NHS BLOOD AND TRANSPLANT

CTAG HEART ADVISORY GROUP

VENTRICULAR ASSIST DEVICES: ISSUES FOR DISCUSSION

SUMMARY

BACKGROUND

1. Prior to 2014, a section examining Ventricular Assist Device (VAD) activity and outcome was included in the joint Royal College of Surgeons (RCS)/ NHS Blood and Transplant (NHSBT) annual report on cardiothoracic transplantation.

2. Following the cessation of the contract between NHSBT and the RCS, NHSBT replaced these reports with the new annual Organ Specific Reports. Separate reports were produced for cardiothoracic transplants and for VAD implants.

3. The first of these reports on VAD activity and outcome was published in March 2015 for adult implants only.

4. The report uses data entered on to the UK VAD database.

5. This paper examines issues raised by centres following publication of the annual report and other issues specifically related to the VAD database.

ACTIONS

6. Members are asked to consider and comment on the actions raised.

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NHS BLOOD AND TRANSPLANT

CARDIOTHORACIC ADVISORY GROUP

VENTRICULAR ASSIST DEVICES: ISSUES FOR DISCUSSION

BACKGROUND

7. The UK Ventricular Assist Device (VAD) database was launched in Autumn 2009 enabling detailed data collection and analysis of risk factors and outcomes for implants nationally.

8. Prior to 2014, a section examining Ventricular Assist Device (VAD) activity and outcome was included in the joint Royal College of Surgeons (RCS)/ NHS Blood and Transplant (NHSBT) annual report on cardiothoracic transplantation.

9. Following the cessation of the contract between NHSBT and the RCS, NHSBT replaced these reports with the new annual Organ Specific Report. Separate reports were produced for cardiothoracic transplants and for VAD implants.

10. The first of these reports on VAD activity and outcome was published in March 2015 for adult implants only using data from the VAD database. ECMO data for either bridging to transplant or primary graft failure post heart transplantation were also included in the VAD report.

11. Before the report was sent to NHS England, Centre Directors and the CTAG Audit Group were given two weeks to comment on the report so that corrections and/or improvements could be made. Nevertheless, the published report generated some criticism.

12. This paper examines the issues raised along with questions specifically related to the VAD database.

13. VAD issues related to the previous RCS/ NHSBT annual report would have been discussed at the VAD Forum but, since this has been reformed to be a meeting involving the Centre Directors alone, the CTAG Clinical Audit Group decided that the report should also be discussed at the CTAG Heart meeting. The roles and responsibilities of NHSBT, the CTAG Clinical Audit Group and the VAD Forum in the preparation and review of future reports to NHS England should be clarified.

ANNUAL REPORT

A. DATA

14. Whilst preparing the data for the annual report, it emerged that some centres had not entered information on the VAD database for all of the devices implanted. In particular, one centre had not entered data since August 2013. It was therefore agreed at the Autumn CTAG Clinical Audit Group meeting that quarterly spreadsheets would be sent to all adult centres asking them to confirm whether the number of devices recorded on the database for the quarter was correct and to amend the database if devices were missing. The latest audit spreadsheets were produced on the 1 April and circulated to all centres with a deadline of the end of April. Due to the tight deadline, the published VAD report therefore did not include all VAD activity.

ACTION: Centres are reminded that VAD/ECMO information should be entered onto the VAD database in a timely manner.

15. Paediatric VAD and ECMO data are not currently included in the annual report as the two paediatric centres (Great Ormond Street and Newcastle) did not start entering data to the VAD database until June 2013. Both centres have now confirmed that they are up to date for VADs implanted since June 2013 hence paediatric data will be included in future reports. It is undecided whether paediatric VAD data should be entered retrospectively and, if so, the cut-off date.

    ACTION: Members are asked to comment on the possibility of entering retrospective paediatric VAD/ECMO data.

16. Individual causes of death data by centre and device type were presented in the annual report. It was suggested that it would be more informative if the causes of death were grouped and not presented on an individual basis. **Table 2** shows the categories available for cause of death recorded on the VAD database along with potential groupings.

    ACTION: Members are asked to consider whether these groupings are appropriate.

Table 2 Potential groupings for causes of death

Level	Group
Arterial embolism	Cardiovascular
Cardiovascular: Myocardial infarction	Cardiovascular
Cardiovascular: Other, please specify	Cardiovascular
RV failure	Cardiovascular
Vtach/Vfib	Cardiovascular
Haemorrhage: Gastrointestinal	Haemorrhage
Haemorrhage: Intraoperative	Haemorrhage
Haemorrhage: Disseminated intravascular coagulation	Haemorrhage
Haemorrhage: Post-operative surgery related	Haemorrhage
Haemorrhage: Pulmonary	Haemorrhage
Haemorrhage: Other, please specify	Haemorrhage
Infection	Infection
Pulm: Pulmonary embolism	Pulmonary
Pulm: Respiratory failure	Pulmonary
Pulm: Other, please specify	Pulmonary
Cancer	Other
CNS cause of death	Other
Device malfunction	Other
Fluid/electrolyte disorder	Other
Haematologic: Other, please specify	Other
Intraop: Not haemorrhage - other, please specify	Other
Liver failure	Other
Other chronic illness, please specify	Other
Pancreatitis	Other
Renal failure	Other
Ruptured aortic aneurysm	Other
Sudden unexplained death	Other
Suicide	Other
Trauma/accident, please specify	Other
Other, please specify	Other
Unknown	Other
Heart failure (after device explant)	Post explant
Arrhythmia (after device explant)	Post explant
Cardiac arrest/sudden cardiac death (after device explant)	Post explant

Cardiogenic shock (after device explant)	Post explant
Bleeding (after device explant)	Post explant
Infection (after device explant)	Post explant
Multi organ failure (after device explant)	Post explant

B. FORMAT OF REPORT

17. As UK VAD and ECMO activity increases, more patients are receiving more than one device. In particular, the number of patients who receive a short-term device or ECMO prior to a long-term device is increasing. In the annual report, activity and outcomes for bridging devices are currently reported **by a patient's first device** and is split into a long-term (LT) section and a short-term (ST) section. Patients who received either a ST or an ECMO and then a LT device are included in the ST section of the report and this is consistent with reports produced for the VADs Forum. However, this year we have received comments suggesting that any patient who received a LT VAD should be presented in the LT section of the report.

18. **Table 1a** and **Table 1b** show the device history for patients who received a bridging VAD/ECMO between 1 April 2004 and 31 March 2014. 93 patients (15%) received more than one device.

Table 1a Device history for patients whose first device was a long-term device, 1 April 2004 to 31 March 2014

LT only	406 (93%)
LT-LT	23 (5%)
LT-LT-LT-LT	1 (0%)
LT-LT-ST	1 (0%)
LT-ST	5 (1%)
LT-ST-ECMO	1 (0%)
LT-ST-LT	1 (0%)
Total	**438 (100%)**

Table 1b Device history for patients whose first device was a short-term device/ ECMO, 1 April 2004 to 31 March 2014

ECMO	36 (20%)
ECMO-ECMO	1 (1%)
ECMO-LT	16 (9%)
ECMO-ST	16 (9%)
ECMO-ST-LT	3 (2%)
ECMO-TAH	2 (2%)
ST only	84 (46%)
ST-LT	20 (11%)
ST-LT-LT	2 (1%)
ST-ST-LT	1 (1%)
Total	**181 (100%)**

19. The options for reporting these cases are:
    a. Leave the whole report based on first implant. Outcomes following first ST VAD are currently reported separately for 1) short-term devices only, 2) ECMO only and 3) patients bridged to long-term devices. This will mean that patient survival following LT VAD implant will not include patient survival for ST-LT patients.

    b. Report all LT and ST activity in the relevant sections irrespective of previous or subsequent VADs implanted, but leave the outcome sections based on first VAD. This would be consistent with the cardiothoracic transplantation report which reports all activity but patient survival from first transplant.

    c. Create a new section for patients who receive a short-term device prior to a long-term device. This would maintain separate cohorts throughout the report.

    d. Report all LT and ST activity in the relevant sections irrespective of previous or subsequent VADs implanted (including the outcome sections). This would enable long-term survival estimates to be produced regardless of whether patients received a short-term device. However, patients would be double counted in the patient survival sections. Also, ST-LT patients are different to patients who receive either only a LT or only ST devices as ST-LT patients would have to survive on the short-term device in order to receive a LT.

20. In order to be consistent throughout the report, changes made to ST-LT activity should also be applied to patients who received a LT then a ST device.

21. Two estimates of survival following VAD implantation are currently presented in the activity report:
    e. *Patient survival* is defined as survival from first implant to patient death. This estimate includes survival following transplant and device explant due to full recovery of ventricular function.
    f. *Survival on a VAD* is defined as survival from first implant to patient death with survival censored at time of device explantation due to full recovery or transplantation.

22. The survival for patients who receive two or more devices is currently defined as time from first VAD implant to the explant of the last device, transplantation or patient death. These survival definitions will need to be changed depending upon the options selected above.

    ACTION: Members are asked to comment on how VAD/ECMO activity and outcomes should be reported for patients who receive more than one device.

23. Patients who received a total artificial heart (TAH) are currently discussed in the text in the introduction section and are excluded from the rest of the report. Seven patients have been reported on the VAD database as receiving a TAH at three centres since 2011.

    ACTION: Members are asked whether a separate TAH section should be added when there is sufficient TAH activity.

VAD DATABASE ISSUES

24. Three centres have recently reported that they have admitted patients who have had a VAD/ECMO implanted at non-transplant centres before being transferred. This was discussed at the CTAG Clinical Audit Group meeting in February and guidance has been circulated to all centres emphasising that only VADs/ECMOs implanted at transplant centres should be entered onto the UK VAD database.

25. Whilst reviewing the individual causes of death for the annual report, it was suggested that cerebral haemorrhage should be added as a cause of death along with four options for CNS cause of death (embolic stroke, bleeding, ischaemic stroke and other please specify).

    ACTION: NHSBT IT to amend the causes of death options on the VAD database.

26. Information on pump thrombosis is not currently collected on the VAD database and **Appendix 1** shows the potential new questions to be added to the database.

    ACTION: Members are asked to consider whether the new section on pump thrombosis is appropriate.

27. As part of the VAD Outcomes project, some of the wording for the adverse event questions for infection and bleeding should be changed due to changes in practice. The proposed question changes are:

    g. Was there a major infection which required drive line surgery or treatment for bacteremia since last report?
    h. Was there a major bleeding since last report? If yes, the bleeding site.

    ACTION: Members are asked to consider whether these changes are appropriate.

28. Some of the information entered on the implant form will be duplicated for patients who receive more than one device in a short period of time (e.g. patients who receive more than one ST/ECMO device within a week of first device). In particular, the information requested in the implant form under “events this hospitalisation (pre-implant)” will be the same on both implant forms.

    ACTION: Members are asked whether the “events this hospitalisation (pre-implant)” field should be for the period from 1) date of admission to implant or from 2) date of last VAD implant if the patient is still in hospital following initial admission.

29. The VAD database does not allow for the explant of an ECMO once a BiVAD is implanted.

    ACTION: Members are asked whether a date of discontinuation of ECMO support should be added to the follow-up forms.

30. VAD episodes end either 1) when a patient receives a transplant, 2) the device is explanted due to full recovery or 3) patient death. However, one centre recently reported that a patient received ECMO support before transplant which was not discontinued until two days after transplant. The VAD database will not allow the explant of the ECMO to be reported as the transplant has ended the episode. There are no post-transplant follow-up forms on the VAD database as patients who receive a transplant are currently followed-up through the transplant registry follow-up forms.

    ACTION: Members are asked whether a date of discontinuation of ECMO support should be collected and if so, where the question should be placed.

ACTIONS

31. Members are asked to consider and comment on the actions raised.

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APPENDIX 1 - Pump thrombosis questions

PUMP THROMBOSIS	
Was there evidence of pump thrombosis since last report?	Yes No
If yes, number of events since last report	
If first pump thrombosis since implant, Date of onset	Unknown
Signs - Select all that apply	Haemolysis
	Increase in pump power
	Decrease in pump power that is otherwise unexplained
	Rise in calculated pump flow reading or fall in measured flow
	Recurrent heart failure that is otherwise unexplained
	Cardiogenic shock
	Pump stop
	Progressive rise in LDH
	Other
If Other, please specify	Free text
Was it an anticoagulation related issue?	Yes No Unknown
Anticoagulation at time of thrombosis Select all that apply	None
	Heparin
	Warfarin
	Other
If Other, please specify	Free text
If on warfarin, INR?	International units
If on heparin, PTT?	seconds
If on heparin, APR?	(no units)
Antiplatelet therapy Select all that apply	Aspirin
	Clopidogrel
	Other
If Other, please specify	Free text
If Aspirin, give dose	mg
If Clopidogrel, give dose	mg
If Other, give dose	mg
Was there any evidence that the patient was not adhering to therapy/monitoring?	Yes No Unknown
If Yes, please specify	Free text
Had anticoagulation been reduced/stopped because of a bleeding complication?	Yes No Unknown
If Yes, please specify	Free text
Was there any drug interaction that affected the patient's anticoagulation?	Yes No Unknown
If Yes, please specify	Free text
Please provide last INR prior to pump thrombosis	International units
Treatment of pump thrombosis Select all that apply	Increased anticoagulation
	Glycoprotein IIb/IIIa inhibitor
	Thrombolysis
	Pump exchange
	Spontaneous resolution
	Other
Specify agents and routes used, and/or details of Other treatment	Free text

Outcome - Select all that apply	Recovery with no sequelae
	Haemorrhage requiring transfusion
	Stroke
	Embolism, other
	Death
	Other
If stroke, please indicate the type	Embolic
	Haemorrhagic
	Other, please specify
If other stroke, please specify	Free text
If haemorrhage, specify site	Free text
If Other embolism and/or Other, please specify	Free text
If second or subsequent pump thrombosis, for most recent event, Date of onset	Unknown
Signs - Select all that apply	Haemolysis
	Increase in pump power
	Decrease in pump power that is otherwise unexplained
	Rise in calculated pump flow reading or fall in measured flow
	Recurrent heart failure that is otherwise unexplained
	Cardiogenic shock
	Pump stop
	Progressive rise in LDH
	Other
If Other, please specify	Free text
Was it an anticoagulation related issue?	Yes No Unknown
Anticoagulation at time of thrombosis Select all that apply	None
	Heparin/Warfarin
	Warfarin
	Other
If Other, please specify	Free text
If on warfarin, INR?	International units
If on heparin, PTT?	seconds
If on heparin, APR?	(no units)
Antiplatelet therapy	Aspirin
	Clopidogrel
	Other
If Other, please specify	Free text
If Aspirin, give dose	mg
If Clopidogrel, give dose	mg
If Other, give dose	mg
Was there any evidence that the patient was not adhering to therapy/monitoring?	Yes No Unknown
If Yes, please specify	Free text
Had anticoagulation been reduced/stopped because of a bleeding complication?	Yes No Unknown
If Yes, please specify	Free text
Was there any drug interaction that affected the patient's anticoagulation?	Yes No Unknown
If Yes, please specify	Free text

Please provide last INR prior to pump thrombosis	International units
Treatment of pump thrombosis Select all that apply	Increased anticoagulation
	Glycoprotein IIb/IIIa inhibitor
	Thrombolysis
	Pump change
	Spontaneous resolution
	Other
Specify agents and routes used, and/or details of Other treatment	Free text
Outcome - Select all that apply	Recovery with no sequelae
	Haemorrhage requiring transfusion
	Stroke (embolic, haemorrhagic)
	Embolism, other
	Death
	Other
If stroke, please indicate the type	Embolic
	Haemorrhagic
	Other, please specify
If other stroke, please specify	Free text
If haemorrhage, specify site	Free text
If Other embolism and/or Other, please specify	Free text