NHS
Blood and Transplant

ANNUAL REPORT ON VENTRICULAR ASSIST DEVICES

REPORT FOR 2013/2014
(1 APRIL 2004 – 31 MARCH 2014)

PUBLISHED JANUARY 2015

PRODUCED IN COLLABORATION WITH NHS ENGLAND

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EXECUTIVE SUMMARY

This report presents key figures about ventricular assist device (VAD) implantation in the UK. The period reported covers 10 years of VAD implant data, from 1 April 2004. The report presents information on the number of VADs implanted and survival analysis after implant, both on a national and centre-specific basis.

Key findings

- 620 patients received a first VAD or ECMO for the intention of bridging to heart transplantation.

- 438 of the 620 patients received a first long-term device with 89% of first long-term implants performed at Newcastle, Papworth and Harefield.

- 88% (95% CI: 85% - 91%) of the 438 first long-term VAD patients were alive at 30 days and 27% went on to receive a transplant.

- 43% were registered on the heart transplant list prior to receiving a first long-term device.

- Long-term VAD duration of support ranged between 0 and 2955 days (8 years) with a median VAD duration (95% CI) estimated to be 396 days (322, 470).

- The national unadjusted rate of patient survival 1 year after first **long-term device** is 68% (95% CI: 63-72). These rates vary between centres, ranging from 50% to 79%.

- The national unadjusted rate of survival on a VAD 1 year after first **long-term device** is 69% (95% CI: 64-73). These rates vary between centres, ranging from 57% to 83%.

- 181 patients received a first short-term device or ECMO for the intention of bridging to heart transplant and 114 received a first short-term device or ECMO for primary graft dysfunction after heart transplantation.

INTRODUCTION

Introduction

The UK ventricular assist device (VAD) service was provisionally designated and commissioned by NHS England from April 2001 as a method to bridge patients with severe heart failure to heart transplantation. Data were collected on all patients implanted with VADs between April 2002 and December 2004 as part of the Evaluation of Ventricular Assist Device Program UK (EVAD) study, funded by the National Institute of Health Research Health Technology Assessment programme. Following the EVAD study, Papworth Hospital continued to record VAD activity at Papworth, Harefield and Newcastle for VADs that were funded by NHS England for the purposes of bridge to transplant. Since January 2007, NHS Blood and Transplant (NHSBT) have been responsible for data collection and reporting.

Data collection had been limited and focused on basic outcome and demographic information. A more extensive audit was launched in the autumn of 2009 enabling more detailed data collection and analysis of risk factors and outcomes for implants at all centres. Centres were asked to retrospectively enter this additional information for all VAD implants performed since 1 January 2005 for long-term devices and 9 May 2002 for short-term devices, in addition to data related to all VADs implanted from 2009 onwards. All VAD data are stored in the VAD database held at NHSBT.

This report presents information on VAD implant activity and patient outcome after implant between 1 April 2004 and 31 March 2014, for all six adult centres performing VAD implants in the UK. Data were obtained from the UK VAD Database as at 10 December 2014.

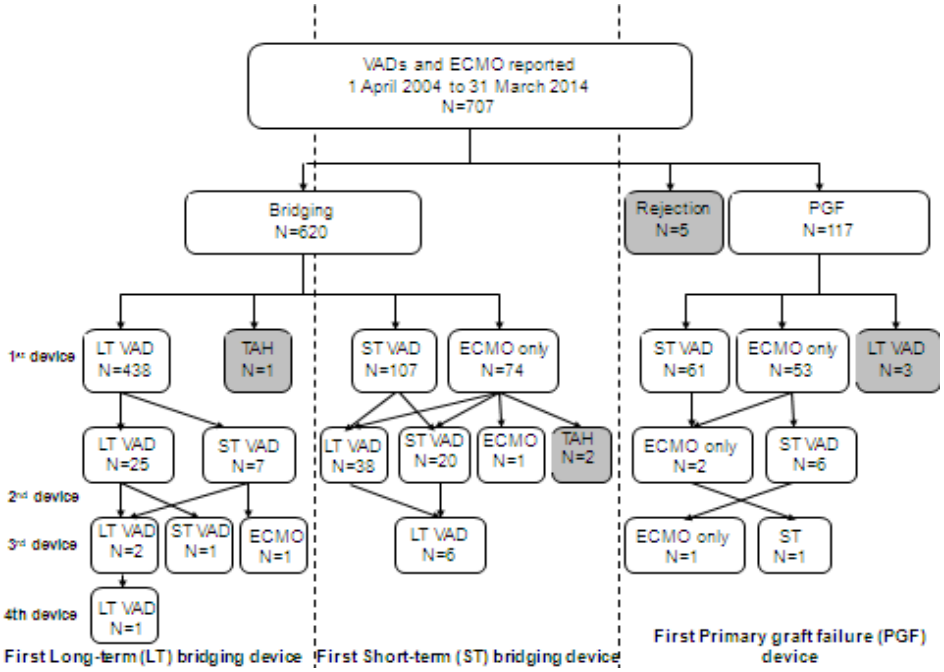
There are two UK paediatric implant centres; Great Ormond Street Hospital (GOSH) and Newcastle (also an adult implant centre). However, GOSH and the Newcastle paediatric department have only recently started entering data. Results therefore exclude paediatrics (age<16 years) at Newcastle and all patients who received a VAD at GOSH.

Methods used are described in the Appendix.

Two patients refused to give consent for their data to be recorded on the VAD database and they are not included in this report.

Figure 1.1 details the VAD and ECMO sequence for 707 patients who are reported as receiving a device between 1 April 2004 and 31 March 2014. Results in this report are presented in three main sections as indicated; the dotted lines and titles at the bottom of the figure indicate which patients are reported in each section.

Figure 1.1 UK VAD and ECMO patients included in this report. Implants between 1 April 2004 to 31 March 2014 (N=number of patients)[1]



[1] Note that the number of short-term devices reported and hence the total number of implants is lower than the true number as only data up until 31 March 2013 are included for Papworth.

Note that some patients included in the bridging section also received a VAD for primary graft dysfunction (PGD) and are included in both sections. Also, some patients may have received concurrent ECMO support with their VAD. Uncommon treatment options (shaded in grey) such as total artificial heart (TAH) bridging, treatment of rejection post-transplant and long-term VADs for PGD are indicated in **Figure 1.1** but are not analysed in the further sections.

Table 1.1 shows the number of patients who received a bridging device and the number of bridging devices implanted between 1 April 2004 and 31 March 2014 at each centre.

Table 1.1 Number of bridging patients and devices implanted, by implant centre, 1 April 2004 to 31 March 2014

Hospital	No. of patients	Type of device				
		LT	ST	ECMO	TAH	Total
Newcastle	**148**	146	6	6	1	**159**
Papworth	**125**	94	20	17	2	**133**
Harefield	**211**	205	51	8	0	**264**
Birmingham	**50**	19	18	22	0	**59**
Manchester	**48**	30	20	13	0	**63**
Glasgow	**38**	16	20	10	0	**46**
All centres	**620**	**510**	**135**	**76**	**3**	**724**

LONG TERM DEVICES USED FOR BRIDGING

Activity

This section considers patients whose first device was a long-term device. Patients who received a short-term device or an ECMO prior to a long-term device are reported in the short-term section. Long-term ventricular assist devices (VADs) were implanted for 438 patients at six adult implant centres in the UK between 1 April 2004 and 31 March 2014. 137 received a device at Newcastle, 160 at Harefield, 91 at Papworth, 24 at Manchester, 16 at Birmingham and 10 at Glasgow.

Data presented in this section includes both left ventricle VADs (LVADs) and VADs implanted into both ventricles (BiVADs) unless otherwise stated.

An additional patient at Papworth received a total artificial heart (TAH) and received a transplant less than two years post-implant. This patient is not included in the summaries below.

Figure 2.1 shows the cumulative number of first long-term VADs implanted each month, overall and by centre, whilst **Figure 2.2** shows the number of VADs by financial year and centre. VAD activity at Harefield and Newcastle has slightly decreased over the last four financial years.

Figure 2.1 Cumulative long-term VAD activity, by month and implant centre, 1 April 2004 to 31 March 2014

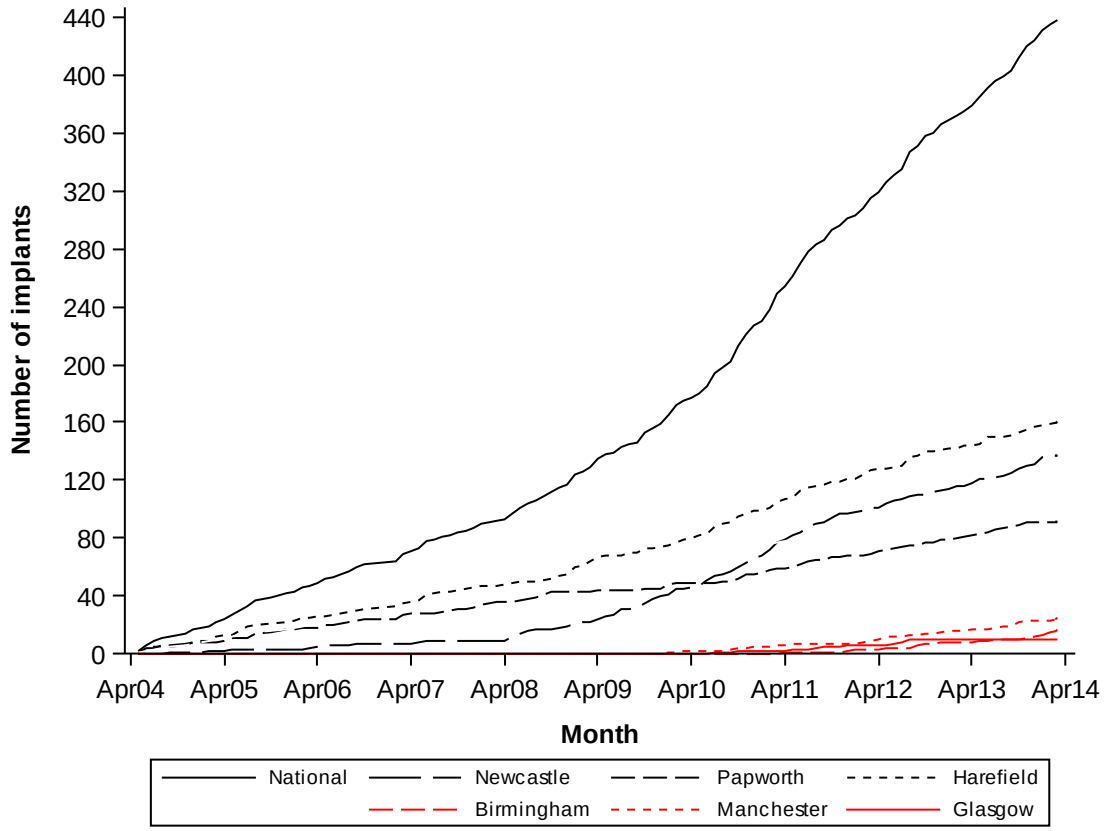


Figure 2.2 Long-term VAD activity, by financial year and implant centre, 1 April 2004 to 31 March 2014

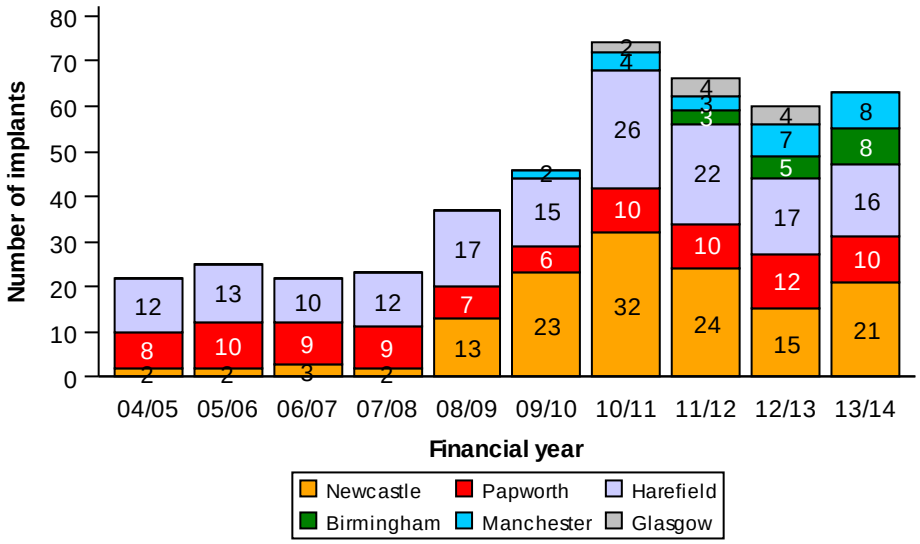


Figure 2.3 shows the number of long-term devices categorised by generation of device. This shows that the majority of long-term devices implanted in the last five years have been third generation devices.

Figure 2.3 Long-term VAD generation, by financial year, 1 April 2004 to 31 March 2014

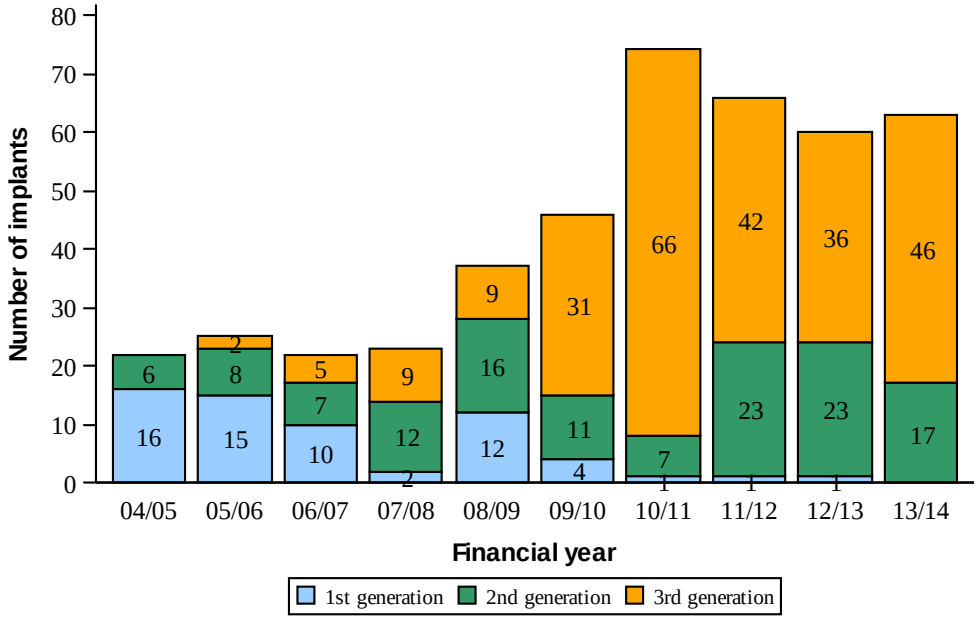


Figure 2.4 shows the INTERMACS patient profile at time of VAD implantation for implants between 2004 and 2014. This shows that profile 2 (progressive decline) is the most common. Patient profile was not collected for patients included in the EVAD study and these are reported in the unknown group.

Figure 2.4 INTERMACS patient profile, by financial year, 1 April 2004 to 31 March 2014

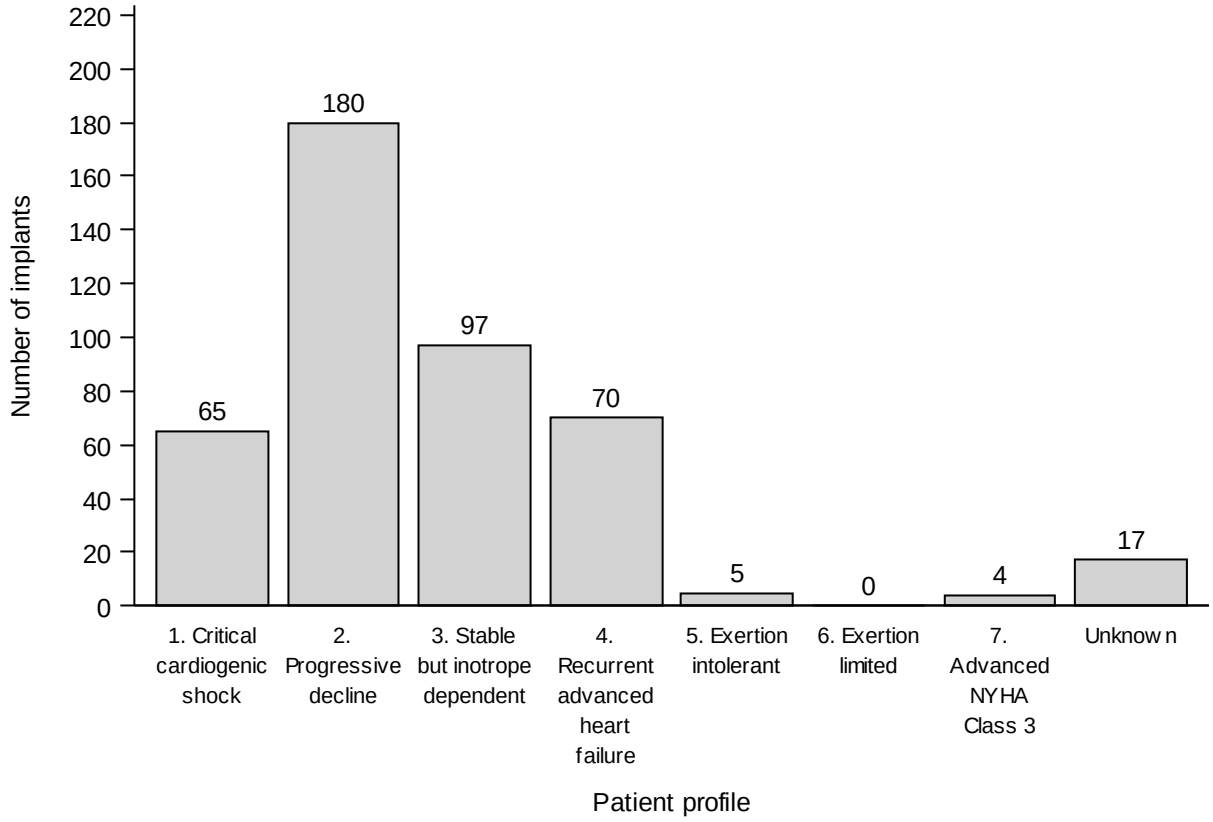


Table 2.1 shows the characteristics of patients whose first device was a long-term device by implant centre. Overall, the most frequently reported cardiothoracic diseases were dilated cardiomyopathy (62%) and ischaemic heart disease (29%). The overall median age at implant was 48.5 years (inter-quartile range 37 - 57 years) and the majority of recipients were male (84%). 74% were on inotropes at time of VAD implant whilst 34% received an IABP prior to VAD implant.

Table 2.2 shows that the most frequently used devices were Heartware (50%) and Heartmate II (24%). Overall 93% received only one long-term device, whilst 6% had their long-term device replaced. The device history for all first long-term device patients is also outlined in sequence in **Table 2.2** .

Table 2.1 Characteristics of patients who received a first long-term device, 1 April 2004 to 31 March 2014, by implant centre

		Newcastle N (%)	Harefield N (%)	Papworth N (%)	Manchester N (%)	Birmingham N (%)	Glasgow N (%)	Total N (%)
Number		137	160	91	24	16	10	**438**
Recipient sex	Male	118 (86)	135 (84)	73 (80)	19 (79)	15 (94)	8 (80)	**368 (84)**
	Female	19 (14)	25 (16)	18 (20)	5 (21)	1 (6)	2 (20)	**70 (16)**
Recipient age	Median (IQR)	50 (36-58)	45 (33-53.5)	49 (41-57)	56 (45.5-63)	55.5 (52.5-59)	32.5 (28-49)	**48.5 (37-57)**
	Missing	0	0	0	0	0	0	**0**
Cardiothoracic disease	Dilated cardiomyopathy	74 (54)	117 (73)	60 (66)	10 (42)	4 (25)	5 (50)	**270 (62)**
	Ischaemic heart disease	46 (34)	29 (18)	24 (26)	12 (50)	12 (75)	3 (30)	**126 (29)**
	Congenital heart disease	10 (7)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	**11 (3)**
	Hypertrophic cardiomyopathy	2 (1)	4 (3)	4 (4)	1 (4)	0 (0)	1 (10)	**12 (3)**
	Restrictive cardiomyopathy	2 (1)	5 (3)	1 (1)	0 (0)	0 (0)	0 (0)	**8 (2)**
	Valvular heart disease	2 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	**3 (1)**
	Infiltrative heart muscle disease	1 (1)	1 (1)	0 (0)	1 (4)	0 (0)	0 (0)	**3 (1)**
	Other	0 (0)	1 (1)	2 (2)	0 (0)	0 (0)	1 (10)	**4 (1)**
	Unknown	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (0)**
INTERMACS patient profile	1. Critical cardiogenic shock	22 (16)	30 (19)	9 (10)	2 (8)	0 (0)	2 (20)	**65 (15)**
	2. Progressive decline	65 (47)	57 (36)	45 (49)	4 (17)	3 (19)	6 (60)	**180 (41)**
	3. Stable but inotrope dependent	16 (12)	47 (29)	16 (18)	5 (21)	12 (75)	1 (10)	**97 (22)**
	4. Recurrent advanced heart failure	30 (22)	16 (10)	13 (14)	10 (42)	1 (6)	0 (0)	**70 (16)**
	5. Exertion intolerant	2 (1)	0 (0)	0 (0)	3 (13)	0 (0)	0 (0)	**5 (1)**
	6. Exertion limited	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**0 (0)**
	7. Advanced NYHA Class 3	1 (1)	2 (1)	0 (0)	0 (0)	0 (0)	1 (10)	**4 (1)**
	Unknown	1 (1)	8 (5)	8 (9)	0 (0)	0 (0)	0 (0)	**17 (4)**
Treatment history prior to long-term VAD implant	None	38 (28)	18 (11)	1 (1)	1 (4)	1 (6)	2 (20)	**61 (14)**
	IABP only	5 (4)	4 (3)	3 (3)	0 (0)	1 (6)	4 (40)	**17 (4)**
	Inotropes only	58 (42)	81 (51)	18 (20)	11 (46)	11 (69)	1 (10)	**180 (41)**
	VAD/ECMO+inotropes	0 (0)	4 (3)	0 (0)	0 (0)	0 (0)	0 (0)	**4 (1)**
	IABP+inotropes	19 (14)	38 (24)	56 (62)	8 (33)	2 (13)	0 (0)	**123 (28)**
	VAD/ECMO+ IABP+inotropes	1 (1)	1 (1)	0 (0)	1 (4)	0 (0)	0 (0)	**3 (1)**
	Unknown	16 (12)	14 (9)	13 (14)	3 (13)	1 (6)	3 (30)	**50 (11)**

Table 2.2 Device type and history of patients who received a first long-term device, 1 April 2004 to 31 March 2014, by implant centre

		Newcastle N (%)	Harefield N (%)	Papworth N (%)	Manchester N (%)	Birmingham N (%)	Glasgow N (%)	Total N (%)
Number		137	160	91	24	16	10	**438**
Device name	Berlin Heart Excor	20 (15)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**20 (5)**
	Heartmate XVE	0 (0)	7 (4)	2 (2)	0 (0)	0 (0)	0 (0)	**9 (2)**
	Heartmate II	0 (0)	60 (38)	0 (0)	19 (79)	16 (100)	10 (100)	**105 (24)**
	Heartware	107 (78)	62 (39)	45 (49)	5 (21)	0 (0)	0 (0)	**219 (50)**
	Jarvik 2000	0 (0)	11 (7)	0 (0)	0 (0)	0 (0)	0 (0)	**11 (3)**
	Micromed DeBakey	3 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**3 (1)**
	Thoratec IVAD	0 (0)	1 (1)	12 (13)	0 (0)	0 (0)	0 (0)	**13 (3)**
	Thoratec PVAD	1 (1)	8 (5)	11 (12)	0 (0)	0 (0)	0 (0)	**20 (5)**
	VentrAssist	6 (4)	0 (0)	21 (23)	0 (0)	0 (0)	0 (0)	**27 (6)**
	Heart Assist 5	0 (0)	2 (1)	0 (0)	0 (0)	0 (0)	0 (0)	**2 (0)**
	Synergy Circulite	0 (0)	9 (6)	0 (0)	0 (0)	0 (0)	0 (0)	**9 (2)**
Device history	LT	130 (95)	137 (86)	90 (99)	24 (100)	15 (94)	10 (100)	**406 (93)**
	LT-LT	7 (5)	15 (9)	1 (1)	0 (0)	0 (0)	0 (0)	**23 (5)**
	LT-LT-LT-LT	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (0)**
	LT-LT-ST	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (0)**
	LT-ST	0 (0)	5 (3)	0 (0)	0 (0)	0 (0)	0 (0)	**5 (1)**
	LT-ST-ECMO	0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	**1 (0)**
	LT-ST-LT	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (0)**

LT-ST indicates that a patient received a long-term device and then a short-term device following explantation of the long-term device

LONG TERM DEVICES USED FOR BRIDGING

Patient Outcomes

Data presented in this section combines LVADs and BiVADs unless otherwise stated.

Table 3.1a shows the long-term VAD outcome of recipients, by centre, for the whole 10 year time period whilst **Table 3.1b** shows the long-term VAD outcome for VADs implanted during the most recent three years (April 2011 – March 2014). Nationally, 118 patients were transplanted, 30 survived explantation of the VAD, 185 died on support, 4 died within a month of explantation and 101 were still on support on 10 December 2014. Deaths which occur more than one year post-transplant or explant are not referenced in these tables.

Table 3.1a Outcome of long-term VADs, by implant centre, 1 April 2004 to 31 March 2014

	Newcastle		Papworth		Harefield		Birmingham		Manchester		Glasgow		Total	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Alive (post transplant)	19	(14)	32	(35)	30	(19)	4	(25)	4	(17)	2	(20)	**91** [5,0]	**(21)**
Alive (post explant)	5	(4)	2	(2)	20	(13)	0	0%	1	(4)	2	(20)	**30** [4,3]	**(7)**
Alive with VAD	38	(28)	17	(19)	28	(18)	6	(38)	11	(46)	1	(10)	**101** [3,0]	**(23)**
Total alive	*62*	*(45)*	*51*	*(56)*	*78*	*(49)*	*10*	*(63)*	*16*	*(67)*	*5*	*(50)*	***222*** [12,3]	***(51)***
Died (post transplant)	10	(7)	3	(3)	12	(8)	0	0%	1	(4)	1	(10)	**27** [2,0]	**(6)**
Died (post explant)	1	(1)	1	(1)	2	(1)	0	0%	0	0%	0	0%	**4**	**(1)**
Died with VAD	64	(47)	36	(40)	68	(43)	6	(38)	7	(29)	4	(40)	**185** [11,4]	**(42)**
Total died	*75*	*(55)*	*40*	*(44)*	*82*	*(51)*	*6*	*(38)*	*8*	*(33)*	*5*	*(50)*	***216*** [13,4]	***(49)***
TOTAL	**137**	**(100)**	**91**	**(100)**	**160**	**(100)**	**16**	**(100)**	**24**	**(100)**	**10**	**(100)**	**438** [25,7]	**(100)**

Superscripts indicate the number of patients receiving a second device, e.g. 2,1 indicates two patients received a second long term device and one patient received a short term device after explantation of a long-term device

Table 3.1b Outcome of long-term VADs, by implant centre, 1 April 2011 to 31 March 2014

	Newcastle		Papworth		Harefield		Birmingham		Manchester		Glasgow		Total	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Alive (post transplant)	5	(8)	5	(16)	11	(20)	4	(25)	3	(17)	2	(25)	**30** [3,0]	**(16)**
Alive (post explant)	1	(2)	1	(3)	2	(4)	0	0%	0	0%	1	(13)	**5** [1,0]	**(3)**
Alive with VAD	26	(43)	13	(41)	18	(33)	6	(38)	10	(56)	1	(13)	**74** [2,0]	**(39)**
Total alive	*32*	*(53)*	*19*	*(59)*	*31*	*(56)*	*10*	*(63)*	*13*	*(72)*	*4*	*(50)*	***109*** [6,0]	***(58)***
Died (post transplant)	3	(5)	1	(3)	1	(2)	0	0%	1	(6)	0	0%	**6** [1,0]	**(3)**
Died (post explant)	1	(2)	0	0%	0	0%	0	0%	0	0%	0	0%	**1**	**(1)**
Died with VAD	24	(40)	12	(38)	23	(42)	6	(38)	4	(22)	4	(50)	**73** [5,2]	**(39)**
Total died	*28*	*(47)*	*13*	*(41)*	*24*	*(44)*	*6*	*(38)*	*5*	*(28)*	*4*	*(50)*	***80*** [6,2]	***(42)***
TOTAL	**60**	**(100)**	**32**	**(100)**	**55**	**(100)**	**16**	**(100)**	**18**	**(100)**	**8**	**(100)**	**189** [12,2]	**(100)**

Superscripts indicate the number of patients receiving a second device, e.g. 2,1 indicates two patients received a second long term device and one patient received a short term device after explantation of a long-term device

Table 3.2a shows the causes of death for the 189 patients who died either post-explant or with a VAD whist **Table 3.2b** shows the causes of death for 27 patients who died post-transplant. Deaths which occur more than one year post-transplant or explant are not referenced in these tables. Deaths post-explant are included in **Table 3.2a** due to very small numbers (n=4).

Table 3.2a Causes of post-implant/explant death for patients who received a first long-term device, 1 April 2004 to 31 March 2014, by implant centre

	Newcastle N (%)	Harefield N (%)	Papworth N (%)	Manchester N (%)	Birmingham N (%)	Glasgow N (%)	Total N (%)
Number	65	70	37	7	6	4	**189**
Cancer	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (1)**
Cardiovascular: Other	3 (5)	3 (4)	0 (0)	1 (14)	0 (0)	0 (0)	**7 (4)**
CNS cause of death	13 (20)	12 (17)	8 (22)	1 (14)	3 (50)	0 (0)	**37 (20)**
Device malfunction	1 (2)	3 (4)	0 (0)	0 (0)	0 (0)	0 (0)	**4 (2)**
Haemorrhage: Gastrointestinal	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (1)**
Haemorrhage: Intraoperative	1 (2)	2 (3)	0 (0)	0 (0)	0 (0)	0 (0)	**3 (2)**
Haemorrhage: Disseminated intravascular coagulation	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (1)**
Haemorrhage: Post-operative surgery related	1 (2)	1 (1)	2 (5)	0 (0)	0 (0)	0 (0)	**4 (2)**
Haemorrhage: Other	5 (8)	4 (6)	5 (14)	2 (29)	0 (0)	0 (0)	**16 (8)**
Infection	7 (11)	3 (4)	2 (5)	0 (0)	0 (0)	0 (0)	**12 (6)**
Liver failure	0 (0)	3 (4)	0 (0)	0 (0)	0 (0)	0 (0)	**3 (2)**
Other chronic illness	1 (2)	3 (4)	0 (0)	0 (0)	0 (0)	1 (25)	**5 (3)**
Pulm: Pulmonary embolism	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (1)**
Pulm: Respiratory failure	1 (2)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	**2 (1)**
Renal failure	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (1)**
RV failure	0 (0)	0 (0)	3 (8)	1 (14)	1 (17)	0 (0)	**5 (3)**
Sudden unexplained death	2 (3)	2 (3)	0 (0)	0 (0)	0 (0)	0 (0)	**4 (2)**
Suicide	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	**1 (1)**
Trauma/accident	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (1)**
Vtach/Vfib	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (1)**
Heart failure (after device explant)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	**1 (1)**
Bleeding (after device explant)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (1)**
Multi organ failure (after device explant)	1 (2)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	**2 (1)**
Other haemorrhage	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (1)**
Other	16 (25)	20 (29)	9 (24)	1 (14)	2 (33)	1 (25)	**49 (26)**
Not reported	9 (14)	8 (11)	5 (14)	1 (14)	0 (0)	2 (50)	**25 (13)**

Table 3.2b Causes of post-transplant death for patients who received a first long-term device, 1 April 2004 to 31 March 2014, by implant centre

	Newcastle N (%)	Harefield N (%)	Papworth N (%)	Manchester N (%)	Birmingham N (%)	Glasgow N (%)	Total N (%)
Number	10	12	3	1	0 (0)	1	**27**
Haemorrhage: Other	1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (4)**
Intraop: Not haemorrhage - other	1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (4)**
Renal failure	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (4)**
Heart failure (after device explant)	1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (4)**
Multi organ failure (after device explant)	0 (0)	3 (25)	0 (0)	0 (0)	0 (0)	0 (0)	**3 (11)**
Other	2 (20)	3 (25)	3 (100)	0 (0)	0 (0)	1 (100)	**9 (33)**
Not reported	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)	0 (0)	**1 (4)**
Sudden unexplained cardiac death	1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (4)**
Cerebro-vascular accident	1 (10)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	**2 (7)**
Early graft dysfunction	3 (30)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**3 (11)**
Multi-system failure	0 (0)	3 (25)	0 (0)	0 (0)	0 (0)	0 (0)	**3 (11)**
Donor organ failure	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (4)**

The outcomes of long-term VAD recipients presented in **Table 3.1** shows the latest status for each patient as at 10 December 2014. However, this does not take into account the variable lengths of follow-up. This data is presented in **Figure 3.1a** and **Table 3.3a** using competing risks methodology to estimate the cumulative incidence of transplant, explant, death or remaining on support over time. **Figure 3.1a** shows the cumulative incidence curves for the national data along with one, two and five-year estimates for the whole cohort. At two-years, it was estimated that 36% of patients remained on support, 22% were transplanted, 7% explanted and 35% had died on support. **Table 3.3a** shows the one-year estimates by centre.

Figure 3.1b shows the cumulative incidence curves for third generation devices only whilst **Table 3.3b** shows the one-year estimates by centre. Birmingham and Glasgow have not implanted any third generation devices whilst the information for Manchester is not presented due to the small number of third generation VADs implanted (n=5). Manchester data is, however, included when calculating the overall one-year incidence rates.

Figure 3.1a Cumulative incidence of transplant, explant, death or remaining on support after implant of first long-term VAD, 1 April 2004 to 31 March 2014

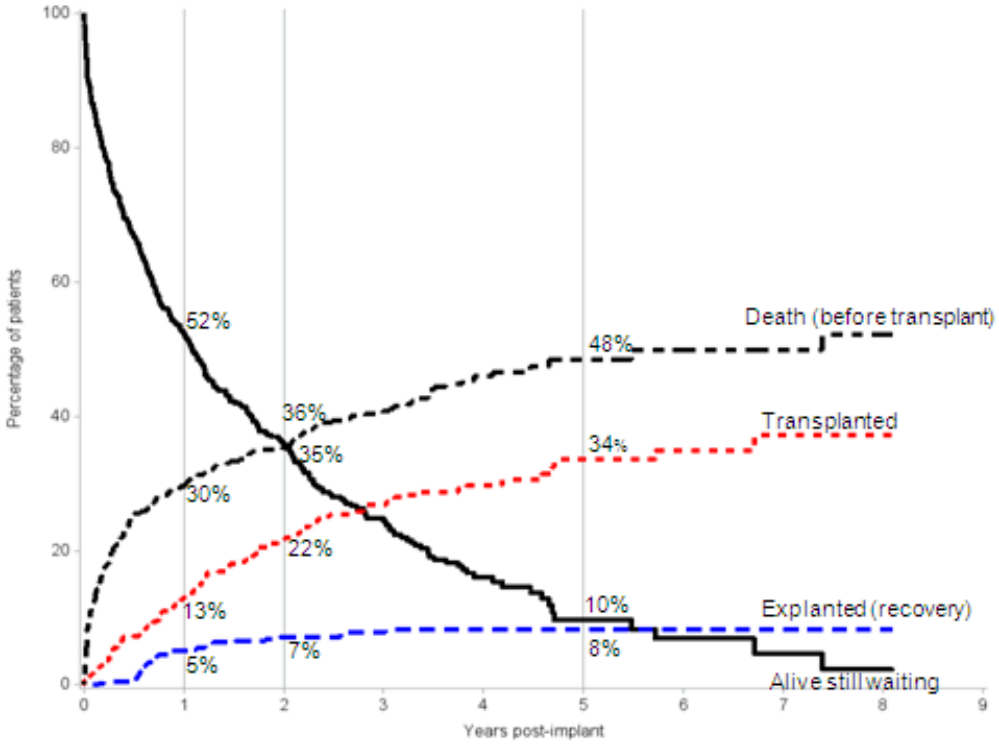


Table 3.3a One-year cumulative incidence of each outcome, by implant centre, 1 April 2004 to 31 March 2014					
Hospital	No. at risk on day 0	Transplant	Explant	Alive on support	Death (before transplant)
Newcastle	137	13%	2%	55%	30%
Papworth	91	23%	1%	43%	33%
Harefield	160	8%	11%	54%	28%
Birmingham	16	8%	0%	51%	41%
Manchester	24	12%	0%	71%	17%
Glasgow	10	10%	10%	40%	40%
All centres	**437**	**13%**	**5%**	**52%**	**30%**

Figure 3.1b Cumulative incidence of transplant, explant, death or remaining on support after implant of first third generation long-term VAD, 1 April 2004 to 31 March 2014

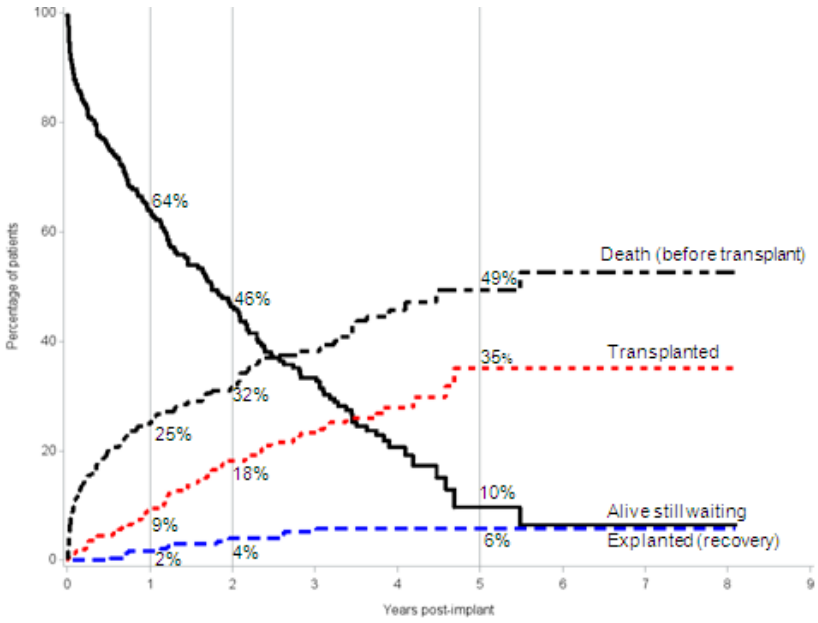


Table 3.3b One-year cumulative incidence of each outcome for third generation devices, by implant centre, 1 April 2004 to 31 March 2014					
Hospital	No. at risk on day 0	Transplant	Explant	Alive on support	Death (before transplant)
Newcastle	113	5%	3%	66%	26%
Papworth	66	15%	0%	59%	26%
Harefield	62	10%	2%	66%	22%
All centres	**246**	**9%**	**2%**	**64%**	**25%**

Centre specific cumulative incidence rates for Manchester are not presented above but are included in the national rate

Table 3.4 shows the proportion of patients registered on the heart transplant list prior to VAD implantation by financial year. The proportion by financial year ranged from 19% to 62% (chi-squared p-value=0.0002).

Table 3.4 Heart transplant registration status at long-term VAD implantation, by financial year, 1 April 2004 to 31 March 2014

Financial year	Listed pre-VAD implant	Listed post-VAD implant	Never listed[1]	Total
	N (%)	N (%)	N (%)	**N (%)**
2004/2005	6 (27)	7 (32)	9 (41)	**22 (100)**
2005/2006	10 (40)	10 (40)	5 (20)	**25 (100)**
2006/2007	12 (55)	6 (27)	4 (18)	**22 (100)**
2007/2008	12 (52)	5 (22)	6 (26)	**23 (100)**
2008/2009	16 (43)	11 (30)	10 (27)	**37 (100)**
2009/2010	24 (52)	9 (20)	13 (28)	**46 (100)**
2010/2011	14 (19)	35 (47)	25 (34)	**74 (100)**
2011/2012	21 (32)	21 (32)	24 (36)	**66 (100)**
2012/2013	37 (62)	14 (23)	9 (15)	**60 (100)**
2013/2014	37 (59)	15 (24)	11 (17)	**63 (100)**
Total	**189 (43)**	**133 (30)**	**116 (27)**	**438 (100)**

[1] As at 10 December 2014

Figure 3.2 shows the Kaplan-Meier incidence curves for time from implant to registration for the subset of patients who were not registered on the transplant list at time of implant. The survival time for patients who had their VADs explanted prior to registration or died on support without being registered were censored at the point of explantation or death.

Figure 3.2 Time from implant of first long-term VAD to registration on the heart transplant list for patients not registered on transplant list at time of receiving first long-term device, 1 April 2004 to 31 March 2014

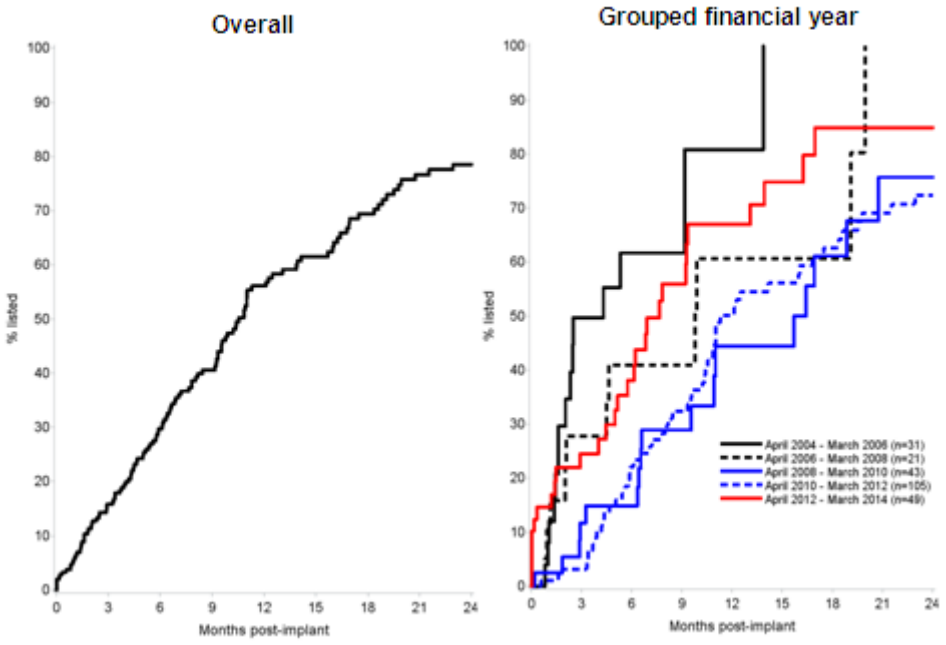


Table 3.5 shows the estimated proportion of patients listed in different time periods for the subset of patients who were not registered on the heart transplant list at time of implant. Overall, an estimated 30% of those not on the list at time of implant were registered within 6 months and 79% within 2 years. There was a statistically significant difference between the grouped financial years (log-rank p-value<0.0001).

Table 3.5 Survival estimates for time from first long-term VAD to registration on transplant list for patients not registered prior to receiving a first long-term device, 1 April 2004 to 31 March 2014

Grouped financial year	No. at risk on day 0	% listed post-implant (95% confidence interval) 6 months		1 year		2 years	
April 2004 – March 2006	31	62	(41 – 82)	81	(49 – 98)	100	(-)
April 2006 – March 2008	21	41	(22 – 68)	61	(36 – 86)	100	(-)
April 2008 – March 2010	43	15	(6 – 32)	44	(27 – 66)	76	(54 – 93)
April 2010 – March 2012	105	22	(15 – 33)	50	(40 – 62)	72	(61 – 82)
April 2012 – March 2014	49	38	(25 – 55)	67	(51 – 82)	85	(68 – 96)
Log-rank p-value		<0.0001		0.0001		<0.0001	
All centres	**249**	**30**	**(24 – 37)**	**56**	**(49 – 64)**	**79**	**(71 – 85)**
Number at risk		126		59		20	

Table 3.6 shows the long-term VAD duration of support. Overall, the long-term VAD duration of support ranged between 0 and 2955 days (eight years). Using the Kaplan-Meier estimation method, median long-term VAD duration for all patients was estimated to be 396 days (95% CI: 322, 470).

Table 3.6 Long-term VAD duration, by implant centre, 1 April 2004 to 31 March 2014

Hospital	No. of implants	No. missing	Range	Median	(95% confidence interval)
Newcastle	137	0	0 - 2093	450	(240, 660)
Papworth	91	0	1 - 2185	262	(109, 415)
Harefield	160	0	1 - 2955	402	(297, 507)
Birmingham	16	0	41 - 824	443	(202, 684)
Manchester	24	0	24 - 1470	416	(0, 915)
Glasgow	10	0	2 - 1015	204	(7, 401)
All centres	**438**	**0**	**0 - 2955**	**396**	**(322, 470)**

Table 3.7a shows Kaplan-Meier estimates of patient survival from time of first implant to death for the whole time period whilst **Table 3.7b** shows the Kaplan-Meier estimates for the most recent three year time period. Patients still alive were censored at the date of last follow-up. Other events such as device explantation or transplantation were not censored. Care should be taken when interpreting survival estimates for Birmingham, Manchester and Glasgow due to the small number of patients at risk. This is reflected in the wide confidence intervals.

Table 3.7a Patient survival after implant of long-term VAD, by implant centre, 1 April 2004 to 31 March 2014

Centre	No. at risk on day 0	% patient survival (95% confidence interval) 30 days		90 days		1 year		2 years		3 years	
Newcastle	137	86	(79 - 91)	80	(72 - 85)	67	(58 - 74)	56	(47 - 64)	50	(41 - 58)
Papworth	91	90	(82 - 95)	80	(70 - 87)	66	(55 - 75)	60	(49 - 69)	58	(47 - 68)
Harefield	160	88	(82 - 92)	81	(74 - 86)	70	(62 - 76)	60	(52 - 67)	52	(43 - 59)
Birmingham	16	100	(-)	94	(63 - 99)	57	(27 - 79)	57	(27 - 79)	57	(27 - 79)
Manchester	24	92	(71 - 98)	88	(66 - 96)	79	(57 - 91)	68	(44 - 84)	58	(31 - 78)
Glasgow	10	80	(41 - 95)	70	(33 - 89)	50	(18 - 75)	50	(18 - 75)	50	(18 - 75)
All centres	**438**	**88**	**(85 - 91)**	**81**	**(77 - 84)**	**68**	**(63 - 72)**	**59**	**(54 - 63)**	**53**	**(48 - 58)**
Number at risk		387		356		279		209		157	

Table 3.7b Patient survival after implant of long-term VAD, by implant centre, 1 April 2011 to 31 March 2014

Centre	No. at risk on day 0	% patient survival (95% confidence interval) 30 days		90 days		1 year		2 years		3 years	
Newcastle	60	83	(71 - 91)	78	(66 - 87)	73	(60 - 82)	58	(43 - 70)	48	(32 - 62)
Papworth	32	91	(74 - 97)	88	(70 - 95)	66	(47 - 79)	57	(37 - 73)	57	(37 - 73)
Harefield	55	87	(75 - 94)	78	(65 - 87)	67	(53 - 78)	57	(42 - 69)	49	(32 - 63)
Birmingham	16	100	(-)	94	(63 - 99)	57	(27 - 79)	57	(27 - 79)	57	(27 - 79)
Manchester	18	94	(67 - 99)	89	(62 - 97)	78	(51 - 91)	61	(30 - 81)	-	(-)
Glasgow	8	75	(31 - 93)	63	(23 - 86)	50	(15 - 77)	50	(15 - 77)	50	(15 - 77)
All centres	**189**	**88**	**(82 - 92)**	**81**	**(75 - 86)**	**68**	**(61 - 75)**	**58**	**(50 - 65)**	**51**	**(42 - 59)**
Number at risk		166		155		111		60		23	

Table 3.8a shows Kaplan-Meier estimates of patient survival during VAD support for the whole ten year time period whilst **Table 3.8b** shows the survival estimates for the most recent three years. Unlike the survival estimates in **Table 3.7**, survival was censored at time of device explantation or transplantation. The survival during VAD support was similar to the overall patient survival due to the majority of patients either being on support at last follow-up or dying whilst on VAD support, and survival during VAD support is identical to overall patient survival in these cases. Again, care should be taken when interpreting survival estimates for Birmingham, Manchester and Glasgow due to the small number of patients at risk.

Table 3.8a Survival during long-term VAD support, by implant centre, 1 April 2004 to 31 March 2014

Centre	No. at risk on day 0	% survival on a device (95% confidence interval) 30 days		90 days		1 year		2 years		3 years	
Newcastle	137	86	(79 - 91)	80	(72 - 86)	68	(59 - 75)	60	(50 - 68)	50	(40 - 60)
Papworth	91	90	(82 - 95)	81	(71 - 88)	64	(52 - 73)	54	(41 - 66)	54	(41 - 66)
Harefield	160	88	(82 - 92)	81	(74 - 86)	72	(65 - 79)	63	(54 - 71)	49	(38 - 59)
Birmingham	16	100	(-)	94	(63 - 99)	57	(27 - 79)	57	(27 - 79)	-	(-)
Manchester	24	92	(71 - 98)	88	(66 - 96)	83	(61 - 93)	77	(53 - 90)	58	(19 - 84)
Glasgow	10	80	(41 - 95)	70	(33 - 89)	60	(25 - 83)	60	(25 - 83)	-	(-)
All centres	**438**	**88**	**(85 - 91)**	**81**	**(77 - 85)**	**69**	**(64 - 73)**	**61**	**(56 - 66)**	**51**	**(45 - 57)**
Number at risk		379		341		212		123		67	

Table 3.8b Survival during long-term VAD support, by implant centre, 1 April 2011 to 31 March 2014

Centre	No. at risk on day 0	% survival on a device (95% confidence interval) 30 days		90 days		1 year		2 years		3 years	
Newcastle	60	83	(71 - 91)	80	(67 - 88)	74	(60 - 83)	64	(49 - 76)	49	(30 - 66)
Papworth	32	91	(74 - 97)	91	(74 - 97)	68	(49 - 81)	56	(35 - 74)	56	(35 - 74)
Harefield	55	87	(75 - 94)	79	(66 - 88)	69	(54 - 80)	56	(40 - 69)	49	(30 - 65)
Birmingham	16	100	(-)	94	(63 - 99)	57	(27 - 79)	57	(27 - 79)	-	(-)
Manchester	18	94	(67 - 99)	89	(62 - 97)	83	(55 - 94)	74	(44 - 90)	-	(-)
Glasgow	8	75	(31 - 93)	63	(23 - 86)	50	(15 - 77)	50	(15 - 77)	-	(-)
All centres	**189**	**88**	**(82 - 92)**	**83**	**(77 - 88)**	**70**	**(63 - 76)**	**60**	**(52 - 68)**	**51**	**(39 - 61)**
Number at risk		163		151		101		44		12	

Table 3.9a and **Table 3.9b** compare patient survival for patients receiving an LVAD only with those receiving both an LVAD and an RVAD (BiVAD). There is evidence of a difference in survival between the two groups (log-rank test, p<0.0001). However, treatment has not been randomised and the pre-implant illness was more severe in the BiVAD group. **Table 3.10a** and **Table 3.10b** shows estimated survival whilst on support, which is similar to the patient survival estimates.

Table 3.9a Patient survival after implant of long-term VAD, by LVAD/BiVAD, 1 April 2004 to 31 March 2014

Device	No. at risk on day 0	% patient survival (95% confidence interval) 30 days		90 days		1 year		2 years		3 years	
LVAD only	354	92	(88 - 94)	86	(81 - 89)	72	(67 - 77)	64	(58 - 68)	57	(51 - 62)
BiVAD	84	75	(64 - 83)	61	(49 - 70)	50	(39 - 60)	40	(29 - 50)	36	(26 - 46)
Overall	**438**	**88**	**(85 - 91)**	**81**	**(77 - 84)**	**68**	**(63 - 72)**	**59**	**(54 - 63)**	**53**	**(48 - 58)**
Number at risk		387		356		279		209		157	

Table 3.9b Patient survival after implant of long-term VAD, by LVAD/BiVAD, 1 April 2011 to 31 March 2014

Device	No. at risk on day 0	% patient survival (95% confidence interval) 30 days		90 days		1 year		2 years		3 years	
LVAD only	167	91	(86 - 94)	85	(79 - 90)	72	(64 - 78)	62	(53 - 69)	54	(44 - 63)
BiVAD	22	64	(40 - 80)	55	(32 - 72)	45	(24 - 64)	30	(13 - 50)	30	(13 - 50)
Overall	**189**	**88**	**(82 - 92)**	**81**	**(75 - 86)**	**68**	**(61 - 75)**	**58**	**(50 - 65)**	**51**	**(42 - 59)**
Number at risk		166		155		111		60		23	

Table 3.10a Survival during long-term VAD support, by LVAD/BiVAD, 1 April 2004 to 31 March 2014

Device	No. at risk on day 0	% survival on a device (95% confidence interval) 30 days		90 days		1 year		2 years		3 years	
LVAD only	354	91	(88 - 94)	86	(82 - 89)	74	(68 - 78)	66	(60 - 71)	56	(49 - 62)
BiVAD	84	74	(63 - 82)	61	(49 - 71)	50	(38 - 60)	37	(25 - 50)	28	(15 - 44)
Overall	**438**	**88**	**(85 - 91)**	**81**	**(77 - 85)**	**69**	**(64 - 73)**	**61**	**(56 - 66)**	**51**	**(45 - 57)**
Number at risk		379		341		212		123		67	

Table 3.10b Survival during long-term VAD support, by LVAD/BiVAD, 1 April 2011 to 31 March 2014

Device	No. at risk on day 0	% survival on a device (95% confidence interval) 30 days		90 days		1 year		2 years		3 years	
LVAD only	167	91	(85 - 94)	86	(80 - 91)	73	(65 - 79)	65	(57 - 72)	54	(42 - 66)
BiVAD	22	63	(39 - 80)	58	(35 - 76)	48	(25 - 67)	24	(7 - 47)	24	(7 - 47)
Overall	**189**	**88**	**(82 - 92)**	**83**	**(77 - 88)**	**70**	**(63 - 76)**	**60**	**(52 - 68)**	**51**	**(39 - 61)**
Number at risk		163		151		101		44		12	

Table 3.11a and **Figure 3.3** compare patient survival for patients receiving a Heartmate II with those receiving a Heartware whilst **Table 3.11b** shows the survival rates for the most recent three years. There is no evidence of a difference in survival between the two groups (log-rank test, p=0.4). **Table 3.12a** and **Table 3.12b** shows estimated survival whilst on support, which is similar to the patient survival estimates.

Table 3.11a Patient survival after implant of long-term VAD, by Heartmate II/ Heartware, 1 April 2004 to 31 March 2014

Device	No. at risk on day 0	% patient survival (95% confidence interval) 30 days		90 days		1 year		2 years		3 years	
Heartmate II	105	90	(83 - 95)	85	(76 - 90)	67	(57 - 75)	58	(47 - 67)	49	(39 - 59)
Heartware	219	88	(83 - 92)	83	(77 - 87)	73	(67 - 79)	63	(56 - 69)	56	(48 - 62)
Overall	**324**	**89**	**(85 - 92)**	**84**	**(79 - 87)**	**71**	**(66 - 76)**	**61**	**(56 - 67)**	**54**	**(48 - 59)**
Number at risk		288		272		213		152		107	

Table 3.11b Patient survival after implant of long-term VAD, by Heartmate II/ Heartware, 1 April 2011 to 31 March 2014

Device	No. at risk on day 0	% patient survival (95% confidence interval) 30 days		90 days		1 year		2 years		3 years	
Heartmate II	52	92	(81 - 97)	85	(72 - 92)	63	(48 - 75)	55	(40 - 68)	55	(40 - 68)
Heartware	124	85	(78 - 91)	80	(72 - 86)	71	(62 - 78)	58	(49 - 67)	50	(38 - 60)
Overall	**176**	**88**	**(82 - 92)**	**81**	**(75 - 86)**	**68**	**(61 - 75)**	**57**	**(49 - 65)**	**51**	**(42 - 60)**
Number at risk		154		143		102		54		23	

Figure 3.3 Overall patient survival after implant of long-term VAD, by device type 1 April 2004 to 31 March 2014

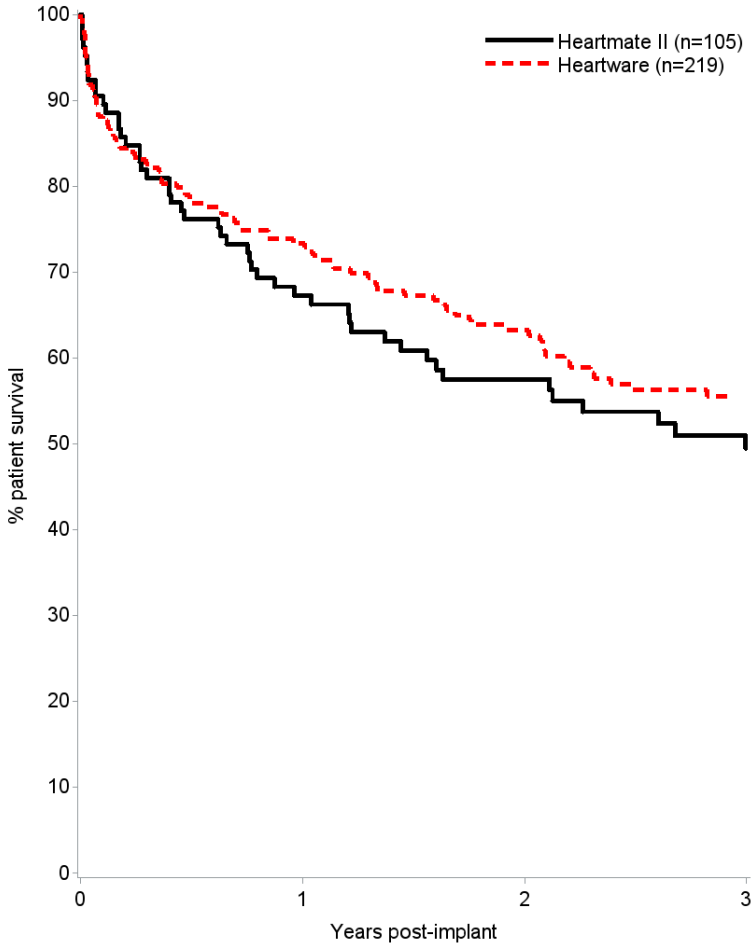


Table 3.12a Survival during long-term VAD support, by Heartmate II/ Heartware, 1 April 2004 to 31 March 2014

Device	No. at risk on day 0	% survival on a device (95% confidence interval) 30 days		90 days		1 year		2 years		3 years	
Heartmate II	105	90	(83 - 95)	85	(76 - 90)	72	(62 - 80)	63	(52 - 73)	48	(33 - 61)
Heartware	219	88	(83 - 92)	84	(79 - 89)	74	(68 - 79)	66	(58 - 72)	55	(46 - 62)
Overall	**324**	**89**	**(85 - 92)**	**84**	**(80 - 88)**	**73**	**(68 - 78)**	**65**	**(59 - 70)**	**53**	**(46 - 60)**
Number at risk		284		268		181		110		59	

Table 3.12b Survival during long-term VAD support, by Heartmate II/ Heartware, 1 April 2011 to 31 March 2014

Device	No. at risk on day 0	% survival on a device (95% confidence interval) 30 days		90 days		1 year		2 years		3 years	
Heartmate II	52	92	(81 - 97)	84	(71 - 92)	66	(51 - 77)	60	(44 - 73)	60	(44 - 73)
Heartware	124	85	(78 - 90)	82	(74 - 88)	72	(63 - 80)	61	(51 - 70)	48	(33 - 61)
Overall	**176**	**87**	**(81 - 92)**	**83**	**(76 - 88)**	**70**	**(63 - 77)**	**61**	**(52 - 68)**	**51**	**(38 - 62)**
Number at risk		151		141		94		42		12	

SHORT TERM DEVICES USED FOR BRIDGING

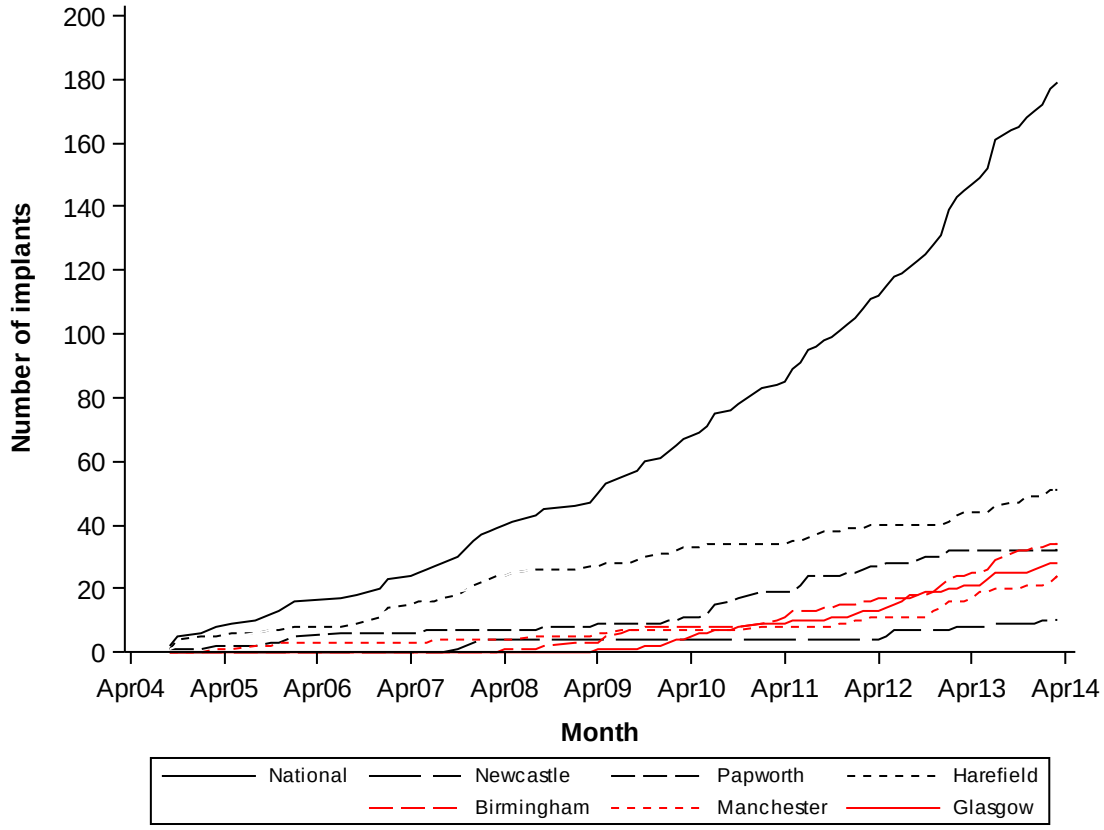
Activity

This section considers patients whose first device was a short-term device. Patients who received a long-term device prior to the short-term device are reported in the long-term section. Data are presented for devices implanted up to 31 March 2014 for all centres apart from Papworth for whom data are presented for devices implanted up to 31 March 2013. One hundred and eighty one patients[1] received a short-term device for bridging at six adult implant centres in the UK between 1 April 2004 and 31 March 2014. Eleven patients received devices at Newcastle, 51 at Harefield, 33[1] at Papworth, 34 at Birmingham, 28 at Glasgow and 24 at Manchester.

Of the 181 patients, one patient at Newcastle and one at Papworth received a total artificial heart (TAH) following a short-period of ECMO only support. Both patients died on the TAH less than a month post-implant. These patients are excluded from this section.

Figure 4.1 shows the cumulative number of VADs implanted each month, overall and by centre, whilst **Figure 4.2** shows the number of VADs by financial year and centre. VAD activity has increased at all centres.

Figure 4.1 Cumulative short-term VAD activity, by month and implant centre, 1 April 2004 to 31 March 2014[1]



[1] Data up to 31 March 2013 included for Papworth

Figure 4.2 Short-term VAD activity, by financial year and implant centre, 1 April 2004 to 31 March 2014[1]

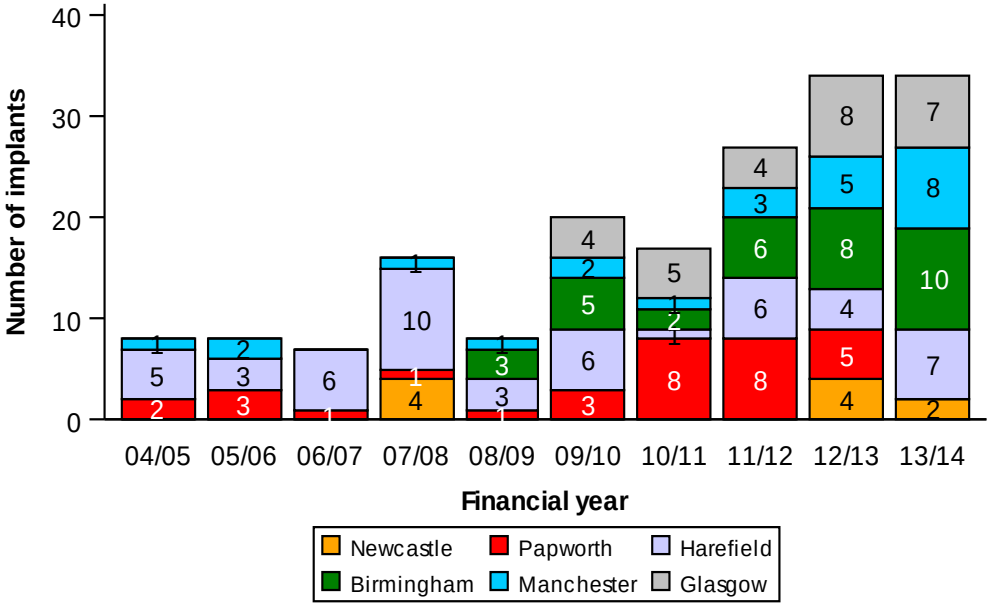
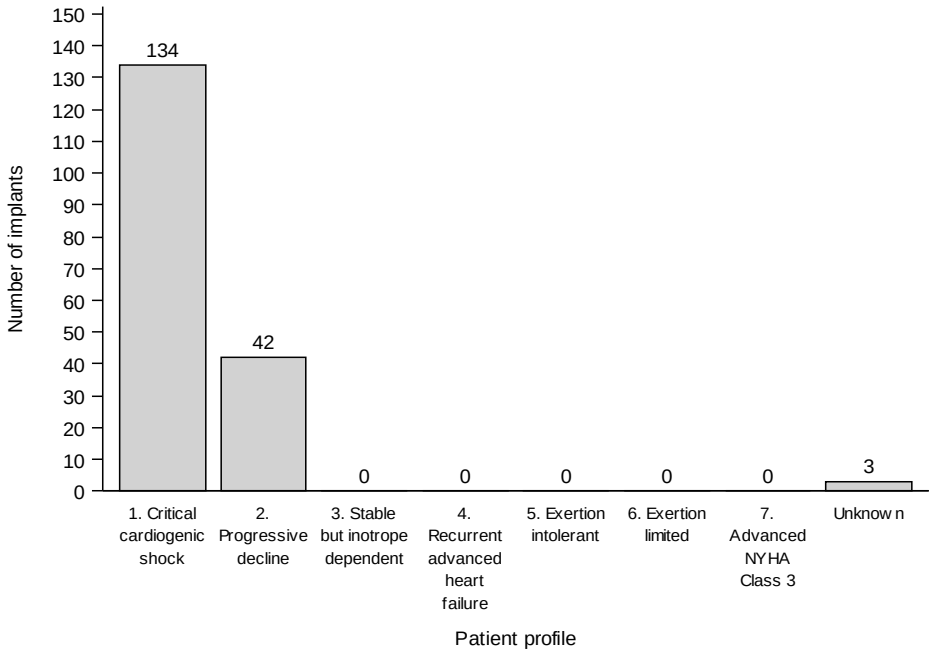


Figure 4.3 shows the INTERMACS patient profile at time of VAD implantation. This shows that 98% of patients were profile 1 (cardiogenic shock) or profile 2 (progressive decline).

Figure 4.3 INTERMACS patient profile, by financial year and implant centre, 1 April 2004 to 31 March 2014[1]



[1] Data up to 31 March 2013 included for Papworth

Table 4.1 shows the characteristics of patients whose first device was a short-term device by implant centre. Overall, the most frequently reported cardiothoracic diseases were dilated cardiomyopathy (56%) and ischaemic heart disease (30%). The overall median age at implant was 42 years (inter-quartile range 28 - 50 years) and the majority of recipients were male (64%). 79% were on inotropes at time of VAD implant whilst 57% received an IABP prior to VAD implant.

Table 4.2 shows that the devices used were Centrimag (59%), ECMO only (40%) and Impella (1%). Overall 67% received only one short-term device or ECMO. The device history for all first short-term device patients is also outlined in sequence in **Table 4.2**.

Table 4.1	Characteristics of patients who received a short-term device for bridging, 1 April 2004 to 31 March 2014[1], by implant centre							
		Newcastle N (%)	Harefield N (%)	Papworth N (%)	Manchester N (%)	Birmingham N (%)	Glasgow N (%)	Total N (%)
Number		10	51	32	24	34	28	**179**
Recipient sex	Male	5 (50)	38 (75)	24 (75)	15 (63)	20 (59)	12 (43)	**114 (64)**
	Female	5 (50)	13 (25)	8 (25)	9 (38)	14 (41)	16 (57)	**65 (36)**
Recipient age	Median (IQR)	51 (37-57)	37 (26-49)	43 (28.5-51)	39.5 (29-45.5)	38 (27-49)	45 (32-50.5)	**42 (28-50)**
	Missing	0	0	0	0	0	0	**0**
Cardiothoracic disease	Dilated cardiomyopathy	3 (30)	34 (67)	18 (56)	13 (54)	23 (68)	10 (36)	**101 (56)**
	Ischaemic heart disease	4 (40)	12 (24)	11 (34)	10 (42)	8 (24)	8 (29)	**53 (30)**
	Congenital heart disease	1 (10)	2 (4)	0 (0)	0 (0)	1 (3)	0 (0)	**4 (2)**
	Hypertrophic cardiomyopathy	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (7)	**2 (1)**
	Restrictive cardiomyopathy	0 (0)	3 (6)	1 (3)	0 (0)	0 (0)	0 (0)	**4 (2)**
	Valvular heart disease	0 (0)	0 (0)	1 (3)	0 (0)	1 (3)	1 (4)	**3 (2)**
	Other	2 (20)	0 (0)	1 (3)	1 (4)	0 (0)	4 (14)	**8 (4)**
	Unknown	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	3 (11)	**4 (2)**
INTERMACS patient profile	1. Critical cardiogenic shock	7 (70)	31 (61)	25 (78)	20 (83)	34 (100)	17 (61)	**134 (75)**
	2. Progressive decline	3 (30)	19 (37)	7 (22)	2 (8)	0 (0)	11 (39)	**42 (23)**
	3. Stable but inotrope dependent	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**0 (0)**
	4. Recurrent advanced heart failure	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**0 (0)**
	5. Exertion intolerant	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**0 (0)**
	6. Exertion limited	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**0 (0)**
	7. Advanced NYHA Class 3	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**0 (0)**
	Unknown	0 (0)	1 (2)	0 (0)	2 (8)	0 (0)	0 (0)	**3 (2)**
Treatment history prior to long-term VAD implant	None	1 (10)	1 (2)	2 (6)	0 (0)	1 (3)	0 (0)	**5 (3)**
	VAD/ECMO only	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (1)**
	IABP only	0 (0)	0 (0)	1 (3)	1 (4)	0 (0)	3 (11)	**5 (3)**
	Inotropes only	2 (20)	15 (29)	10 (31)	2 (8)	7 (21)	4 (14)	**40 (22)**
	VAD/ECMO+inotropes	0 (0)	3 (6)	0 (0)	0 (0)	0 (0)	0 (0)	**3 (2)**
	IABP,inotropes	4 (40)	19 (37)	14 (44)	13 (54)	21 (62)	10 (36)	**81 (45)**
	VAD/ECMO, IABP,inotropes	0 (0)	5 (10)	1 (3)	0 (0)	0 (0)	0 (0)	**6 (3)**
	Unknown	3 (30)	7 (14)	4 (13)	8 (33)	5 (15)	11 (39)	**38 (21)**

[1] Data up to 31 March 2013 included for Papworth

Table 4.2 Device type and history of patients who received a short-term device for bridging, 1 April 2004 to 31 March 2014[1], by implant centre

		Newcastle N (%)	Harefield N (%)	Papworth N (%)	Manchester N (%)	Birmingham N (%)	Glasgow N (%)	Total N (%)
Number		10	51	32	24	34	28	**179**
Device name	Impella	0 (0)	0 (0)	0 (0)	0 (0)	2 (6)	0 (0)	**2 (1)**
	Centrimag	5 (50)	43 (84)	16 (50)	12 (50)	11 (32)	18 (64)	**105 (59)**
	ECMO only	5 (50)	8 (16)	16 (50)	12 (50)	21 (62)	10 (36)	**72 (40)**
Device history	ECMO	2 (20)	0 (0)	10 (31)	3 (13)	14 (41)	7 (25)	**36 (20)**
	ECMO-ECMO	0 (0)	0 (0)	0 (0)	1 (4)	0 (0)	0 (0)	**1 (1)**
	ECMO-LT	2 (20)	7 (14)	2 (6)	1 (4)	3 (9)	1 (4)	**16 (9)**
	ECMO-ST	1 (10)	1 (2)	4 (13)	5 (21)	4 (12)	1 (4)	**16 (9)**
	ECMO-ST-LT	0 (0)	0 (0)	0 (0)	2 (8)	0 (0)	1 (4)	**3 (2)**
	ST	5 (50)	26 (51)	16 (50)	10 (42)	13 (38)	14 (50)	**84 (47)**
	ST-LT	0 (0)	16 (31)	0 (0)	0 (0)	0 (0)	4 (14)	**20 (11)**
	ST-LT-LT	0 (0)	1 (2)	0 (0)	1 (4)	0 (0)	0 (0)	**2 (1)**
	ST-ST-LT	0 (0)	0 (0)	0 (0)	1 (4)	0 (0)	0 (0)	**1 (1)**

ST-LT indicates that a patient received a short-term device and then a long-term device following explantation of the short-term device

[1] Data up to 31 March 2013 included for Papworth

SHORT TERM DEVICES USED FOR BRIDGING

Patient Outcomes

Patient outcomes presented in this section are split into three groups based on devices received; ECMO only, short-term devices and bridge to long-term device. The short-term devices group consists of patients who received either only short-term devices or both ECMO and a short term device at different points in time.

Tables 5.1a, 5.1b and **5.1c** show the final VAD outcome of recipients, by centre and devices received. Nationally for ECMO only and short-term device patients, 46 patients were transplanted, 23 survived explantation of the VAD, 58 died on support, 9 died shortly after explantation and 1 patient was still on support at 10 December 2014. 42 patients were bridged to a long-term device When combining activity across the three device groups, the overall number of patients alive at time of analysis was 84 out of 179 (47%).

Table 5.1a **Outcome for patients who received short-term devices only, by implant centre, 1 April 2004 to 31 March 2014**

	Newcastle		Papworth		Harefield		Birmingham		Manchester		Glasgow		Total	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Alive (post transplant)	1	(17)	10	(50)	5	(19)	6	(35)	6	(40)	2	(13)	**30**	**(30)**
Alive (post explant)	0	(0)	1	(5)	5	(19)	2	(12)	0	(0)	5	(33)	**13**	**(13)**
Alive with VAD	0	(0)	0	(0)	0	(0)	0	(0)	1	(7)	0	(0)	**1**	**(1)**
Total alive	*1*	*(17)*	*11*	*(55)*	*10*	*(37)*	*8*	*(47)*	*7*	*(47)*	*7*	*(47)*	***44***	***(44)***
Died (post transplant)	0	(0)	1	(5)	0	(0)	2	(12)	1	(7)	0	(0)	**4**	**(4)**
Died (post explant)	1	(17)	1	(5)	2	(7)	2	(12)	0	(0)	2	(13)	**8**	**(8)**
Died with VAD	4	(67)	7	(35)	15	(56)	5	(29)	7	(47)	6	(40)	***44***	***(44)***
Total died	*5*	*(83)*	*9*	*(45)*	*17*	*(63)*	*9*	*(53)*	*8*	*(53)*	*8*	*(53)*	***56***	***(56)***
TOTAL	**6**	**(100)**	**20**	**(100)**	**27**	**(100)**	**17**	**(100)**	**15**	**(100)**	**15**	**(100)**	**100**	**(100)**

Table 5.1b **Outcome for patients who received ECMO only, by implant centre, 1 April 2004 to 31 March 2014**

	Newcastle		Papworth		Harefield		Birmingham		Manchester		Glasgow		Total	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Alive (post transplant)	0	(0)	2	(20)	0	(0)	4	(29)	1	(25)	1	(14)	**8**	**(22)**
Alive (post explant)	2	(100)	3	(30)	0	(0)	3	(21)	0	(0)	2	(29)	**10**	**(27)**
Alive with VAD	0	(0)	0	(0)	0	(0)	0	(0)	0	(0)	0	(0)	**0**	**(0)**
Total alive	*2*	*(100)*	*5*	*(50)*	*0*	*(0)*	*7*	*(50)*	*1*	*(25)*	*3*	*(43)*	***18***	***(49)***
Died (post transplant)	0	(0)	0	(0)	0	(0)	4	(29)	0	(0)	0	(0)	**4**	**(11)**
Died (post explant)	0	(0)	0	(0)	0	(0)	0	(0)	0	(0)	1	(14)	**1**	**(3)**
Died with VAD	0	(0)	5	(50)	0	(0)	3	(21)	3	(75)	3	(43)	**14**	**(38)**
Total died	*0*	*(0)*	*5*	*(50)*	*0*	*(0)*	*7*	*(50)*	*3*	*(75)*	*4*	*(57)*	***19***	***(51)***
TOTAL	**2**	**(100)**	**10**	**(100)**	**0**	**(0)**	**14**	**(100)**	**4**	**(100)**	**7**	**(100)**	**37**	**(100)**

Table 5.1c	Outcome for patients who received bridged to long-term devices, by implant centre, 1 April 2004 to 31 March 2014													
	Newcastle		Papworth		Harefield		Birmingham		Manchester		Glasgow		Total	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Alive (post transplant)	0	(0)	1	(50)	5	(21)	1	(33)	2	(40)	1	(17)	**10**	**(24)**
Alive (post explant)	0	(0)	0	(0)	3	(13)	0	(0)	0	(0)	1	(17)	**4**	**(10)**
Alive with VAD	0	(0)	0	(0)	5	(21)	1	(33)	1	(20)	1	(17)	**8**	**(19)**
Total alive	*0*	*(0)*	*1*	*(50)*	*13*	*(54)*	*2*	*(67)*	*3*	*(60)*	*3*	*(50)*	***22***	***(52)***
Died (post transplant)	1	(50)	1	(50)	1	(4)	0	(0)	0	(0)	0	(0)	**3**	**(7)**
Died (post explant)	0	(0)	0	(0)	1	(4)	0	(0)	0	(0)	0	(0)	**1**	**(2)**
Died with VAD	1	(50)	0	(0)	9	(38)	1	(33)	2	(40)	3	(50)	**16**	**(38)**
Total died	*2*	*(100)*	*1*	*(50)*	*11*	*(46)*	*1*	*(33)*	*2*	*(40)*	*3*	*(50)*	***20***	***(48)***
TOTAL	**2**	**(100)**	**2**	**(100)**	**24**	**(100)**	**3**	**(100)**	**5**	**(100)**	**6**	**(100)**	**42**	**(100)**

Tables 5.2a, 5.2b and **5.2c** show the causes of death, by centre and devices received, for all patients who sadly died. Deaths which occur more than one year post-transplant or explant are not referenced in these tables.

Table 5.2a Causes of death for patients who received a short-term device only, 1 April 2004 to 31 March 2014, by implant centre

	Newcastle N (%)	Harefield N (%)	Papworth N (%)	Manchester N (%)	Birmingham N (%)	Glasgow N (%)	Total N (%)
Number	5	17	9	8	9	8	**56**
Arterial embolism	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (13)	**1 (2)**
Cardiovascular: Myocardial infarction	1 (20)	1 (6)	0 (0)	2 (25)	0 (0)	1 (13)	**5 (9)**
Cardiovascular: Other	1 (20)	3 (18)	0 (0)	0 (0)	0 (0)	1 (13)	**5 (9)**
CNS cause of death	1 (20)	2 (12)	3 (33)	1 (13)	0 (0)	1 (13)	**8 (14)**
Haemorrhage: Post-operative surgery related	0 (0)	0 (0)	1 (11)	0 (0)	0 (0)	1 (13)	**2 (4)**
Haemorrhage: Other	0 (0)	3 (18)	1 (11)	0 (0)	0 (0)	0 (0)	**4 (7)**
Cardiogenic shock (after device explant)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (13)	**1 (2)**
Infection (after device explant)	0 (0)	0 (0)	0 (0)	0 (0)	1 (11)	0 (0)	**1 (2)**
Multi organ failure (after device explant)	0 (0)	0 (0)	0 (0)	3 (38)	0 (0)	0 (0)	**3 (5)**
Other causes of cardiac failure	0 (0)	0 (0)	0 (0)	0 (0)	1 (11)	0 (0)	**1 (2)**
Pulmonary infection (bacterial)	0 (0)	0 (0)	1 (11)	0 (0)	1 (11)	0 (0)	**2 (4)**
Other	1 (20)	8 (47)	3 (33)	1 (13)	4 (44)	1 (13)	**18 (32)**
Not reported	1 (20)	0 (0)	0 (0)	1 (13)	2 (22)	1 (13)	**5 (9)**

Table 5.2b Causes of death for patients who received a ECMO only, 1 April 2004 to 31 March 2014, by implant centre

	Newcastle N (%)	Harefield N (%)	Papworth N (%)	Manchester N (%)	Birmingham N (%)	Glasgow N (%)	Total N (%)
Number	0 (0)	0 (0)	5	3	7	4	**19**
Cardiovascular: Myocardial infarction	0 (0)	0 (0)	0 (0)	1 (33)	0 (0)	0 (0)	**1 (5)**
Cardiovascular: Other	0 (0)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	**1 (5)**
CNS cause of death	0 (0)	0 (0)	1 (20)	0 (0)	0 (0)	0 (0)	**1 (5)**
Infection	0 (0)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	**1 (5)**
Multi organ failure (after device explant)	0 (0)	0 (0)	0 (0)	1 (33)	0 (0)	1 (25)	**2 (11)**
Early graft dysfunction	0 (0)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	**1 (5)**
Other	0 (0)	0 (0)	3 (60)	1 (33)	3 (43)	2 (50)	**9 (47)**
Not reported	0 (0)	0 (0)	1 (20)	0 (0)	1 (14)	1 (25)	**3 (16)**

Table 5.2c Causes of death for patients who were bridged to long-term device, 1 April 2004 to 31 March 2014, by implant centre

	Newcastle N (%)	Harefield N (%)	Papworth N (%)	Manchester N (%)	Birmingham N (%)	Glasgow N (%)	Total N (%)
Number	2	11	1	2	1	3	**20**
Cancer	0 (0)	0 (0)	0 (0)	1 (50)	0 (0)	0 (0)	**1 (5)**
Cardiovascular: Myocardial infarction	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (5)**
Device malfunction	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (5)**
Haemorrhage: Disseminated intravascular coagulation	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (33)	**1 (5)**
Infection	0 (0)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)	**1 (5)**
Pulm: Pulmonary embolism	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (5)**
RV failure	0 (0)	0 (0)	0 (0)	1 (50)	0 (0)	0 (0)	**1 (5)**
Heart failure (after device explant)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (5)**
Cardiogenic shock (after device explant)	1 (50)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (5)**
Multi-system failure	1 (50)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (5)**
Other	0 (0)	5 (45)	1 (100)	0 (0)	0 (0)	2 (67)	**8 (40)**
Not reported	0 (0)	2 (18)	0 (0)	0 (0)	0 (0)	0 (0)	**2 (10)**

Tables 5.3a, 5.3b and **5.3c** shows the short-term VAD duration of support by centre and devices received. Combining all device groups, the short-term VAD duration of support ranged between 0 and 175 days. Using the Kaplan-Meier estimation method, median short-term VAD duration for all patients was estimated to be 16 days (95% CI: 11, 21 days). For those who were bridged onto a long-term device, their subsequent long-term VAD duration ranged from 7 to 1350 days (three years).

Table 5.3a **Short-term VAD duration for patients who received short-term devices only, by implant centre, 1 April 2004 to 31 March 2014**

Centre	No. of implants	No. missing	Range	Median	(95% confidence interval)
Newcastle	6	0	2 - 17	5	(0, 13)
Papworth	20	0	2 - 175	31	(2, 60)
Harefield	27	0	1 - 104	28	(18, 38)
Birmingham	17	0	1 - 50	13	(5, 21)
Manchester	15	0	2 - 110	27	(20, 34)
Glasgow	15	0	1 - 106	24	(21, 27)
All centres	**100**	**0**	**1 - 175**	**23**	**(18, 28)**

Table 5.3b **ECMO only VAD duration, by implant centre, 1 April 2004 to 31 March 2014**

Centre	No. of implants	No. missing	Range	Median	(95% confidence interval)
Newcastle	2	0	4 - 13	4	(-)
Harefield	0	0	-	-	-
Papworth	10	0	0 - 35	5	(0, 10)
Birmingham	14	0	1 - 18	4	(0, 10)
Manchester	4	0	1 - 9	5	(0, 11)
Glasgow	7	0	0 - 10	5	(0, 13)
All centres	**37**	**0**	**0 - 35**	**5**	**(3, 7)**

Table 5.3c	Short-term VAD duration for patients bridged to long-term device, by implant centre, 1 April 2004 to 31 March 2014				
Centre	No. of implants	No. missing	Range	Median	(95% confidence interval)
Newcastle	2	0	2 - 16	2	(-)
Papworth	2	0	3 - 3	3	(-)
Harefield	24	0	2 - 74	28	(24, 32)
Birmingham	3	0	7 - 13	13	(-)
Manchester	5	0	3 - 79	38	(29, 47)
Glasgow	6	0	2 - 64	45	(0, 91)
All centres	**42**	**0**	**2 - 79**	**28**	**(14, 42)**

Table 5.4 shows Kaplan-Meier estimates of overall patient survival from time of first implant to death for patients receiving a short-term VAD or ECMO. Patients still alive were censored at the date of last follow-up. Other events such as device explantation or transplantation were not censored. Patients bridged from ECMO only support to a long-term device were included in the bridged to long-term device group whilst patients who received a short-term device were included in the short-term device group. There is no statistical comparison of the outcomes due to selection bias in the bridged to long-term device group, as the patients must have survived until the device was replaced.

Table 5.4 Patient survival after implant of short-term VAD, by device group, 1 April 2004 to 31 March 2014

Device	No. at risk on day 0	% patient survival (95% confidence interval) 30 days		90 days		1 year		2 years		3 years	
ST only	100	64	(54 - 73)	52	(42 - 61)	44	(34 - 53)	41	(31 - 51)	41	(31 - 51)
ECMO only	37	59	(42 - 73)	54	(37 - 68)	49	(32 - 63)	49	(32 - 63)	49	(32 - 63)
Bridged to LTD	42	98	(84 - 100)	81	(66 - 90)	64	(47 - 76)	57	(40 - 71)	47	(29 - 62)
Overall	**179**	**71**	**(64 - 77)**	**59**	**(52 - 66)**	**49**	**(42 - 57)**	**47**	**(39 - 54)**	**44**	**(36 - 51)**
Number at risk		128		106		81		58		44	

Table 5.5 shows patient survival during VAD support by device group. Unlike the survival estimates presented in **Table 5.4**, survival was censored at time of device explantation or transplantation. Survival during VAD support was lower than the overall patient survival, as survival post-transplant and explant are not considered. However, care should be taken in interpreting the survival estimates beyond 90 days due to the small number of patients at risk. In addition, ECMO only support was typically very short; all but four of the 37 patients were on support for 15 days or less.

Table 5.5 Survival during short-term VAD support, by device group, 1 April 2004 to 31 March 2014

Device	No. at risk on day 0	% survival on a device (95% confidence interval) 30 days		90 days		1 year		2 years		3 years	
ST only	100	58	(46 - 68)	43	(30 - 56)	-	(-)	-	(-)	-	(-)
ECMO only	37	32	(7 - 61)	0	(-)	-	(-)	-	(-)	-	(-)
Bridged to LTD	42	98	(84 - 100)	80	(64 - 89)	66	(48 - 80)	54	(32 - 72)	47	(25 - 67)
Overall	**179**	**67**	**(59 - 74)**	**52**	**(42 - 60)**	**39**	**(29 - 50)**	**32**	**(20 - 45)**	**28**	**(16 - 42)**
Number at risk	.	80		40		18		8		5	

SHORT TERM DEVICES USED POST-HEART TRANSPLANT

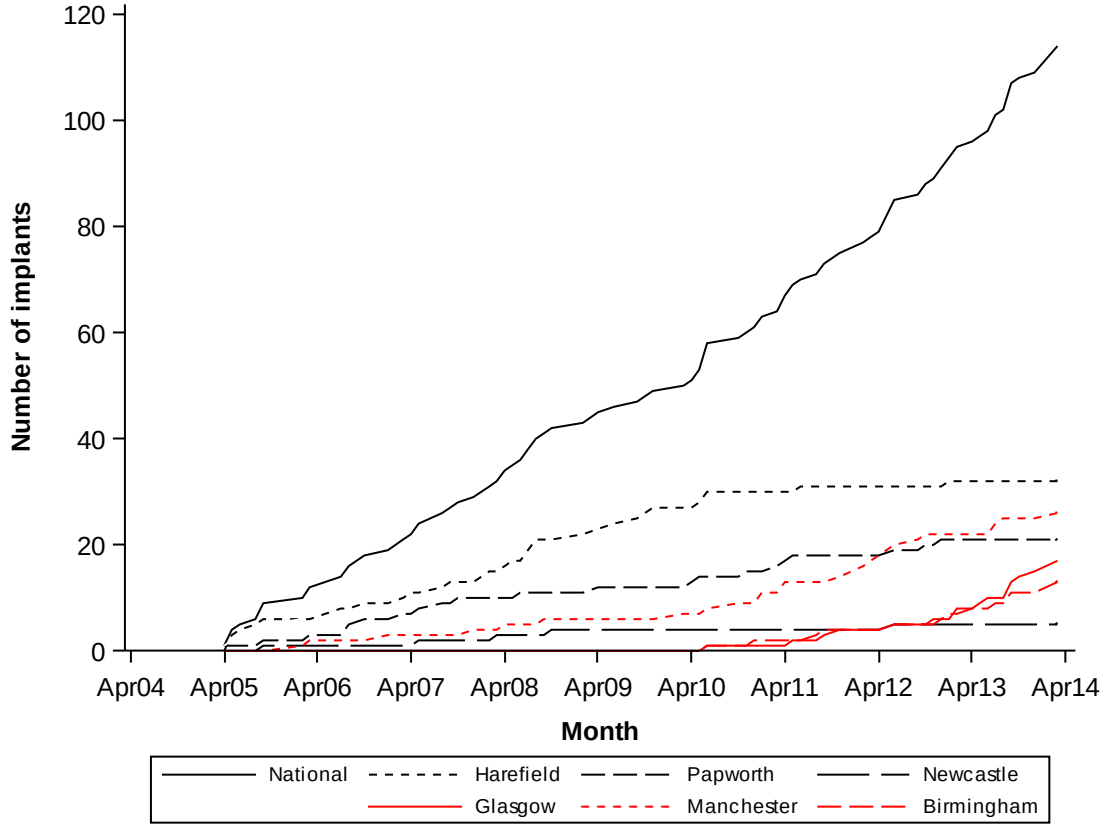
Activity

One hundred and fourteen patients received a short-term device for primary graft dysfunction at six adult implant centres in the UK between 1 April 2004 and 31 March 2014. Data are presented for devices implanted up to 31 March 2014 for all centres apart from Papworth for whom data are presented for devices implanted up to 31 March 2013. Five patients received devices at Newcastle, 32 at Harefield, 21 at Papworth[1], 13 at Birmingham, 17 at Glasgow and 26 at Manchester.

In addition to the 114 patients above, five patients received short-term devices for rejection more than 30 days post-heart transplant. One patient was at Papworth, two at Newcastle, one at Birmingham and one at Glasgow. Four patients died on support and one patient was successfully re-transplanted. Finally, three patients at Newcastle received a Berlin Heart for primary graft dysfunction; all three died on support. These patients are all excluded from this section.

Figure 6.1 shows the cumulative number of VADs implanted each month, overall and by centre, whilst **Figure 6.2** shows the number of VADs by financial year and centre. VAD activity has increased at all centres.

Figure 6.1 Cumulative short-term VADs used for primary graft dysfunction, by month and implant centre, 1 April 2004 to 31 March 2014[1]



[1] Data up to 31 March 2013 included for Papworth

Figure 6.2 Short-term VADs used for primary graft dysfunction, by financial year and implant centre, 1 April 2004 to 31 March 2014[1]

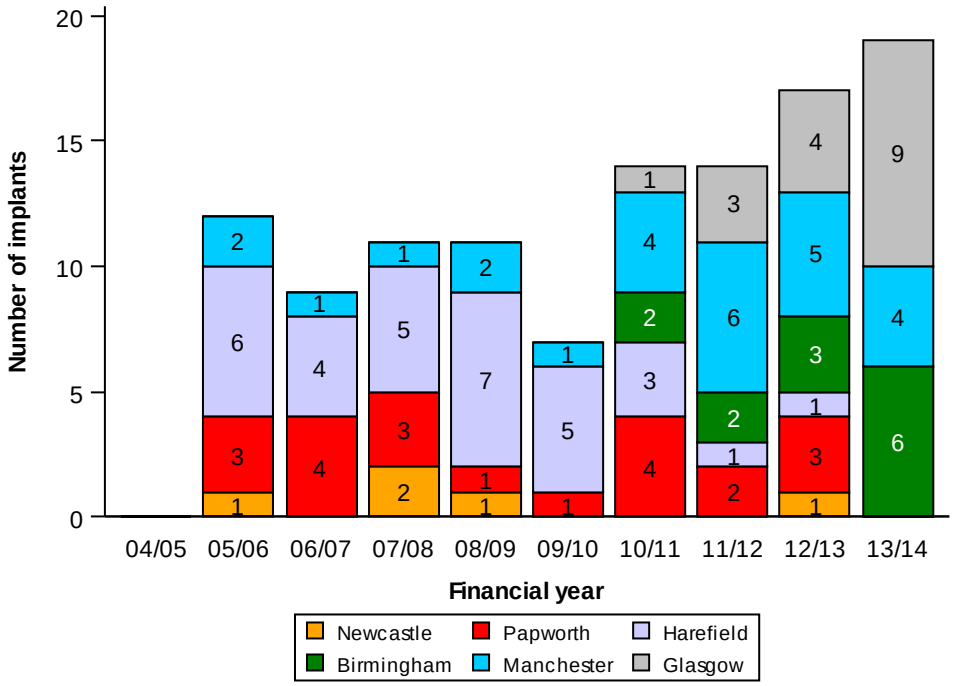


Table 6.1 shows the characteristics of patients who received short-term devices for primary graft dysfunction, by implant centre. Overall, the most frequently reported cardiothoracic diseases were dilated cardiomyopathy (55%) and ischaemic heart disease (22%). The overall median age at implant was 49 years (inter-quartile range 39 - 56 years) and the majority of recipients were male (75%). 38% were on inotropes at time of VAD implant whilst 33% received an IABP prior to VAD implant.

Table 6.2 shows that the most frequently used devices were ECMO only (46%) and Centrimag (53%). Overall 93% received only one short-term device. The device history for all first short-term device patients is outlined in sequence in **Table 6.2**.

[1] Data up to 31 March 2013 included for Papworth

Table 6.1 Characteristics of patients who received a short-term device for primary graft dysfunction, 1 April 2004 to 31 March 2014, by implant centre

		Newcastle N (%)	Harefield N (%)	Papworth N (%)	Manchester N (%)	Birmingham N (%)	Glasgow N (%)	Total N (%)
Number		5	32	21	26	13	17	**114**
Recipient sex	Male	2 (40)	25 (78)	16 (76)	21 (81)	10 (77)	11 (65)	**85 (75)**
	Female	3 (60)	7 (22)	5 (24)	5 (19)	3 (23)	6 (35)	**29 (25)**
Recipient age	Median (IQR)	48 (44-48)	50.5 (35-56)	49 (40-54)	48.5 (41-57)	52 (39-58)	48 (38-52)	**49 (39-56)**
	Missing	0	0	0	0	0	0	**0**
Cardiothoracic disease	Dilated cardiomyopathy	0 (0)	30 (94)	8 (38)	12 (46)	6 (46)	7 (41)	**63 (55)**
	Ischaemic heart disease	2 (40)	1 (3)	6 (29)	9 (35)	4 (31)	3 (18)	**25 (22)**
	Congenital heart disease	1 (20)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (1)**
	Hypertrophic cardiomyopathy	1 (20)	0 (0)	2 (10)	1 (4)	1 (8)	1 (6)	**6 (5)**
	Restrictive cardiomyopathy	0 (0)	1 (3)	1 (5)	0 (0)	0 (0)	2 (12)	**4 (4)**
	Valvular heart disease	0 (0)	0 (0)	0 (0)	2 (8)	0 (0)	1 (6)	**3 (3)**
	Infiltrative heart muscle disease	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	**1 (1)**
	Other	0 (0)	0 (0)	3 (14)	2 (8)	0 (0)	3 (18)	**8 (7)**
	Unknown	1 (20)	0 (0)	1 (5)	0 (0)	1 (8)	0 (0)	**3 (3)**
INTERMACS patient profile	1. Critical cardiogenic shock	5 (100)	5 (16)	21 (100)	3 (12)	13 (100)	12 (71)	**59 (52)**
	2. Progressive decline	0 (0)	24 (75)	0 (0)	8 (31)	0 (0)	4 (24)	**36 (32)**
	3. Stable but inotrope dependent	0 (0)	0 (0)	0 (0)	2 (8)	0 (0)	1 (6)	**3 (3)**
	4. Recurrent advanced heart failure	0 (0)	2 (6)	0 (0)	9 (35)	0 (0)	0 (0)	**11 (10)**
	5. Exertion intolerant	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**0 (0)**
	6. Exertion limited	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**0 (0)**
	7. Advanced NYHA Class 3	0 (0)	1 (3)	0 (0)	2 (8)	0 (0)	0 (0)	**3 (3)**
	Unknown	0 (0)	0 (0)	0 (0)	2 (8)	0 (0)	0 (0)	**2 (2)**
Treatment history prior to long-term VAD implant	None	0 (0)	3 (9)	8 (38)	5 (19)	0 (0)	0 (0)	**16 (14)**
	VAD/ECMO only	0 (0)	4 (13)	1 (5)	0 (0)	1 (8)	0 (0)	**6 (5)**
	IABP only	0 (0)	0 (0)	0 (0)	3 (12)	2 (15)	1 (6)	**6 (5)**
	Inotropes only	0 (0)	2 (6)	5 (24)	2 (8)	4 (31)	0 (0)	**13 (11)**
	VAD/ECMO+IABP	1 (20)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	**2 (2)**
	VAD/ECMO+inotropes	0 (0)	2 (6)	1 (5)	0 (0)	1 (8)	0 (0)	**4 (4)**
	IABP,inotropes	4 (80)	2 (6)	0 (0)	1 (4)	1 (8)	2 (12)	**10 (9)**
	VAD/ECMO, IABP,inotropes	0 (0)	3 (9)	2 (10)	0 (0)	3 (23)	1 (6)	**9 (8)**
	Unknown	0 (0)	15 (47)	4 (19)	15 (58)	1 (8)	13 (76)	**48 (42)**

[1] Data up to 31 March 2013 included for Papworth

Table 6.2	Device type and history of patients who received a short-term device for primary graft dysfunction, 1 April 2004 to 31 March 2014, by implant centre							
		Newcastle N (%)	Harefield N (%)	Papworth N (%)	Manchester N (%)	Birmingham N (%)	Glasgow N (%)	Total N (%)
Number		5	32	21	26	13	17	**114**
Device name	Biomedicus	0 (0)	0 (0)	0 (0)	1 (4)	0 (0)	0 (0)	**1 (1)**
	Centrimag	4 (80)	31 (97)	11 (52)	4 (15)	6 (46)	4 (24)	**60 (53)**
	ECMO only	1 (20)	1 (3)	10 (48)	21 (81)	7 (54)	13 (76)	**53 (46)**
Device history	ECMO	1 (20)	1 (3)	10 (48)	16 (62)	7 (54)	11 (65)	**46 (40)**
	ECMO-ECMO-ST	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	**1 (1)**
	ECMO-ST	0 (0)	0 (0)	0 (0)	4 (15)	0 (0)	1 (6)	**5 (4)**
	ECMO-ST-ECMO	0 (0)	0 (0)	0 (0)	1 (4)	0 (0)	0 (0)	**1 (1)**
	ST	4 (80)	31 (97)	11 (52)	5 (19)	5 (38)	4 (24)	**60 (53)**
	ST-ECMO	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	**1 (1)**

[1] Data up to 31 March 2013 included for Papworth

SHORT TERM DEVICES USED POST HEART TRANSPLANT

Patient Outcomes

Table 7.1 shows the VAD outcome for the 114 patients who received a short-term device for PGD. Nationally, 8 patients were transplanted, 46 survived explantation of the VAD, 48 died on support and 12 died within a month of explantation. **Table 7.2** shows the causes of death.

Table 7.3 shows the VAD duration of support by centre. Overall, the short-term VAD duration of support ranged between 0 and 76 days. Using the Kaplan-Meier estimation method, median VAD duration for all patients was estimated to be 6 days (95% CI: 5, 7).

Table 7.1 Outcome of short-term devices used for primary graft dysfunction, by implant centre, 1 April 2004 to 31 March 2014

	Newcastle		Papworth		Harefield		Birmingham		Manchester		Glasgow		Total	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Alive (post transplant)	0	(0)	3	(14)	1	(3)	0	(0)	1	(4)	0	(0)	**5**	**(4)**
Alive (post explant)	1	(20)	5	(24)	9	(28)	5	(38)	16	(62)	10	(59)	**46**	**(40)**
Alive with VAD	0	(0)	0	(0)	0	(0)	0	(0)	0	(0)	0	(0)	**0**	**(0)**
Total alive	*1*	*(20)*	*8*	*(38)*	*10*	*(31)*	*5*	*(38)*	*17*	*(65)*	*10*	*(59)*	***51***	***(45)***
Died (post transplant)	0	(0)	0	(0)	2	(6)	1	(8)	0	(0)	0	(0)	**3**	**(3)**
Died (post explant)	1	(20)	1	(5)	5	(16)	4	(31)	0	(0)	1	(6)	**12**	**(11)**
Died with VAD	3	(60)	12	(57)	15	(47)	3	(23)	9	(35)	6	(35)	**48**	**(42)**
Total died	*4*	*(80)*	*13*	*(62)*	*22*	*(69)*	*8*	*(62)*	*9*	*(35)*	*7*	*(41)*	***63***	***(55)***
TOTAL	**5**	**(100)**	**21**	**(100)**	**32**	**(100)**	**13**	**(100)**	**26**	**(100)**	**17**	**(100)**	**114**	**(100)**

Table 7.2 Causes of death for patients who received short-term devices used for primary graft dysfunction, 1 April 2004 to 31 March 2014, by implant centre

	Newcastle N (%)	Harefield N (%)	Papworth N (%)	Manchester N (%)	Birmingham N (%)	Glasgow N (%)	Total N (%)
Number	4	22	13	9	8	7	**63**
Cardiovascular: Myocardial infarction	0 (0)	0 (0)	0 (0)	1 (11)	0 (0)	0 (0)	**1 (2)**
Cardiovascular: Other	0 (0)	0 (0)	1 (8)	0 (0)	1 (13)	0 (0)	**2 (3)**
CNS cause of death	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	**1 (2)**
Haemorrhage: Other	0 (0)	0 (0)	1 (8)	1 (11)	0 (0)	0 (0)	**2 (3)**
Intraop: Not haemorrhage - other	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (14)	**1 (2)**
Pulm: Pulmonary embolism	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (14)	**1 (2)**
Renal failure	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (2)**
RV failure	0 (0)	0 (0)	0 (0)	1 (11)	0 (0)	0 (0)	**1 (2)**
Vtach/Vfib	1 (25)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (2)**
Multi organ failure (after device explant)	0 (0)	4 (18)	0 (0)	0 (0)	1 (13)	0 (0)	**5 (8)**
Other causes of cardiac failure	0 (0)	0 (0)	0 (0)	0 (0)	1 (13)	0 (0)	**1 (2)**
Other haemorrhage	1 (25)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (2)**
Renal failure	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (2)**
Multi-system failure	0 (0)	0 (0)	0 (0)	1 (11)	0 (0)	0 (0)	**1 (2)**
Donor organ failure	0 (0)	1 (5)	1 (8)	1 (11)	0 (0)	0 (0)	**3 (5)**
Other	2 (50)	15 (68)	9 (69)	2 (22)	4 (50)	5 (71)	**37 (59)**
Not reported	0 (0)	0 (0)	0 (0)	2 (22)	1 (13)	0 (0)	**3 (5)**

Table 7.3	Short-term devices used for primary graft dysfunction VAD duration, by implant centre, 1 April 2004 to 31 March 2014				
Centre	No. of implants	No. missing	Range	Median	(95% confidence interval)
Newcastle	5	0	2 - 15	5	(3, 7)
Papworth	21	0	0 - 20	7	(4, 10)
Harefield	32	0	1 - 45	10	(4, 16)
Birmingham	13	0	2 - 23	5	(3, 7)
Manchester	26	0	1 - 76	7	(3, 11)
Glasgow	17	0	0 - 53	5	(3, 7)
All centres	**114**	**0**	**0 - 76**	**6**	**(5, 7)**

Table 7.4 shows Kaplan-Meier estimates of patient survival from time of implant of a short-term device for primary graft dysfunction to death. Patients still alive were censored at the date of last follow-up. Other events such as device explantation or transplantation were not censored. Care should be taken when interpreting survival estimates for all centres in particular Newcastle due to the small number of patients at risk. This is reflected in the wide confidence intervals. Patient survival during VAD support is not presented due to all patients being on support for less than 90 days.

Table 7.4 Patient survival after implant of short-term devices used for primary graft dysfunction, by implant centre, 1 April 2004 to 31 March 2014

Centre	No. at risk on day 0	% patient survival (95% confidence interval) 30 days	90 days	1 year	2 years	3 years
Newcastle	5	20 (1 - 58)	20 (1 - 58)	20 (1 - 58)	20 (1 - 58)	20 (1 - 58)
Papworth	21	43 (22 - 62)	38 (18 - 58)	38 (18 - 58)	38 (18 - 58)	38 (18 - 58)
Harefield	32	56 (38 - 71)	38 (21 - 54)	31 (16 - 47)	31 (16 - 47)	31 (16 - 47)
Birmingham	13	54 (25 - 76)	54 (25 - 76)	38 (14 - 63)	38 (14 - 63)	38 (14 - 63)
Manchester	26	73 (52 - 86)	65 (44 - 80)	65 (44 - 80)	65 (44 - 80)	60 (38 - 76)
Glasgow	17	59 (33 - 78)	59 (33 - 78)	59 (33 - 78)	- (-)	- (-)
Overall	**114**	**56 (47 - 65)**	**48 (39 - 57)**	**45 (35 - 54)**	**45 (35 - 54)**	**43 (34 - 52)**
Number at risk		64	55	44	32	24

APPENDIX

A1: METHODS

VAD data are collected for all long-term devices used for the purposes of bridging and for all short-term devices and ECMO used for bridging or in the treatment of primary graft dysfunction following heart transplantation. Devices used post-cardiotomy are not funded via the NHS England bridge to transplant or recovery programme and so are excluded. Results are reported for implants between 1 April 2004 and 31 March 2014.

This report presents both patient survival and survival on VAD support. Patient survival describes survival from VAD implant to death, regardless of intervening events such as transplantation or device explantation. Survival on VAD support describes survival only while on a device and is therefore time from VAD implant to death on the device, censoring at transplantation or explantation. If a patient is alive at either the last follow-up or 30 September 2014, then information about the survival of the patient is censored.

A2: GLOSSARY OF TERMS

Confidence interval (CI)
When an estimate of a quantity such as a survival rate is obtained from data, the value of the estimate depends on the set of patients whose data were used. If, by chance, data from a different set of patients had been used, the value of the estimate may have been different. There is therefore some uncertainty linked with any estimate. A confidence interval is a range of values whose width gives an indication of the uncertainty or precision of an estimate. The number of VADs implanted or patients analysed influences the width of a confidence interval. Smaller data sets tend to lead to wider confidence intervals compared to larger data sets. Estimates from larger data sets are therefore more precise than those from smaller data sets. Confidence intervals are calculated with a stated probability, usually 95%. We then say that there is a 95% chance that the confidence interval includes the true value of the quantity we wish to estimate.

Confidence limit
The upper and lower bounds of a confidence interval.

ECMO
Extra corporeal Membrane Oxygenation

Generation of long-term devices
There have been important advances in both VAD technology and patient management over the last decade. VADs can broadly be divided into first, second and third generation devices.

The *first generation VADs* are pulsatile volume displacement pumps. These pumps provide excellent haemodynamic support but have constraints, particularly their large size, the presence of a large diameter lead (which is more prone to infection), an audible pump, the need for medium-large body habitus and limited long-term durability as they were only designed for up to 1 year of support.

Berlin Heart Incor, Berlin Heart Excor, Heartmate XVE, Thoratec IVAD and Thoratec PVAD are all first generation devices.

The *second generation VADs* are axial flow pumps that are smaller than the 1st generation VADs (for example the second generation *Heartmate II* is 1/7th the size and ¼ the weight of the first generation *Heartmate XVE* device). They are easier to insert into patients with smaller body habitus. The smaller diameter drivelines appear to result in lower rates of driveline infection. These continuous flow pumps are quiet in operation and only have a single moving part, the rotor, and hence are expected to be more durable than 1st generation VADs and are now being widely used.

Heartmate II, Jarvik 2000, Micromed DeBakey, Heart Assist 5 and Circulite Synergy are second generation devices.

A number of *third generation VADs* are now also in clinical use or clinical trials. These are bearingless continuous flow pumps with an impeller that is either magnetic levitation or hydrodynamically suspended. Since there are no mechanical bearings inside these VADs, there is no mechanical wear and tear, and durability should be much longer. Third generation VADs are expected to last for 5-10 years.

Heartware and VentrAssist are both third generation devices.

Inter-quartile range
The values between which the middle 50% of the data fall. The lower boundary is the lower quartile, the upper boundary the upper quartile.

INTERMACS patient profile
Level 1: Critical cardiogenic shock describes the patient who is "crashing and burning"; in which patients have life–threatening hypotension despite rapidly escalating inotropic support, occasionally with IABP placement as well, with critical organ hypoperfusion often confirmed by worsening acidosis and lactate levels. Patients may have less than 24 hours survival expected without mechanical support.

Level 2: Progressive decline describes the patient who has been demonstrated "dependent" on inotropic support but nonetheless shows signs of continuing deterioration in nutrition, renal function, fluid retention, or other major status indicator. Level 2 can also describe a patient with refractory volume overload, perhaps with evidence of impaired perfusion, in whom inotropic infusions *cannot be maintained* due to tachyarrhythmia, clinical ischemia, or other intolerance.

Level 3: Stable but inotrope dependent describes the patient who is clinically stable on mild–moderate doses of intravenous inotropes after repeated documentation of failure to wean without symptomatic hypotension, worsening symptoms, or progressive organ dysfunction (usually renal). It is critical to monitor nutrition, renal function, fluid balance, and overall status carefully in order to distinguish between patients who are truly stable at Level 3 and those who have unappreciated decline rendering them Level 2.

Level 4: is the level of "recurrent" rather than "refractory" decompensation. After interventions such as hospitalization for intravenous diuretics, these patients can be stabilized briefly on an oral regimen at close to normal volume status. However, they experience brief relapses into fluid retention. These patients should be carefully considered for more intensive management and surveillance programs, by which some may be recognized to have poor compliance that would compromise outcomes with any therapy.

Level 5: describes patients who are comfortable at rest but are exercise intolerant for most activity, living predominantly within the house or housebound. They have no congestive symptoms, but may have chronically elevated volume status, frequently with renal dysfunction, and may be characterized as housebound.

Level 6: is a similar patient who is generally without any evidence of fluid overload and able to do some mild activity. Activities of daily living are comfortable and minor activities outside the home such as visiting friends or going to a restaurant can be performed, but fatigue results within a few minutes or any meaningful physical exertion.

Level 7: describes patients who are clinically stable with a reasonable level of comfortable activity, despite history of previous decompensation that is not recent. Any decompensation requiring intravenous diuretics or hospitalization within the previous 2 weeks should make the person a Level 4 or lower.

ISHLT Mechanically Assisted Circulatory Support Registry Users'Guide (2012). Birmingham, AL (http://www.ishlt.org/ContentDocuments/IMACS_Users_Guide_Final_032414.pdf)

Kaplan-Meier method
A method that allows patients with incomplete follow-up information to be included in estimating survival rates. For example, when estimating one year patient survival rates, a patient may be followed up for only nine months before they relocate. If we calculated a crude survival estimate using the number of patients who survived for at least a year, this patient would have to be excluded as it is not known whether or not the patient was still alive at one year after VAD implantation. The Kaplan-Meier method allows information about such patients to be used for the length of time that they are followed-up, when this information would otherwise be discarded. Such instances of incomplete follow-up are not uncommon and the Kaplan-Meier method allows the computation of estimates that are more meaningful in these cases.

Long-term devices (LT)
Long-term devices are implantable and intended to support the patient for years. Patients can be discharged from hospital with a LT device.

Median
The midpoint in a series of numbers, so that half the data values are larger than the median, and half are smaller.

Patient survival rate
The percentage of patients who are still alive (regardless of whether the patient has received a transplant or the device has been explanted). This is usually specified for a given time period after VAD implantation. For example, a five-year patient survival rate is the percentage of patients who are still alive five years after their first VAD implantation.

Primary graft dysfunction
Primary graft dysfunction (PGD) is defined as all VADs and ECMOs used for graft failure within 30 days of heart transplantation.

***p* value**
In the context of comparing survival rates across centres, the *p* value is the probability that the differences observed in the rates across centres occurred by chance. As this is a probability, it takes values between 0 and 1. If the *p* value is small, say less than 0.05, this implies that the differences are unlikely to be due to chance and there may be some identifiable cause for these differences. If the *p* value is large, say greater than 0.1, then it is quite likely that any differences seen are due to chance.

Rejection
Rejection is defined as all VADs and ECMOs used for graft failure more than 30 days of heart transplantation.

Risk factors
These are the patient characteristics that influence the length of time that a patient is likely to survive following a VAD implantation.

Short-term (ST) devices
Short-term devices are intended to support for a short period of time (days or weeks). Patients cannot leave hospital with the device.

Survival on a VAD rate
The percentage of patients who are still alive and on VAD support. Unlike patient survival, survival was censored at time of device explantation or transplantation. This is usually specified for a given time period after VAD implantation. For example, a five-year survival on a VAD rate is the percentage of patients who are still alive on support five years after their first VAD implantation.

TAH
Total artificial heart

Unadjusted survival rate
Unadjusted survival rates do not take account of risk factors and are based only on the number of VAD implants at a given centre and the number and timing of those that fail within the post-VAD implantation period of interest. In this case, unlike for risk-adjusted rates, all patients are assumed to be equally likely to die at any given time. However, some centres may have lower unadjusted survival rates than others simply because they tend to undertake VAD implants that have increased risks of death. All results presented in this report are unadjusted as the risk factors affecting post-VAD implantation have not yet been examined.

VAD
Ventricular Assist Device

VAD database
Database used for an ongoing extensive audit to capture in-depth data prior to and at time of VAD implant, explant, transplant and death along with follow-up at various time points post-implant and post-explant.

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