other inflammatory markers in grading severity of primary graft dysfunction according to the new ISHLT guidelines. The new guidelines places emphasis on inotrope scores, LVEF and MCS as grades of severity and he is looking to prospectively collect samples from recipients at 6,12, and 24 hours post reperfusion to ascertain if a suitable biomarker can be used as an addition to the current guidelines. This work would be supervised by Prof Nawwar Al-Attar and Dr Nick Banner and is intended to build on the previous research of Mr Vamsidhar Dronavalli (previous CTAG fellow who also looked at the role of biomarkers in PGD); Vamsi is collaborating in this initiative.

iv) Sanjeet is working on a scoring system called the Glasgow Transplant Score. Using a modified Delphi technique, a scoring system was created and retrospectively validated in their cohort in Glasgow. He is working on a preoperative scoring system to risk stratify patients with input from other allied health professionals (psychology, physiotherapy, nutrition) to create a multidisciplinary scoring system. He will then prospectively validate this. A protocol has been submitted for peer review at Glasgow. He is supervised by Prof Nawwar Al-Attar and Dr Tony Vassalos.