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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 collection on all patients implanted with VADs began in April 2002 and, since January 2007, NHS Blood and Transplant (NHSBT) have been responsible for data collection and reporting.

This report key figures about VAD and Extra Corporeal Membrane Oxygenation (ECMO) implantation between 1 April 2005 and 31 March 2015, for all six adult cardiothoracic transplant centres performing VAD and ECMO implants in the UK for either

- bridging to heart transplant
- primary graft dysfunction (PGD)
- rejection post heart transplantation.

The report presents information on the number of VADs and ECMOs implanted and survival analysis after implant, both on a national and centre-specific basis.

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 in 2013. Results therefore exclude paediatrics (age<16 years) at Newcastle and all patients who received a VAD/ECMO at GOSH.

Patients can receive either a long-term or a short-term device. ECMOs are included in the short-term device sections whilst total Artificial Hearts (TAHs) are included in the long-term sections. Patients can receive more than one device (for example a patient may receive a short-term device and then a long-term device). Patients who receive a short-term device or ECMO and then a long-term device are classed as “bridged to long-term device”.

Key findings

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

- 553 of the 735 patients received a long-term device with 85% of all long-term implants performed at Newcastle, Papworth and Harefield.

- 89% (95% CI: 86% - 92%) of the 460 first continuous long-term VAD patients were estimated to be alive at 30 days.

- Long-term VAD duration of support ranged between 0 and 3290 days (9 years) with a median VAD duration (95% CI) estimated to be 520 days (418, 622).

- The national unadjusted rate of patient survival 1 year after first continuous **long-term device** is 71% (95% CI: 66-75). These rates vary between centres, ranging from 50% to 81%.

- The national unadjusted rate of survival on a VAD 1 year after first continuous **long-term device** is 73% (95% CI: 68-77). These rates vary between centres, ranging from 60% to 84%.

- 53 patients received a short-term device or ECMO before receiving long-term device. These patients are not included in the patient outcome summaries above.

- 245 patients received a short-term device or ECMO for the intention of bridging to heart transplant and 135 received a 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 (NIHR) Health Technology Assessment (HTA) 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 data for all VAD/ECMO 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 devices implanted since 2009. The data collected via this more extensive audit are stored in the VAD database held at NHSBT and are presented in this report.

This report presents information on VAD and ECMO implant activity and patient outcome after implant between 1 April 2005 and 31 March 2015, for all six adult centres performing VAD and ECMO implants in the UK for either

- bridging to heart transplant,
- primary graft dysfunction (PGD)
- rejection post heart transplantation.

Data were obtained from the UK VAD Database held at NHSBT as at 25 November 2015.

There are two UK paediatric implant centres; Great Ormond Street Hospital and Newcastle (also an adult implant centre). However, Great Ormond Street and the Newcastle paediatric department have only recently started entering data in 2013. Results therefore exclude paediatrics (age<16 years) at Newcastle and all patients who received a VAD/ECMO at Great Ormond Street.

Methods used are described in the Appendix.

Five patients refused to give consent for their data to be recorded on the VAD database between 1 April 2005 and 31 March 2015 and they are not included in this report.

Table 1.1 shows the number of patients who received a device for bridging to heart transplantation and the number of devices implanted between 1 April 2005 and 31 March 2015 at each centre, whilst **Table 1.2** shows the equivalent information for patients who received a device for either PGD or rejection.

Results in this report are presented in four main sections:

- long-term
- bridge to long-term
- short-term
- primary graft dysfunction (PGD)

Note that some patients included in the bridging section also received a VAD or ECMO for primary graft dysfunction (PGD) and are included in both sections. Also, some patients may have received concurrent ECMO support with their VAD and these are reported as VAD implantations. Uncommon treatment options such as total artificial heart (TAH) bridging, treatment of rejection several years post-transplant and long-term VADs for PGD are mentioned in the relevant sections in text only. Rejection is defined as all VADs and ECMOs used for graft failure more than 30 days post heart transplant.

Table 1.1 Number of bridging to transplant patients and devices implanted, by implant centre, 1 April 2005 to 31 March 2015

Hospital	No. of patients	Type of device				
		LT	ST	ECMO	TAH	Total
Newcastle	**172**	172	7	6	1	**186**
Papworth	**134**	96	28	24	2	**150**
Harefield	**236**	236	54	14	5	**309**
Birmingham	**73**	30	31	27	0	**88**
Manchester	**73**	43	33	20	0	**96**
Glasgow	**47**	16	29	12	0	**57**
All centres	**735**	**593**	**182**	**103**	**8**	**886**

LT=Long-term, ST-short-term, ECMO=Extra Corporeal Membrane Oxygenation, TAH= Total artificial heart

Table 1.2 Number of PGD and rejection patients and devices implanted, by implant centre, 1 April 2005 to 31 March 2015

Hospital	No. of patients	Primary graft dysfunction Type of device				Rejection Type of device		
		LT	ST	ECMO	Total	ST	ECMO	Total
Newcastle	**11**	3	4	2	**9**	2	0	**2**
Papworth	**23**	0	11	11	**22**	1	0	**1**
Harefield	**38**	0	31	7	**38**	0	0	**0**
Birmingham	**16**	0	6	11	**17**	0	1	**1**
Manchester	**29**	0	10	25	**35**	0	0	**0**
Glasgow	**25**	0	9	21	**30**	1	1	**2**
All centres	**142**	**3**	**71**	**77**	**151**	**4**	**2**	**6**

LT=Long-term, ST-short-term, ECMO=Extra Corporeal Membrane Oxygenation

Table 1.3 and **Table 1.4** detail the VAD and ECMO sequence for 834 patients who are reported as receiving a device between 1 April 2005 and 31 March 2015 (42 received both a bridging device and a PGD device whilst one received separate devices for bridging, PGD and rejection).

Table 1.3 Number of bridging patients, by device history and inclusion in section, 1 April 2005 to 31 March 2015

Device history	No. of patients	Long-term section		Section Bridged to long-term section	Short-term section	
		Activity (Pages 11 – 17)	Outcome[1] (Pages 18 – 32)	Outcome (Pages 33 – 40)	Activity (Pages 41 – 46)	Outcome (Pages 47 – 51)
LT	456	456	425			
LT-LT	28	28	23			
LT-LT-LT-LT	1	1				
LT-LT-ST	1	1	1		1	
LT-LT-ST-LT	1	1			1	
LT-ST	4	4	4		4	
LT-ST-ECMO	1	1	1		1	
LT-ST-LT	1	1	1		1	
LT-TAH	2	2	2			
LT/LT-ECMO	1	1	1		1	
LT/LT-LT/ST	1	1	1		1	
LT/ST	1	1	1		1	
TAH	3					
ST	106				106	105
ST-LT	23	23		23	23	
ST-LT-LT	2	2		2	2	
ST-ST	3				3	3
ST-ST-LT	1	1		1	1	
ECMO	40				40	40
ECMO-ECMO	1				1	1
ECMO-LT	21	21		21	21	
ECMO-ST	25				25	25
ECMO-ST-LT	6	6		6	6	
ECMO-ST/LT	1	1			1	
ECMO-TAH	3				3	
ECMO/ECMO-ST	1				1	1
ECMO/LT	1	1			1	
Overall	**735**	**553**	**460**	**53**	**245**	**175**

[1] First devices that were continuous long-term devices

LT=Long-term, ST-short-term, ECMO=Extra Corporeal Membrane Oxygenation, TAH= Total artificial heart

LT-ST indicates that a patient received a long-term device and then a short-term device immediately following explantation of a long-term device
LT/ST indicates that a patient had two episodes and received a long-term device which was explanted and then a short-term device after a period of no support

Shading indicate where device histories would not be analysed

Table 1.4 **UK VAD and ECMO patients who received a device following heart transplantation for either primary graft failure or rejection, 1 April 2005 to 31 March 2015**

Device history	No. of patients	Primary graft dysfunction section		Rejection[1]
		Activity (Pages 52 – 56)	Outcome (Pages 57 – 60)	
LT[1]	3			0
ST	64	61	61	3
ST-ECMO	1	1	1	0
ECMO	65	65	65	1
ECMO-ECMO-ST	1	1	1	0
ECMO-ST	6	5	5	1
ECMO/ST	1	1	1	0
ECMO/ST-ECMO	1	1	1	0
Overall	**142**	**135**	**135**	**5**

[1] Included in text only

LT=Long-term, ST-short-term, ECMO=Extra Corporeal Membrane Oxygenation, TAH= Total artificial heart

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

LT/ST indicates that a patient had two episodes and received a long-term device which was explanted and then a short-term device after a period of no support

Shading indicate where device histories would not be analysed

Table 1.5 shows the bridging device activity rates per million population by country/ Strategic Health Authority of patients residence, both overall and for the most recent three year time period. The overall bridging device rate was 11.3 pmp and ranged from 8.0 to 27.6 pmp across the Strategic Health Authorities. The overall bridging device rate for the most recent three years was 5.2 pmp and ranged from 2.4 to 11.1 pmp across the Strategic Health Authorities.

Table 1.5 First bridging device (includes VADs, ECMOs and TAHs) rates per million population (pmp) in the UK, by Country/ Strategic Health Authority

Country/ Strategic Health Authority	Overall[1] (1 April 2005 – 31 March 2015)		Three year[2] (1 April 2012 – 31 March 2015)		Last year[3] (1 April 2014 – 31 March 2015)	
	N	pmp	N	pmp	N	pmp
North East	72	(27.6)	29	(11.1)	12	(4.6)
North West	71	(10.0)	44	(6.2)	20	(2.8)
Yorkshire and The Humber	56	(10.5)	23	(4.3)	7	(1.3)
North of England	**199**	**(13.2)**	**96**	**(6.4)**	**39**	**(2.6)**
East Midlands	37	(8.0)	11	(2.4)	4	(0.9)
West Midlands	55	(9.7)	37	(6.5)	16	(2.8)
East of England	69	(11.6)	23	(3.9)	10	(1.7)
Midlands and East	**161**	**(9.9)**	**71**	**(4.4)**	**30**	**(1.8)**
London	**93**	**(11.0)**	**37**	**(4.4)**	**17**	**(2.0)**
South East Coast	66	(14.5)	25	(5.5)	12	(2.6)
South Central	39	(9.2)	15	(3.5)	5	(1.2)
South West	55	(10.2)	25	(4.6)	11	(2.0)
South of England	**160**	**(11.3)**	**65**	**(4.6)**	**28**	**(2.0)**
England	**613**	**(11.4)**	**269**	**(5.0)**	**114**	**(2.1)**
Isle of Man	**1**	**(12.5)**	**1**	**(12.5)**	**0**	**(0.0)**
Channel Islands	**0**	**(0.0)**	**0**	**(0.0)**	**0**	**(0.0)**
Wales	**40**	**(13.0)**	**27**	**(8.8)**	**16**	**(5.2)**
Scotland	**56**	**(10.5)**	**28**	**(5.3)**	**10**	**(1.9)**
Northern Ireland	**17**	**(9.3)**	**7**	**(3.8)**	**2**	**(1.1)**
TOTAL	**727**	**(11.3)**	**332**	**(5.2)**	**142**	**(2.2)**

[1] Excludes 4 recipients whose postcode was unknown and 4 recipients who reside overseas
[2] Excludes 1 recipients whose postcode was unknown and 2 recipients who reside overseas
[3] Excludes 0 recipients whose postcode was unknown and 1 recipient who resides overseas

LONG TERM DEVICES USED FOR BRIDGING

Activity

This section considers all patients who received a long-term device for bridging to heart transplantation regardless of whether they received a previous device.

All figures and tables in this section, apart from **Table 2.1**, present information on a per long-term device basis as opposed to per patient. **Table 2.1** shows the characteristics of patients who received a long-term device on a per patient basis.

593 long-term ventricular assist devices were implanted for 553 patients at six adult implant centres in the UK between 1 April 2005 and 31 March 2015. 163 patients received a device at Newcastle (172 devices), 207 at Harefield (236 devices), 95 at Papworth (96 devices), 42 at Manchester (43 devices), 30 at Birmingham (30 devices) and 16 at Glasgow (16 devices).

An additional eight patients received total artificial hearts (TAH). These patients are not included in the summaries below.

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

Figure 2.1 shows the cumulative number of long-term VADs implanted each month, overall and by centre, whilst **Figure 2.2** shows the number of long-term VADs by financial year and centre. Long-term VAD activity at Newcastle, Harefield, Manchester and Birmingham has increased.

Figure 2.1 Cumulative long-term VAD activity, by month and implant centre, 1 April 2005 to 31 March 2015

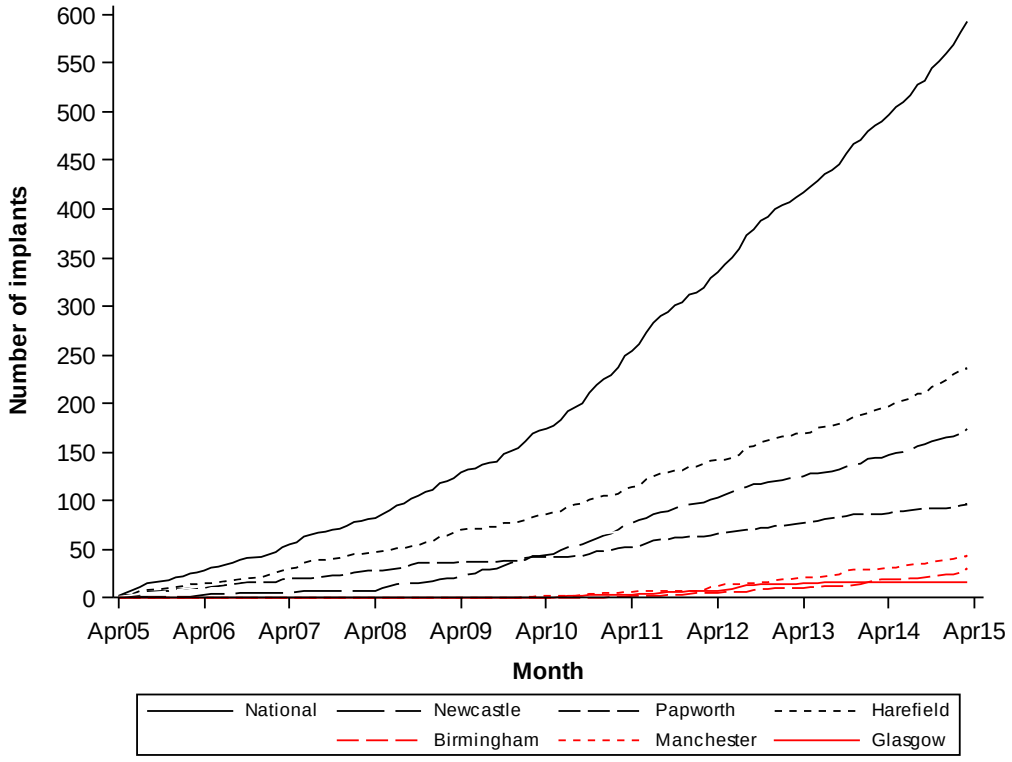


Figure 2.2 Long-term VAD activity, by financial year and implant centre, 1 April 2005 to 31 March 2015

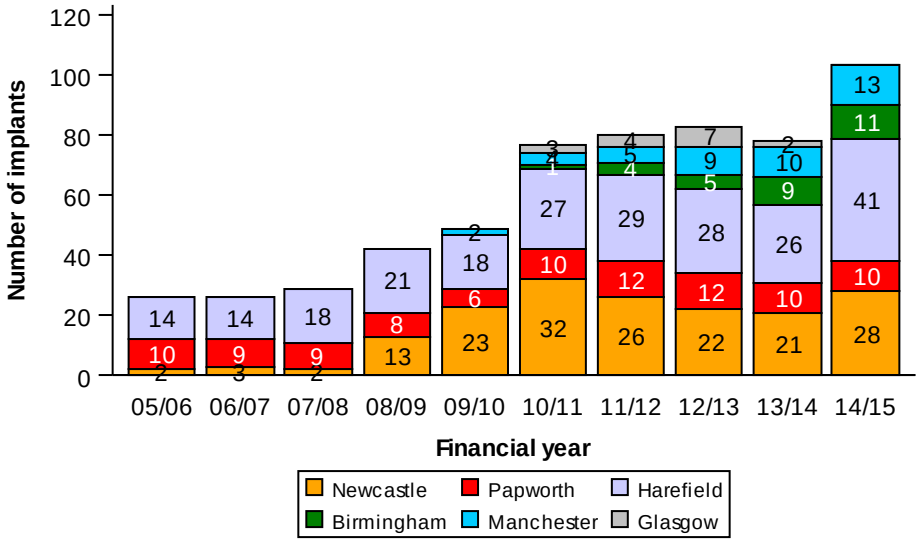


Figure 2.3 shows the number of long-term devices categorised by generation of device and shows the majority of long-term devices implanted in the last five years were third generation.

Figure 2.3 Long-term VAD generation, by financial year and device generation, 1 April 2005 to 31 March 2015

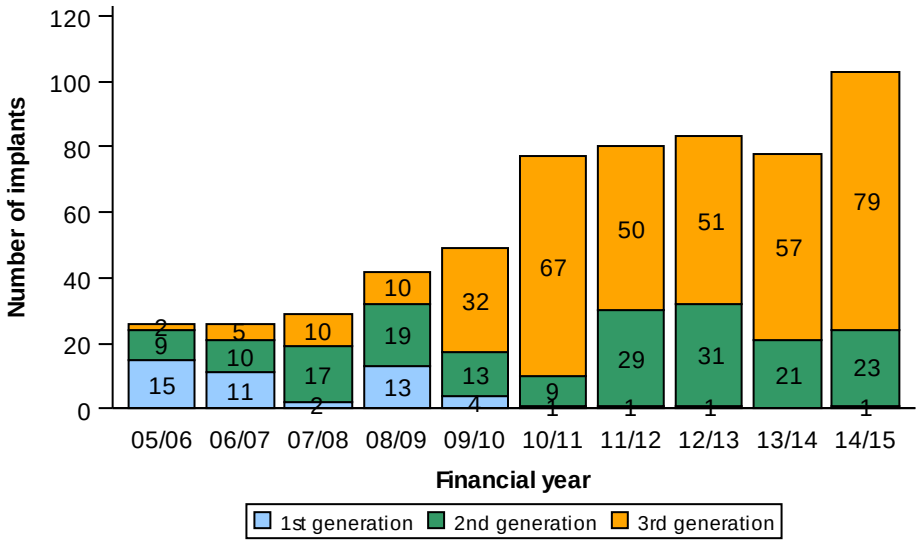


Figure 2.4 shows the INTERMACS patient profile at time of long-term VAD implantation and shows that profile 2 (progressive decline) is the most common.

Figure 2.4 INTERMACS patient profile for all long-term VADs implanted, 1 April 2005 to 31 March 2015

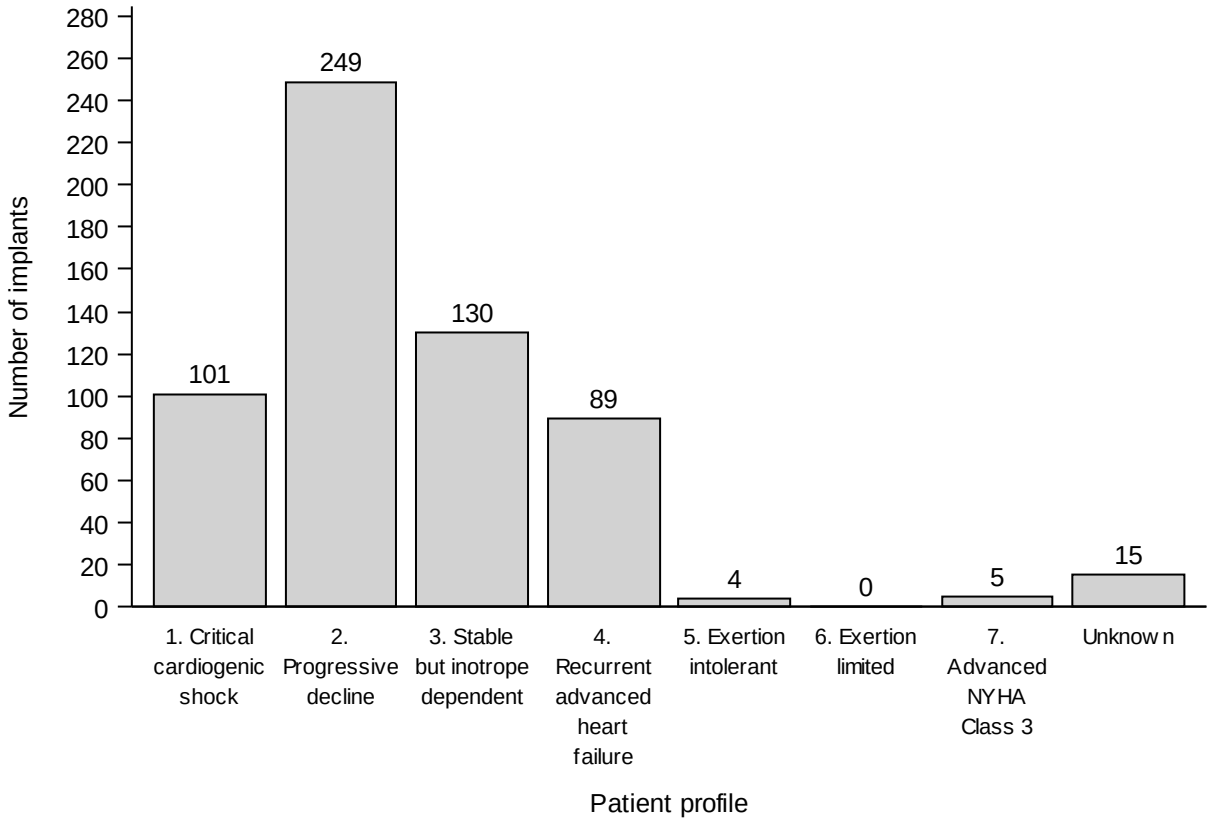


Table 2.1 shows the characteristics of patients who received a long-term device by implant centre. Overall, the most frequently reported cardiothoracic diseases were dilated cardiomyopathy (60%) and ischaemic heart disease (29%). The overall median age at implant was 48 years (inter-quartile range 36 - 56 years) and the majority of recipients were male (83%).

Overall 82% received only one long-term device. The device history for all long-term device patients is outlined in sequence in **Table 2.1**.

Unlike **Table 2.1**, which presents information on a per patient basis, **Table 2.2** presents characteristics on a per device basis. **Table 2.2** shows that the most frequently used devices were Heartware (56%) and Heartmate II (26%). 70% were on inotropes at time of VAD implant whilst 34% received an IABP prior to VAD implant.

Table 2.1 Characteristics of patients who received a long-term device, 1 April 2005 to 31 March 2015, by centre

		Newcastle N (%)	Harefield N (%)	Papworth N (%)	Manchester N (%)	Birmingham N (%)	Glasgow N (%)	Total N (%)
Number		163	207	95	42	30	16	**553**
Recipient sex	Male	142 (87)	173 (84)	76 (80)	32 (76)	28 (93)	10 (63)	**461 (83)**
	Female	21 (13)	34 (16)	19 (20)	10 (24)	2 (7)	6 (38)	**92 (17)**
Recipient age	Median (IQR)	51 (36-58)	46 (33-54)	48 (41-56)	52 (40-57)	55.5 (49-61)	35.5 (30-48)	**48 (36-56)**
	Missing	0	0	0	0	0	0	**0**
Cardiothoracic disease	Dilated cardiomyopathy	85 (52)	144 (70)	62 (65)	19 (45)	15 (50)	9 (56)	**334 (60)**
	Ischaemic heart disease	57 (35)	39 (19)	27 (28)	19 (45)	15 (50)	5 (31)	**162 (29)**
	Congenital heart disease	13 (8)	3 (1)	0 (0)	0 (0)	0 (0)	0 (0)	**16 (3)**
	Hypertrophic cardiomyopathy	2 (1)	7 (3)	4 (4)	1 (2)	0 (0)	1 (6)	**15 (3)**
	Restrictive cardiomyopathy	2 (1)	5 (2)	1 (1)	0 (0)	0 (0)	0 (0)	**8 (1)**
	Valvular heart disease	3 (2)	1 (0)	0 (0)	2 (5)	0 (0)	0 (0)	**6 (1)**
	Infiltrative heart muscle disease	1 (1)	1 (0)	0 (0)	1 (2)	0 (0)	0 (0)	**3 (1)**
	Other	0 (0)	1 (0)	1 (1)	0 (0)	0 (0)	1 (6)	**3 (1)**
	Unknown	0 (0)	6 (3)	0 (0)	0 (0)	0 (0)	0 (0)	**6 (1)**
Device history	LT	151 (93)	148 (71)	90 (95)	32 (76)	25 (83)	10 (63)	**456 (82)**
	LT-LT	9 (6)	18 (9)	1 (1)	0 (0)	0 (0)	0 (0)	**28 (5)**
	LT-LT-LT-LT	0 (0)	1 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (0)**
	LT-LT-ST	0 (0)	1 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (0)**
	LT-LT-ST-LT	0 (0)	1 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (0)**
	LT-ST	1 (1)	3 (1)	0 (0)	0 (0)	0 (0)	0 (0)	**4 (1)**
	LT-ST-ECMO	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	**1 (0)**
	LT-ST-LT	0 (0)	1 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (0)**
	LT-TAH	0 (0)	2 (1)	0 (0)	0 (0)	0 (0)	0 (0)	**2 (0)**
	LT/LT-ECMO	0 (0)	1 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (0)**
	LT/LT-LT/ST	0 (0)	1 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (0)**
	LT/ST	0 (0)	1 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (0)**
	ST-LT	0 (0)	17 (8)	0 (0)	1 (2)	1 (3)	4 (25)	**23 (4)**
	ST-LT-LT	0 (0)	1 (0)	0 (0)	1 (2)	0 (0)	0 (0)	**2 (0)**
	ST-ST-LT	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	**1 (0)**
	ECMO-LT	2 (1)	8 (4)	4 (4)	3 (7)	3 (10)	1 (6)	**21 (4)**
	ECMO-ST-LT	0 (0)	1 (0)	0 (0)	4 (10)	0 (0)	1 (6)	**6 (1)**
	ECMO-ST/LT	0 (0)	1 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (0)**
	ECMO/LT	0 (0)	1 (0)	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 immediately following explantation of a long-term device
LT/ST indicates that a patient had two episodes and received a long-term device which was explanted and then a short-term device after a period of no support

Table 2.2	Patient characteristics for all long-term devices, 1 April 2005 to 31 March 2015, by centre							
		Newcastle N (%)	Harefield N (%)	Papworth N (%)	Manchester N (%)	Birmingham N (%)	Glasgow N (%)	Total N (%)
Number		172	236	96	43	30	16	**593**
INTERMACS patient profile	1. Critical cardiogenic shock	29 (17)	53 (22)	11 (11)	2 (5)	3 (10)	3 (19)	**101 (17)**
	2. Progressive decline	80 (47)	92 (39)	51 (53)	11 (26)	6 (20)	9 (56)	**249 (42)**
	3. Stable but inotrope dependent	23 (13)	50 (21)	19 (20)	16 (37)	20 (67)	2 (13)	**130 (22)**
	4. Recurrent advanced heart failure	37 (22)	23 (10)	15 (16)	12 (28)	1 (3)	1 (6)	**89 (15)**
	5. Exertion intolerant	2 (1)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	**4 (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)	3 (1)	0 (0)	0 (0)	0 (0)	1 (6)	**5 (1)**
	Unknown	0 (0)	15 (6)	0 (0)	0 (0)	0 (0)	0 (0)	**15 (3)**
Treatment history prior to long-term VAD implant	None	42 (24)	28 (12)	1 (1)	1 (2)	1 (3)	2 (13)	**75 (13)**
	VAD/ECMO only	6 (3)	8 (3)	0 (0)	0 (0)	0 (0)	0 (0)	**14 (2)**
	IABP only	5 (3)	4 (2)	3 (3)	0 (0)	1 (3)	4 (25)	**17 (3)**
	Inotropes only	66 (38)	89 (38)	18 (19)	14 (33)	18 (60)	1 (6)	**206 (35)**
	VAD/ECMO+IABP	1 (1)	6 (3)	1 (1)	3 (7)	0 (0)	2 (13)	**13 (2)**
	VAD/ECMO+inotropes	3 (2)	20 (8)	0 (0)	0 (0)	1 (3)	0 (0)	**24 (4)**
	IABP,inotropes	19 (11)	40 (17)	64 (67)	10 (23)	3 (10)	0 (0)	**136 (23)**
	VAD/ECMO, IABP,inotropes	4 (2)	8 (3)	3 (3)	5 (12)	3 (10)	0 (0)	**23 (4)**
	Unknown	26 (15)	33 (14)	6 (6)	10 (23)	3 (10)	7 (44)	**85 (14)**
Device name	Berlin Heart Excor	21 (12)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**21 (4)**
	Heartmate XVE	0 (0)	5 (2)	2 (2)	0 (0)	0 (0)	0 (0)	**7 (1)**
	Heartmate II	0 (0)	77 (33)	0 (0)	30 (70)	30 (100)	15 (94)	**152 (26)**
	Heartware	142 (83)	122 (52)	57 (59)	13 (30)	0 (0)	1 (6)	**335 (56)**
	Jarvik 2000	0 (0)	8 (3)	0 (0)	0 (0)	0 (0)	0 (0)	**8 (1)**
	Micromed DeBakey	2 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**2 (0)**
	Thoratec IVAD	0 (0)	1 (0)	7 (7)	0 (0)	0 (0)	0 (0)	**8 (1)**
	Thoratec PVAD	0 (0)	4 (2)	9 (9)	0 (0)	0 (0)	0 (0)	**13 (2)**
	VentrAssist	6 (3)	0 (0)	21 (22)	0 (0)	0 (0)	0 (0)	**27 (5)**
	Heart Assist 5	0 (0)	4 (2)	0 (0)	0 (0)	0 (0)	0 (0)	**4 (1)**
	Circulite Synergy	0 (0)	15 (6)	0 (0)	0 (0)	0 (0)	0 (0)	**15 (3)**
	Heartware MVAD	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (0)**

Table 2.3 shows the first long-term VAD activity rates per million population by country/ Strategic Health Authority of patients residence, both overall and for the most recent three year time period. The overall long-term VAD rate was 8.5 pmp and ranged from 4.6 to 26.8 across the Strategic Health Authorities. The overall first long-term VAD rate for the most recent three years was 3.6 pmp and ranged from 2 to 10.7 across the Strategic Health Authorities.

Table 2.3 Long-term VAD patient rates per million population (pmp) in the UK, by Country/ Strategic Health Authority

	Overall[1] (1 April 2005 – 31 March 2015)		Three year[2] (1 April 2012 – 31 March 2015)		Last year[3] (1 April 2014 – 31 March 2015)	
Country/ Strategic Health Authority	N	pmp	N	pmp	N	pmp
North East	70	(26.8)	28	(10.7)	12	(4.6)
North West	49	(6.9)	26	(3.7)	12	(1.7)
Yorkshire and The Humber	51	(9.6)	22	(4.1)	7	(1.3)
North of England	**170**	**(11.3)**	**76**	**(5.0)**	**31**	**(2.1)**
East Midlands	28	(6.1)	9	(2.0)	3	(0.7)
West Midlands	26	(4.6)	19	(3.4)	9	(1.6)
East of England	51	(8.6)	15	(2.5)	5	(0.8)
Midlands and East	**105**	**(6.5)**	**43**	**(2.7)**	**17**	**(1.0)**
London	**79**	**(9.4)**	**33**	**(3.9)**	**14**	**(1.7)**
South East Coast	53	(11.6)	18	(4.0)	9	(2.0)
South Central	34	(8.0)	13	(3.1)	4	(0.9)
South West	46	(8.6)	22	(4.1)	10	(1.9)
South of England	**133**	**(9.4)**	**53**	**(3.7)**	**23**	**(1.6)**
England	**487**	**(9.0)**	**205**	**(3.8)**	**85**	**(1.6)**
Isle of Man	**1**	**(12.5)**	**1**	**(12.5)**	**0**	**(0.0)**
Channel Islands	**0**	**(0.0)**	**0**	**(0.0)**	**0**	**(0.0)**
Wales	**16**	**(5.2)**	**11**	**(3.6)**	**6**	**(1.9)**
Scotland	**25**	**(4.7)**	**10**	**(1.9)**	**1**	**(0.2)**
Northern Ireland	**17**	**(9.3)**	**7**	**(3.8)**	**2**	**(1.1)**
TOTAL	**546**	**(8.5)**	**234**	**(3.6)**	**94**	**(1.5)**

[1] Excludes 3 recipients whose postcode was unknown and 4 recipients who reside overseas
[2] Excludes 1 recipients whose postcode was unknown and 2 recipients who reside overseas
[3] Excludes 0 recipients whose postcode was unknown and 1 recipients who reside overseas

LONG TERM DEVICES USED FOR BRIDGING

Patient Outcomes

This section considers patients whose first device was a continuous long-term device. It excludes 55 patients who either received a short-term device or ECMO prior to the long-term device (included in bridged to long-term device section) along with 38 patients who received either a Berlin Heart Excor, Thoratec PVAD, Thoratec IVAD, Heartmate XVE or Circulite Synergy.

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. Nationally, 112 patients were transplanted, 24 survived explantation of the VAD, 189 died on support, 5 died post-explantation (all within a month of explantation) and 130 were still on support on 25 November 2015. Deaths which occured more than one year post-transplant or explant are not referenced in these tables.

Table 3.1b shows the long-term VAD outcome of recipients who received devices during the most recent three years (April 2012 - March 2015).

Table 3.1a Outcome of long-term VADs, by implant centre, 1 April 2005 to 31 March 2015

	Newcastle		Papworth		Harefield		Birmingham		Manchester		Glasgow		Total	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Alive (post transplant)	21	(13)	24	(32)	26	(17)	4	(15)	4	(13)	2	(20)	**81** [8, 0]	**(18)**
Alive (post explant)	6	(4)	1	(1)	14	(9)	0	(0)	1	(3)	2	(20)	**24** [6, 4]	**(5)**
Alive with VAD	42	(26)	17	(23)	42	(27)	10	(38)	18	(56)	1	(10)	**130** [6, 0]	**(28)**
Total alive	*69*	*(43)*	*42*	*(57)*	*82*	*(52)*	*14*	*(54)*	*23*	*(72)*	*5*	*(50)*	***235*** [20, 4]	***(51)***
Died (post transplant)	12	(7)	4	(5)	12	(8)	1	(4)	1	(3)	1	(10)	**31** [8, 0]	**(7)**
Died (post explant)	2	(1)	1	(1)	2	(1)	0	(0)	0	(0)	0	(0)	**5**	**(1)**
Died with VAD	78	(48)	27	(36)	61	(39)	11	(42)	8	(25)	4	(40)	**189** [24, 10]	**(41)**
Total died	*92*	*(57)*	*32*	*(43)*	*75*	*(48)*	*12*	*(46)*	*9*	*(28)*	*5*	*(50)*	***225*** [32, 10]	***(49)***
TOTAL	**161**	**(100)**	**74**	**(100)**	**157**	**(100)**	**26**	**(100)**	**32**	**(100)**	**10**	**(100)**	**460**	**(100)**

Superscripts indicate the number of patients receiving a second device following explantation of their long-term 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 2012 to 31 March 2015

	Newcastle		Papworth		Harefield		Birmingham		Manchester		Glasgow		Total	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Alive (post transplant)	4	(6)	4	(13)	8	(14)	3	(13)	3	(13)	0	(0)	**22**	**(11)**
Alive (post explant)	1	(2)	0	(0)	1	(2)	0	(0)	0	(0)	1	(25)	**3**	**(2)**
Alive with VAD	28	(45)	13	(43)	29	(52)	10	(43)	16	(70)	0	(0)	**96**[2, 0]	**(48)**
Total alive	*33*	*(53)*	*17*	*(57)*	*38*	*(68)*	*13*	*(57)*	*19*	*(83)*	*1*	*(25)*	***121***[2, 0]	***(61)***
Died (post transplant)	3	(5)	1	(3)	3	(5)	1	(4)	1	(4)	0	(0)	**9**[1, 0]	**(5)**
Died (post explant)	1	(2)	0	(0)	0	(0)	0	(0)	0	(0)	0	(0)	**1**	**(1)**
Died with VAD	25	(40)	12	(40)	15	(27)	9	(39)	3	(13)	3	(75)	**67**[1, 2]	**(34)**
Total died	*29*	*(47)*	*13*	*(43)*	*18*	*(32)*	*10*	*(43)*	*4*	*(17)*	*3*	*(75)*	***77***[2 ,2]	***(39)***
TOTAL	**62**	**(100)**	**30**	**(100)**	**56**	**(100)**	**23**	**(100)**	**23**	**(100)**	**4**	**(100)**	**198** [4, 2]	**(100)**

Superscripts indicate the number of patients receiving a second device following explantation of their long-term 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 3.2 shows the causes of death for the 194 patients who died either post-explant or with a VAD over the whole ten year period. Deaths which occur more than one year post-explant are not referenced in these tables. Deaths post-explant are included in **Table 3.2** due to very small numbers (n=5). An additional 31 patients died within the first year post-transplant.

Following clinical review of the causes of death, 27 deaths were identified as deaths due to intracranial haemorrhage, 13 due to pump thrombosis, four due to ischaemic stroke and two deaths due to aortic regurgitation.

Table 3.2 Causes of death for patients who received a first long-term device, 1 April 2005 to 31 March 2015, by centre

	Newcastle N (%)	Harefield N (%)	Papworth N (%)	Manchester N (%)	Birmingham N (%)	Glasgow N (%)	Total N (%)
Number	80	63	28	8	11	4	**194**
Cardiovascular	5 (6)	2 (3)	3 (11)	2 (25)	1 (9)	0 (0)	**13 (7)**
Haemorrhage	9 (11)	10 (16)	7 (25)	3 (38)	0 (0)	0 (0)	**29 (15)**
Infection	8 (10)	3 (5)	1 (4)	0 (0)	0 (0)	0 (0)	**12 (6)**
Renal failure	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (1)**
Liver failure	0 (0)	2 (3)	0 (0)	0 (0)	0 (0)	0 (0)	**2 (1)**
Pulmonary	1 (1)	2 (3)	0 (0)	0 (0)	0 (0)	0 (0)	**3 (2)**
Device malfunction	1 (1)	3 (5)	1 (4)	0 (0)	0 (0)	0 (0)	**5 (3)**
Other	55 (69)	39 (62)	15 (54)	3 (38)	10 (91)	4 (100)	**126 (65)**
Post-explant	1 (1)	1 (2)	1 (4)	0 (0)	0 (0)	0 (0)	**3 (2)**

The outcomes of long-term first VAD recipients presented in **Table 3.1** shows the latest status for each patient as at 25 November 2015. 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 42% of patients remained on support, 19% were transplanted, 6% explanted and 33% 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 across all centres.

Figure 3.1a Cumulative incidence of each outcome for long-term first devices, 1 April 2005 to 31 March 2015

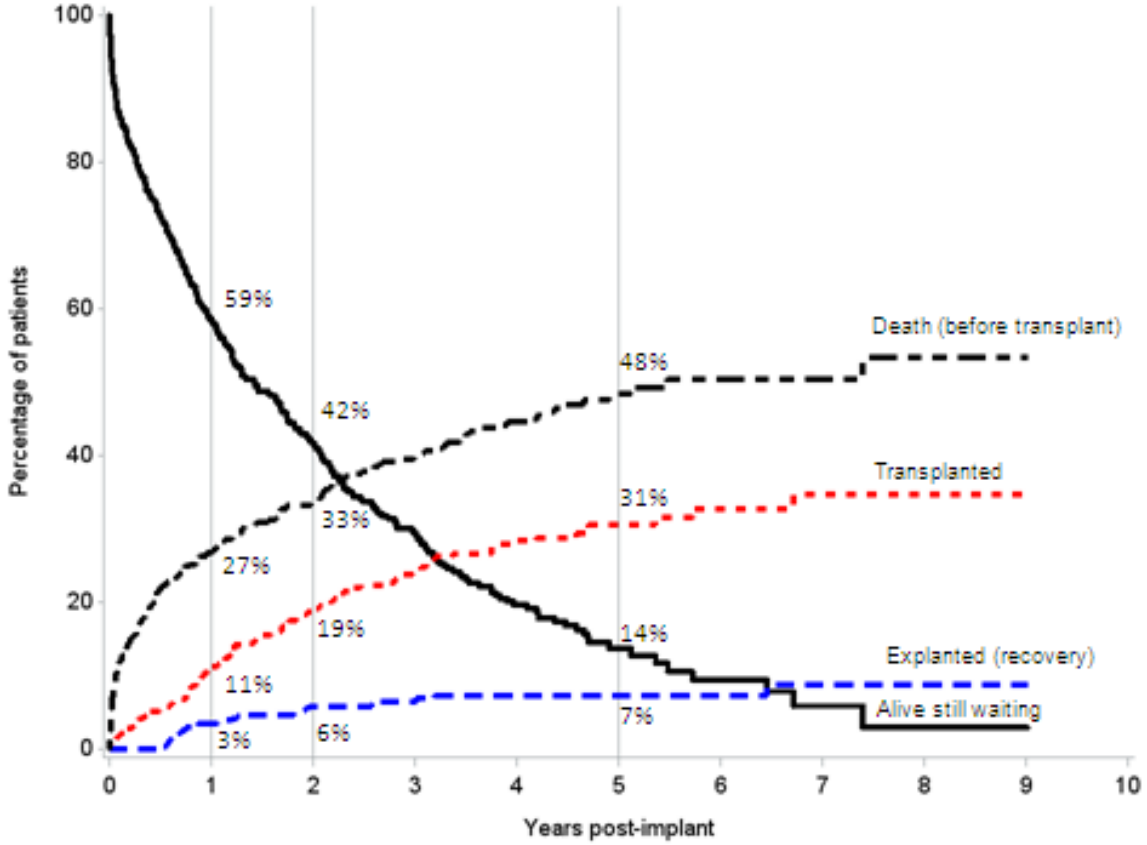


Table 3.3a	One-year cumulative incidence of each outcome, by centre, 1 April 2005 to 31 March 2015				
Hospital	No. at risk on day 0	Transplanted	Explanted	Alive on support	Death (before transplant)
		%	%	%	%
Newcastle	161	13	7	42	38
Papworth	74	14	7	41	38
Harefield	157	9	7	45	38
Birmingham	26	12	7	43	38
Manchester	32	9	7	55	29
Glasgow	10	8	10	59	23
All centres	**460**	**11**	**3**	**59**	**27**

Figure 3.1b Cumulative incidence of each outcome for third generation long-term first devices, 1 April 2005 to 31 March 2015

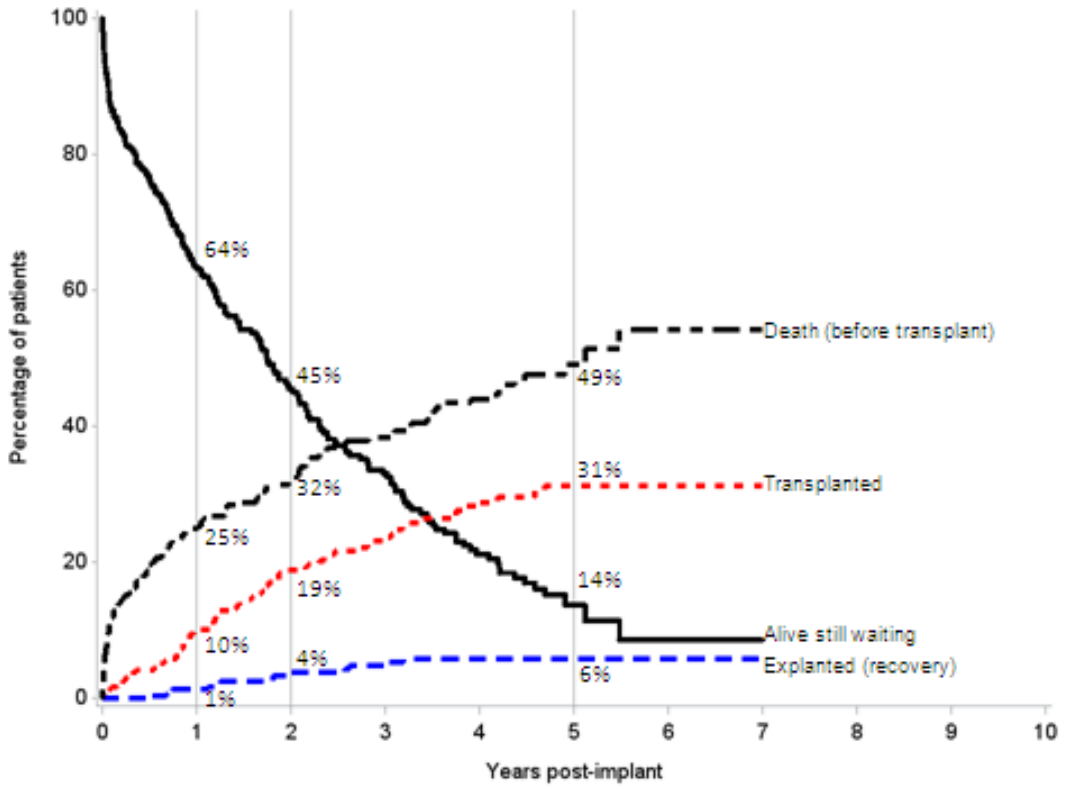


Table 3.3b	One-year cumulative incidence of each outcome for third generation devices, by centre, 1 April 2005 to 31 March 2015				
Hospital	No. at risk on day 0	Transplanted %	Explanted %	Alive on support %	Death (before transplant) %
Newcastle	138	7	2	65	26
Papworth	74	14	2	58	26
Harefield	92	11	2	61	26
All centres	**309**	**10**	**1**	**63**	**25**

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 18% to 63% (chi-squared p-value <0.0001).

Table 3.4	Heart transplant registration status at long-term VAD implantation, by financial year, 1 April 2005 to 31 March 2015			
Financial year	Listed pre-VAD implant N (%)	Listed post-VAD implant N (%)	Never listed N (%)	Total N (%)
2005/2006	6 (60)	4 (40)	0 (0)	**10 (100)**
2006/2007	8 (53)	4 (27)	3 (20)	**15 (100)**
2007/2008	12 (55)	5 (23)	5 (23)	**22 (100)**
2008/2009	16 (44)	11 (31)	9 (25)	**36 (100)**
2009/2010	22 (50)	9 (20)	13 (30)	**44 (100)**
2010/2011	13 (18)	35 (48)	25 (34)	**73 (100)**
2011/2012	20 (32)	20 (32)	22 (35)	**62 (100)**
2012/2013	34 (63)	13 (24)	7 (13)	**54 (100)**
2013/2014	37 (60)	15 (24)	10 (16)	**62 (100)**
2014/2015	42 (51)	4 (5)	36 (44)	**82 (100)**
Total	**210 (46)**	**120 (26)**	**130 (28)**	**460 (100)**

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, respectively.

Figure 3.2 Time from implant of first long-term VAD to registration on the heart transplant list for people not registered on the transplant list at time of receiving first long-term device, 1 April 2005 to 31 March 2015

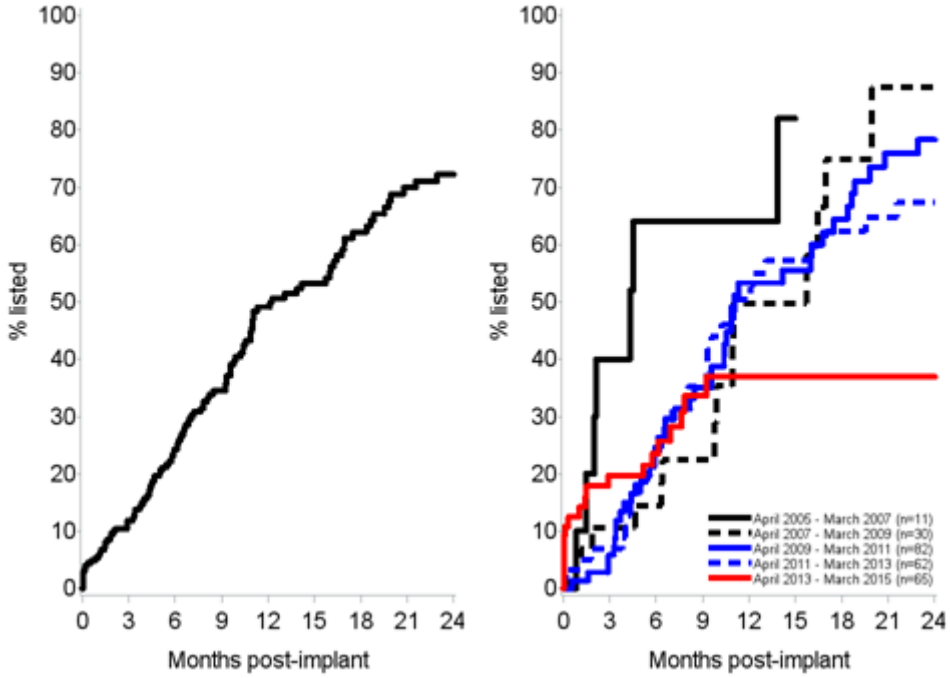


Table 3.5 shows the estimated proportion of patients listed in different time periods for the subset of patients who were not registered on the heart transplant list at time of implant. Overall, an estimated 24% of those not on the list at time of implant were registered within 6 months and 72% within 2 years. There was a statistically significant difference at 6 months post-implant between the grouped financial years (log-rank p-value=0.02). However, there was no evidence of a difference at one year and two years post-implant (log-rank p-value>0.1).

Table 3.5 Survival estimates for time first continuous long-term VAD to registration on transplant list for patients not registered prior to receiving a first long-term device, by financial year, 1 April 2005 to 31 March 2015

Grouped financial year	No. at risk on day 0	% listed post-implant (95% confidence interval) 6 months		1 year		2 years	
April 2005 - March 2007	11	64	(35 - 91)	64	(35 - 91)	82	(48 - 99)
April 2007 - March 2009	30	15	(6 - 34)	50	(29 - 75)	87	(60 - 99)
April 2009 - March 2011	82	25	(16 - 37)	53	(41 - 67)	78	(66 - 89)
April 2011 - March 2013	62	23	(14 - 37)	50	(37 - 65)	67	(54 - 80)
April 2013 - March 2015	65	24	(15 - 37)	37	(25 - 53)	37	(25 - 53)
Log-rank p-value		0.02		0.3		0.11	
Overall	**250**	**24**	**(19 - 31)**	**49**	**(42 - 57)**	**72**	**(64 - 80)**

Table 3.6 shows the long-term VAD duration of support. Overall, the long-term VAD duration of support ranged between 0 and 3290 days (nine years). Using the Kaplan-Meier estimation method, median long-term VAD duration for all patients was estimated to be 520 days (95% CI: 418, 622).

Table 3.6 Long-term VAD duration, by implant centre, 1 April 2005 to 31 March 2015

Hospital	No. of implants	No. missing	Range	Median	(95% confidence interval)
Newcastle	161	0	0 - 2428	473	(279, 667)
Papworth	74	0	3 - 2551	597	(396, 798)
Harefield	157	0	1 - 3290	486	(327, 645)
Birmingham	26	0	41 - 1144	443	(281, 605)
Manchester	32	0	24 - 1806	1383	(297, 2469)
Glasgow	10	0	2 - 1350	204	(7, 401)
All centres	**460**	**0**	**0 - 3290**	**520**	**(418, 622)**

A. Patient survival

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 2005 to 31 March 2015

Centre	No. at risk on day 0	% patient survival (95% confidence interval) 30 days		90 days		1 year		2 years		3 years	
Newcastle	161	86	(80 - 91)	80	(73 - 86)	67	(59 - 74)	54	(46 - 62)	48	(40 - 56)
Papworth	74	92	(83 - 96)	86	(76 - 92)	73	(61 - 82)	64	(51 - 74)	62	(49 - 72)
Harefield	157	89	(82 - 93)	83	(76 - 88)	73	(66 - 80)	63	(54 - 70)	53	(44 - 61)
Birmingham	26	100	(-)	96	(76 - 99)	62	(39 - 79)	56	(32 - 74)	47	(22 - 68)
Manchester	32	94	(77 - 98)	91	(74 - 97)	81	(63 - 91)	73	(53 - 86)	67	(45 - 82)
Glasgow	10	80	(41 - 95)	70	(33 - 89)	50	(18 - 75)	50	(18 - 75)	50	(18 - 75)
All centres	**460**	**89**	**(86 - 92)**	**83**	**(80 - 87)**	**71**	**(66 - 75)**	**60**	**(55 - 64)**	**53**	**(48 - 58)**
Number at risk		410		385		289		207		161	

Table 3.7b Patient survival after implant of long-term VAD, by implant centre, 1 April 2012 to 31 March 2015

Centre	No. at risk on day 0	% patient survival (95% confidence interval) 30 days		90 days		1 year		2 years		3 years	
Newcastle	62	82	(70 - 90)	74	(61 - 83)	67	(53 - 77)	43	(27 - 58)	39	(22 - 55)
Papworth	30	87	(68 - 95)	87	(68 - 95)	66	(46 - 80)	56	(35 - 73)	47	(23 - 67)
Harefield	56	86	(73 - 93)	79	(65 - 87)	72	(58 - 82)	65	(49 - 78)	60	(41 - 74)
Birmingham	23	100	(-)	100	(-)	68	(43 - 83)	60	(34 - 79)	48	(20 - 72)
Manchester	23	100	(-)	96	(73 - 99)	83	(60 - 93)	76	(50 - 89)	76	(50 - 89)
Glasgow	4	50	(6 - 84)	25	(1 - 67)	25	(1 - 67)	25	(1 - 67)	25	(1 - 67)
All centres	**198**	**87**	**(82 - 91)**	**82**	**(76 - 87)**	**69**	**(62 - 75)**	**57**	**(49 - 65)**	**50**	**(40 - 59)**
Number at risk		173		162		101		46		17	

Table 3.8a compares overall 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<0.001). However, treatment has not been randomised and it is likely that the pre-implant illness was more severe in the BiVAD group. **Table 3.8b** present patient survival rates for patients who received long-term VADs during the last three years.

Table 3.8a Patient survival after implant of long-term VAD, by LVAD/BiVAD, 1 April 2005 to 31 March 2015

Device	No. at risk on day 0	% patient survival (95% confidence interval) 30 days		90 days		1 year		2 years		3 years	
LVAD only	390	92	(89 - 95)	87	(84 - 90)	74	(69 - 78)	64	(58 - 68)	57	(51 - 62)
BiVAD	70	71	(59 - 81)	61	(49 - 72)	51	(39 - 62)	39	(28 - 50)	36	(25 - 47)
Overall	**460**	**89**	**(86 - 92)**	**83**	**(80 - 87)**	**71**	**(66 - 75)**	**60**	**(55 - 64)**	**53**	**(48 - 58)**
Number at risk		410		385		289		207		161	

Table 3.8b Patient survival after implant of long-term VAD, by LVAD/BiVAD, 1 April 2012 to 31 March 2015

Device	No. at risk on day 0	% patient survival (95% confidence interval) 30 days		90 days		1 year		2 years		3 years	
LVAD only	172	92	(87 - 96)	88	(83 - 92)	75	(67 - 81)	61	(52 - 69)	53	(41 - 63)
BiVAD	26	54	(33 - 71)	38	(20 - 56)	35	(17 - 52)	29	(13 - 48)	29	(13 - 48)
Overall	**198**	**87**	**(82 - 91)**	**82**	**(76 - 87)**	**69**	**(62 - 75)**	**57**	**(49 - 65)**	**50**	**(40 - 59)**
Number at risk		173		162		101		46		17	

Table 3.9a and **Figure 3.3** compare patient survival for patients who received the two frequently implanted device types: Heartmate II and Heartware. There is no evidence of a difference in survival between the two groups (log-rank test, p≥0.19). **Table 3.9b** present survival rates for patients who received long-term VADs during the last three years.

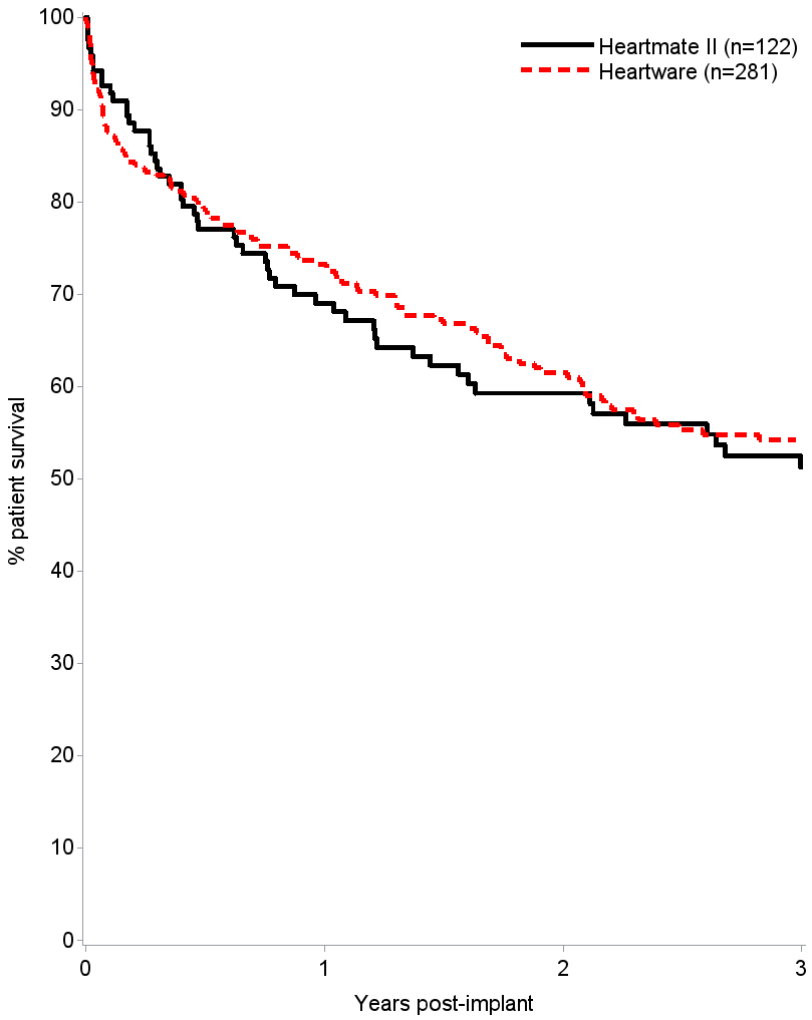
Table 3.9a Patient survival after implant of long-term VAD, by Heartmate II/ Heartware, 1 April 2005 to 31 March 2015

Device	No. at risk on day 0	% patient survival (95% confidence interval) 30 days		90 days		1 year		2 years		3 years	
Heartmate II	122	93	(86 - 96)	88	(80 - 92)	69	(60 - 77)	59	(50 - 68)	51	(41 - 60)
Heartware	281	88	(84 - 92)	83	(78 - 87)	73	(68 - 78)	62	(55 - 67)	54	(48 - 60)
Overall	**403**	**90**	**(86 - 92)**	**85**	**(81 - 88)**	**72**	**(67 - 76)**	**61**	**(56 - 66)**	**53**	**(48 - 58)**
Number at risk		361		342		254		178		133	

Table 3.9b Patient survival after implant of long-term VAD, by Heartmate II/ Heartware, 1 April 2012 to 31 March 2015

Device	No. at risk on day 0	% patient survival (95% confidence interval) 30 days		90 days		1 year		2 years		3 years	
Heartmate II	51	94	(83 - 98)	90	(78 - 96)	68	(53 - 79)	61	(45 - 74)	55	(35 - 71)
Heartware	144	85	(79 - 90)	79	(72 - 85)	70	(62 - 77)	55	(45 - 64)	48	(37 - 59)
Overall	**195**	**88**	**(82 - 92)**	**82**	**(76 - 87)**	**69**	**(62 - 76)**	**57**	**(48 - 65)**	**50**	**(40 - 59)**
Number at risk		171		160		99		45		17	

Figure 3.3 Overall patient survival after implant of long-term VAD, by device type, 1 April 2005 to 31 March 2015



B. Survival on a device

Table 3.10a shows Kaplan-Meier estimates of patient survival during VAD support for the whole ten year time period whilst **Table 3.10b** shows the survival estimates for the most recent three years. Unlike the survival estimates in **section A**, 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; 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 3.10a Survival during long-term VAD support, by implant centre, 1 April 2005 to 31 March 2015

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	161	86	(80 - 91)	81	(74 - 87)	69	(60 - 75)	58	(49 - 66)	49	(40 - 58)
Papworth	74	92	(83 - 96)	88	(78 - 93)	73	(61 - 82)	64	(50 - 75)	60	(46 - 72)
Harefield	157	88	(82 - 93)	83	(76 - 88)	77	(69 - 83)	69	(60 - 76)	53	(42 - 63)
Birmingham	26	100	(-)	96	(76 - 99)	64	(39 - 81)	57	(32 - 76)	57	(32 - 76)
Manchester	32	94	(77 - 98)	91	(74 - 97)	84	(66 - 93)	79	(60 - 90)	70	(41 - 86)
Glasgow	10	80	(41 - 95)	70	(33 - 89)	60	(25 - 83)	60	(25 - 83)	60	(25 - 83)
All centres	**460**	**89**	**(86 - 92)**	**84**	**(81 - 87)**	**73**	**(68 - 77)**	**64**	**(59 - 69)**	**54**	**(48 - 60)**
Number at risk		401		374		238		139		83	

Table 3.10b Survival during long-term VAD support, by implant centre, 1 April 2012 to 31 March 2015

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	62	82	(70 - 90)	77	(65 - 86)	69	(56 - 80)	50	(33 - 65)	43	(24 - 61)
Papworth	30	87	(68 - 95)	87	(68 - 95)	66	(46 - 80)	61	(39 - 76)	45	(17 - 71)
Harefield	56	86	(73 - 92)	80	(67 - 88)	76	(62 - 85)	76	(62 - 85)	65	(39 - 82)
Birmingham	23	100	(-)	100	(-)	70	(44 - 86)	61	(34 - 81)	61	(34 - 81)
Manchester	23	100	(-)	96	(73 - 99)	86	(63 - 95)	86	(63 - 95)	86	(63 - 95)
Glasgow	4	50	(6 - 84)	25	(1 - 67)	25	(1 - 67)		(-)		(-)
All centres	**198**	**87**	**(82 - 91)**	**83**	**(77 - 88)**	**72**	**(65 - 78)**	**63**	**(54 - 71)**	**55**	**(43 - 65)**
Number at risk		170		158		90		31		8	

Table 3.11a compares survival whilst on support 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<0.001). However, treatment has not been randomised and it is likely that the pre-implant illness was more severe in the BiVAD group. **Table 3.11b** present survival rates for patients who received long-term VADs during the last three years.

Table 3.11a Survival during long-term VAD support, by LVAD/BiVAD, 1 April 2005 to 31 March 2015

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	390	92	(89 - 95)	88	(84 - 91)	76	(71 - 80)	68	(63 - 73)	58	(51 - 64)
BiVAD	70	70	(58 - 80)	64	(51 - 74)	53	(40 - 64)	40	(26 - 53)	31	(17 - 46)
Overall	**460**	**89**	**(86 - 92)**	**84**	**(81 - 87)**	**73**	**(68 - 77)**	**64**	**(59 - 69)**	**54**	**(48 - 60)**
Number at risk		401		374		238		139		83	

Table 3.11b Survival during long-term VAD support, by LVAD/BiVAD, 1 April 2012 to 31 March 2015

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	172	92	(87 - 96)	89	(83 - 93)	77	(69 - 82)	67	(57 - 75)	57	(43 - 69)
BiVAD	26	53	(32 - 70)	44	(25 - 62)	39	(20 - 58)	39	(20 - 58)	39	(20 - 58)
Overall	**198**	**87**	**(82 - 91)**	**83**	**(77 - 88)**	**72**	**(65 - 78)**	**63**	**(54 - 71)**	**55**	**(43 - 65)**
Number at risk		170		158		90		31		8	

Table 3.12a compares survival whilst on support for patients who received the two frequently implanted device types: Heartmate II and Heartware, over the whole ten year period whilst **Table 3.12b** present survival rates for patients who received long-term VADs during the last three years.

Table 3.12a Survival during long-term VAD support, by Heartmate II/ Heartware, 1 April 2005 to 31 March 2015

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	122	93	(86 - 96)	88	(80 - 92)	74	(65 - 81)	65	(55 - 74)	53	(40 - 65)
Heartware	279	88	(84 - 91)	85	(80 - 89)	75	(70 - 80)	66	(60 - 72)	56	(48 - 63)
Overall	**401**	**89**	**(86 - 92)**	**86**	**(82 - 89)**	**75**	**(70 - 79)**	**66**	**(61 - 71)**	**55**	**(48 - 61)**
Number at risk		354		335		219		129		73	

Table 3.12b Survival during long-term VAD support, by Heartmate II/ Heartware, 1 April 2012 to 31 March 2015

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	51	94	(83 - 98)	90	(78 - 96)	71	(55 - 82)	67	(51 - 79)	67	(51 - 79)
Heartware	142	85	(78 - 90)	81	(74 - 87)	74	(66 - 81)	63	(52 - 72)	51	(36 - 65)
Overall	**193**	**87**	**(82 - 91)**	**84**	**(78 - 88)**	**73**	**(66 - 79)**	**64**	**(55 - 72)**	**56**	**(44 - 67)**
Number at risk		166		156		89		31		6	

BRIDGED TO LONG-TERM DEVICES

Patient Outcome

This section includes patients who received a long-term device following a short period of short-term VAD or ECMO support.

Fifty-three patients were bridged from a short-term device or ECMO to a long-term device at six adult centres in the UK between 1 April 2005 and 31 March 2015. **Table 4.1a** shows the number of short-term and long-term devices used overall, whilst **Table 4.1b** shows similar information for the most recent three years. 27 patients (51%) were bridged to long-term device at Harefield, whilst Birmingham, Papworth and Newcastle performed less than five during the ten year period. Forty-eight patients (91%) received either a Heartmate II or Heartware following a period of short-term device support.

Table 4.1a Device types for patients bridged from a short-term device to a long-term device, by implant centre, 1 April 2005 to 31 March 2015

Short-term devices		Long-term devices		Newcastle		Papworth		Harefield		Birmingham		Manchester		Glasgow		Total	
Device 1	Device 2	Device 1	Device 2	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Overall				**2**	**(100)**	**4**	**(100)**	**27**	**(100)**	**4**	**(100)**	**10**	**(100)**	**6**	**(100)**	**53**	**(100)**
Centrimag		Heartmate II						10	(37)			1	(10)	3	(50)	14	(100)
Centrimag		Heartware						4	(15)					1	(17)	5	(100)
Centrimag		Heart Assist 5						1	(4)							1	(100)
Centrimag		Heart Assist 5	Heartware					1	(4)							1	(100)
Centrimag		Heartmate XVE						1	(4)							1	(100)
Centrimag		Heartware	Heartware									1	(10)			1	(100)
Centrimag		Jarvik 2000						1	(4)							1	(100)
Centrimag	Centrimag	Heartware										1	(10)			1	(100)
ECMO only		Heartware		2	(100)	3	(75)	8	(30)			2	(20)			15	(100)
ECMO only		Heartmate II								3	(75)	1	(10)	1	(17)	5	(100)
ECMO only	Centrimag	Heartware						1	(4)			3	(30)			4	(100)
ECMO only	Centrimag	Heartmate II										1	(10)	1	(17)	2	(100)
ECMO only		Thoratec PVAD				1	(25)									1	(100)
Impella		Heartmate II								1	(25)					1	(100)

Table 4.1b Device types for patients bridged from a short-term device to a long-term device, by implant centre, 1 April 2012 to 31 March 2015

Short-term devices		Long-term devices		Newcastle		Papworth		Harefield		Birmingham		Manchester		Glasgow		Total	
Device 1	Device 2	Device 1	Device 2	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Overall				**2**	**(100)**	**2**	**(100)**	**11**	**(100)**	**2**	**(100)**	**8**	**(100)**	**5**	**(100)**	**30**	**(100)**
Centrimag		Heartmate II										1	(13)	2	(4)	3	(1)
Centrimag		Heartware						2	(18)					1	(2)	3	(1)
Centrimag		Heartware	Heartware									1	(13)			1	(1)
ECMO only		Heartware		2	(1)	2	(1)	8	(73)			1	(13)			13	(1)
ECMO only	Centrimag	Heartware						1	(9)			3	(38)			4	(1)
ECMO only		Heartmate II								1	(5)	1	(13)	1	(2)	3	(1)
ECMO only	Centrimag	Heartmate II										1	(13)	1	(2)	2	(1)
Impella		Heartmate II								1	(5)					1	(1)

Table 4.2a shows the long-term VAD outcome of recipients, by centre, for the whole 10 year time period. Nationally, 16 patients were transplanted, 4 survived explantation of the long-term VAD, 17 died on support, 1 died post device explantation (within a month of explantation) and 15 were still on support on 15 October 2015.

Table 4.2b shows the outcome of long-term VADs implanted during the most recent three years (April 2012 - March 2015). Deaths which occurred more than one year post-transplant or one-year post-explant are not referenced in either tables.

Table 4.2a Outcome of patients bridged to a long-term device, by implant centre, 1 April 2005 to 31 March 2015

	Newcastle		Papworth		Harefield		Birmingham		Manchester		Glasgow		Total	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Alive (post transplant)	0	(0)	2	(50)	4	(15)	2	(50)	2	(20)	1	(17)	**11**	**(21)**
Alive (post explant)	0	(0)	0	(0)	2	(7)	0	(0)	1	(10)	1	(17)	**4**	**(8)**
Alive with VAD	0	(0)	0	(0)	8	(30)	1	(25)	5	(50)	1	(17)	**15**	**(28)**
Total alive	*0*	*(0)*	*2*	*(50)*	*14*	*(52)*	*3*	*(75)*	*8*	*(80)*	*3*	*(50)*	***30***	***(57)***
Died (post transplant)	1	(50)	1	(25)	3	(11)	0	(0)	0	(0)	0	(0)	**5**	**(9)**
Died (post explant)	0	(0)	0	(0)	1	(4)	0	(0)	0	(0)	0	(0)	**1**	**(2)**
Died with VAD	1	(50)	1	(25)	9	(33)	1	(25)	2	(20)	3	(50)	**17**	**(32)**
Total died	*2*	*(100)*	*2*	*(50)*	*13*	*(48)*	*1*	*(25)*	*2*	*(20)*	*3*	*(50)*	***23***	***(43)***
TOTAL	**2**	**(100)**	**4**	**(100)**	**27**	**(100)**	**4**	**(100)**	**10**	**(100)**	**6**	**(100)**	**53**	**(100)**

Table 4.2b Outcome of patients bridged to a long-term device, by implant centre, 1 April 2012 to 31 March 2015

	Newcastle		Papworth		Harefield		Birmingham		Manchester		Glasgow		Total	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Alive (post transplant)	0	(0)	1	(50)	1	(9)	1	(50)	2	(25)	0	(0)	**5**	**(17)**
Alive (post explant)	0	(0)	0	(0)	0	(0)	0	(0)	1	(13)	1	(20)	**2**	**(7)**
Alive with VAD	0	(0)	0	(0)	5	(45)	0	(0)	5	(63)	1	(20)	**11**	**(37)**
Total alive	*0*	*(0)*	*1*	*(50)*	*6*	*(55)*	*1*	*(50)*	*8*	*(100)*	*2*	*(40)*	***18***	***(60)***
Died (post transplant)	1	(50)	0	(0)	3	(27)	0	(0)	0	(0)	0	(0)	**4**	**(13)**
Died with VAD	1	(50)	1	(50)	2	(18)	1	(50)	0	(0)	3	(60)	**8**	**(27)**
Total died	*2*	*(100)*	*1*	*(50)*	*5*	*(45)*	*1*	*(50)*	*0*	*(0)*	*3*	*(60)*	***12***	***(40)***
TOTAL	**2**	**(100)**	**2**	**(100)**	**11**	**(100)**	**2**	**(100)**	**8**	**(100)**	**5**	**(100)**	**30**	**(100)**

Table 4.3 shows the causes of death for the 23 patients who died following long-term VAD implantation. Deaths which occur more than one year post-explant are not referenced in these tables. Deaths post-explant are included in **Table 4.3** due to very small numbers (n=1).

Table 4.3 Causes of death for patients who received a bridged to long-term device, 1 April 2005 to 31 March 2015, by centre

	Newcastle N (%)	Harefield N (%)	Papworth N (%)	Manchester N (%)	Birmingham N (%)	Glasgow N (%)	Total N (%)
Number	2	13	2	2	1	3	**23**
Cardiovascular	0 (0)	0 (0)	0 (0)	1 (50)	0 (0)	0 (0)	**1 (4)**
Haemorrhage	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (33)	**1 (4)**
Infection	0 (0)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)	**1 (4)**
Pulmonary	0 (0)	1 (8)	1 (50)	0 (0)	0 (0)	0 (0)	**2 (9)**
Device malfunction	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (4)**
Other	1 (50)	10 (77)	1 (50)	1 (50)	0 (0)	2 (67)	**15 (65)**
Post-explant	1 (50)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	**2 (9)**

Table 4.4 shows the overall VAD duration and the duration of short-term and long-term devices, separately, for the whole ten years. The overall device duration ranged between 25 and 2169 days (6 years). Using the Kaplan-Meier estimation method, median overall device duration was estimated to be 338 days (95% CI: 190, 486).

Table 4.4 VAD duration for patients bridged to long-term device, by implant centre, 1 April 2005 to 31 March 2015

Hospital	No. of implants	No. missing	Range	Median	(95% confidence interval)
Overall duration					
Newcastle	2	0	240 - 691	240	(-)
Papworth	4	0	25 - 564	107	(0, 256)
Harefield	27	0	27 - 2169	338	(124, 552)
Birmingham	4	0	31 - 1693	35	(0, 228)
Manchester	10	0	184 - 551	437	(385, 489)
Glasgow	6	0	30 - 1410	63	(0, 353)
All centres	**53**	**0**	**25 - 2169**	**338**	**(190, 486)**
ST device duration					
Newcastle	2	0	2 - 16	2	(-)
Papworth	4	0	1 - 15	3	(1, 5)
Harefield	27	0	2 - 74	20	(13, 27)
Birmingham	4	0	7 - 14	8	(2, 14)
Manchester	10	0	1 - 79	33	(0, 83)
Glasgow	6	0	2 - 64	23	(0, 55)
All centres	**53**	**0**	**1 - 79**	**18**	**(13, 23)**
LT VAD duration					
Newcastle	2	0	238 - 675	238	(-)
Papworth	4	0	10 - 561	106	(0, 267)
Harefield	27	0	18 - 2146	310	(67, 553)
Birmingham	4	0	22 - 1685	24	(0, 212)
Manchester	10	0	180 - 503	377	(362, 392)
Glasgow	6	0	7 - 1346	13	(0, 246)
All centres	**53**	**0**	**7 - 2146**	**310**	**(169, 451)**

Table 4.5 shows, by centre, Kaplan-Meier estimates of patient survival from time of first short-term device implant to death for the whole 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. Survival estimates for Newcastle, Papworth Birmingham and Glasgow are not presented due to the small number of patients at risk. Patients at all four centres are, however, included in the overall number of patients at risk.

Table 4.5 Patient survival after implant of short-term device for patients bridged to a long-term device, by implant centre, 1 April 2005 to 31 March 2015

Centre	No. at risk on day 0	% patient survival (95% confidence interval) 30 days		90 days		1 year		2 years		3 years	
Harefield	27	100	(-)	89	(69 - 96)	66	(44 - 80)	66	(44 - 80)	44	(23 - 63)
Manchester	10	100	(-)	100	(-)	89	(43 - 98)	71	(23 - 92)	-	(-)
Overall	53	96	(86 - 99)	85	(72 - 92)	67	(52 - 78)	61	(46 - 74)	49	(33 - 63)
Number at risk		52		45		30		21		14	

Centre specific survival rates for Newcastle, Papworth, Birmingham and Glasgow are not presented above but are included in the national rate

Table 4.6 shows Kaplan-Meier estimates of patient survival during long-term VAD support for the whole ten year time period. Unlike the survival estimates in **Table 4.5**, survival was from point of long-term device implantation to death with survival time censored at time of device explantation or transplantation. Again, survival estimates for Newcastle, Papworth Birmingham and Glasgow are not presented due to the small number of patients at risk, but patients at all four centres are, however, included in the overall number of patients at risk Two-year and three year survival estimates are not presented due to the small number of patients at risk.

Table 4.6 Survival during long-term device support, by implant centre, 1 April 2005 to 31 March 2015

Centre	No. at risk on day 0	% survival on a device (95% confidence interval) 30 days		90 days		1 year	
Harefield	27	96	(76 - 99)	89	(69 - 96)	67	(42 - 83)
Manchester	10	100	(-)	100	(-)	89	(43 - 98)
Overall	53	89	(77 - 95)	85	(72 - 92)	72	(56 - 83)
Number at risk		45		41		21	

Centre specific survival rates for Newcastle, Papworth, Birmingham and Glasgow are not presented above but are included in the national rate

Table 4.7 shows patient survival from first short-term device by whether the patient received a short-term device prior to the long-term device or an ECMO only. Patients who received an ECMO and a short-term device prior to a long-term device are included in the short-term device group. Care should be taken when interpreting survival estimates due to the small number of patients at risk. Statistical comparisons are not presented due to the type of short-term devices used being confounded with the implanting centres as three of the centres did not implant any short-term devices into patients who subsequently received a long-term device.

Table 4.7 Patient survival after implant of short-term device for patients bridged to a long-term device, by device group, 1 April 2005 to 31 March 2015

Device	No. at risk on day 0	% patient survival (95% confidence interval) 30 days		90 days		1 year		2 years		3 years	
ECMO only	21	95	(71 - 99)	86	(62 - 95)	65	(39 - 81)	60	(33 - 79)	50	(20 - 74)
ST device	32	97	(80 - 100)	84	(66 - 93)	68	(48 - 81)	68	(48 - 81)	48	(27 - 67)
Overall	**53**	**96**	**(86 - 99)**	**85**	**(72 - 92)**	**67**	**(52 - 78)**	**61**	**(46 - 74)**	**49**	**(33 - 63)**
Number at risk		52		45		30		21		14	

Table 4.8 shows estimated survival whilst on long-term device support. Similar to **Table 4.6** survival was from point of long-term device implantation to death with survival time censored at time of device explantation or transplantation. Again, care should be taken when interpreting survival estimates due to the small number of patients at risk. Two-year and three year survival estimates are not presented due to the small number of patients at risk.

Table 4.8 Survival during long-term device support, by device group, 1 April 2005 to 31 March 2015

Device	No. at risk on day 0	% survival on a device (95% confidence interval) 30 days		90 days		1 year	
ECMO only	21	90	(67 - 98)	85	(61 - 95)	85	(61 - 95)
ST device	32	88	(70 - 95)	84	(66 - 93)	66	(45 - 80)
Overall	**53**	**89**	**(77 - 95)**	**85**	**(72 - 92)**	**72**	**(56 - 83)**
Number at risk		45		41		21	

SHORT TERM DEVICES USED FOR BRIDGING

Activity

This section considers all patients who received a short-term device or ECMO for bridging to heart transplantation regardless of whether they received a previous device.

All figures and tables in this section, apart from **Table 5.1**, present information on a per device basis as opposed to per patient. **Table 5.1** shows the characteristics of patients who received a short-term device on a per patient basis.

Two hundred eighty-five short-term ventricular assist devices (VADs) or ECMOs were implanted for 245 patients at six adult implant centres in the UK between 1 April 2005 and 31 March 2015. Twelve patients received 13 devices at Newcastle, 65 at Harefield (68 devices), 42 at Papworth (52 devices), 48 at Birmingham (58 devices), 37 at Glasgow (41 devices) and 41 at Manchester (53 devices).

Figure 5.1 shows the cumulative number of short-term VADs/ECMOs implanted each month, overall and by centre, whilst **Figure 5.2** shows the number of short-term VADs/ECMOs by financial year and centre. Short term device/ ECMO activity has increased at all centres except Newcastle.

Figure 5.1 Cumulative short-term VAD/ECMO activity, by month and implant centre, 1 April 2005 to 31 March 2015

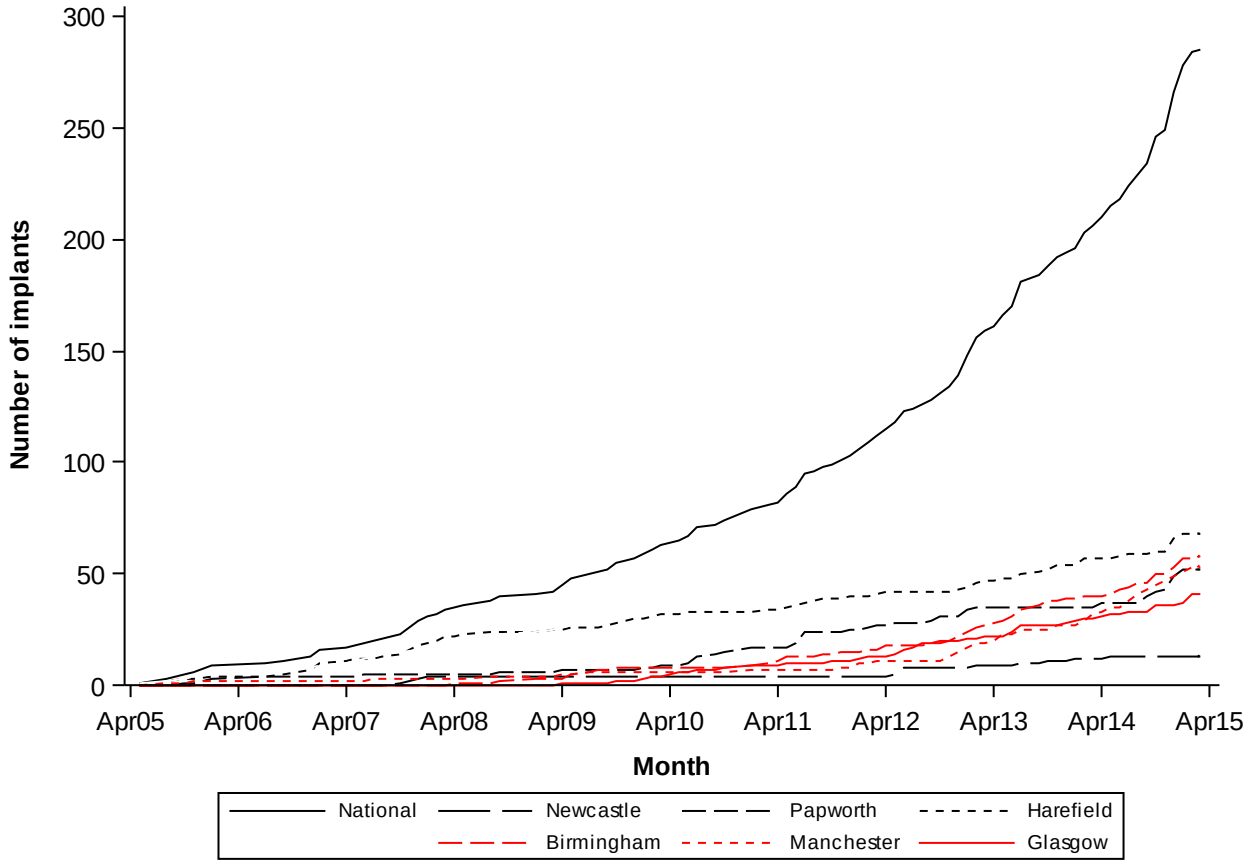


Figure 5.2 Short-term VAD/ECMO activity, by financial year and implant centre, 1 April 2005 to 31 March 2015

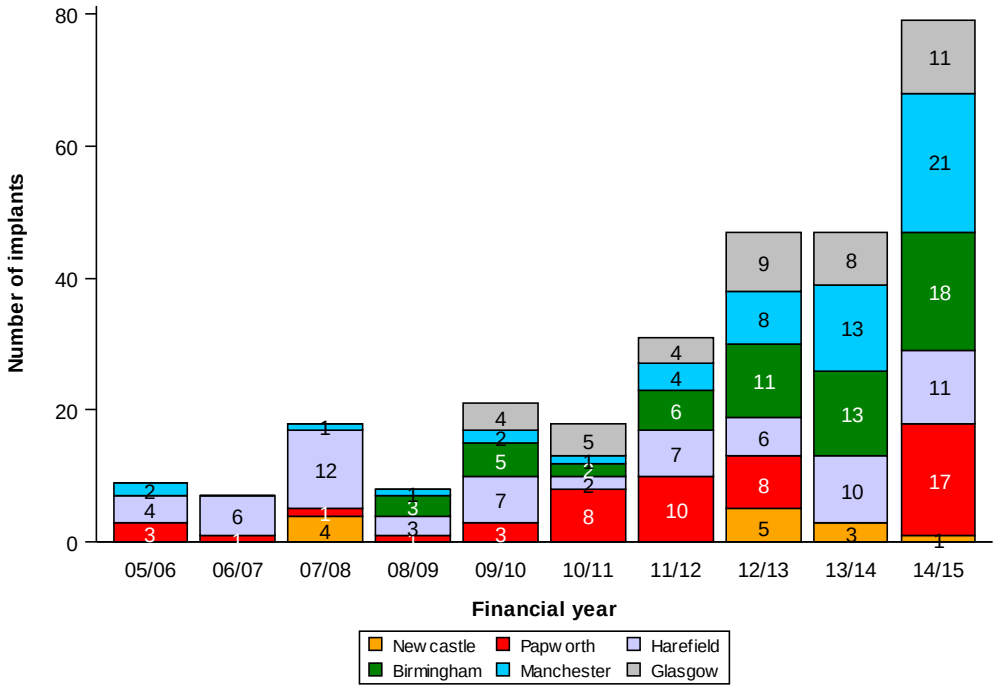


Figure 5.3 shows the [INTERMACS patient profile] at time of short-term VAD/ECMO implantation and shows that profile 1 (cardiogenic shock) is the most common.

Figure 5.3 INTERMACS patient profile for all bridging short-term devices and ECMOs, 1 April 2005 to 31 March 2015

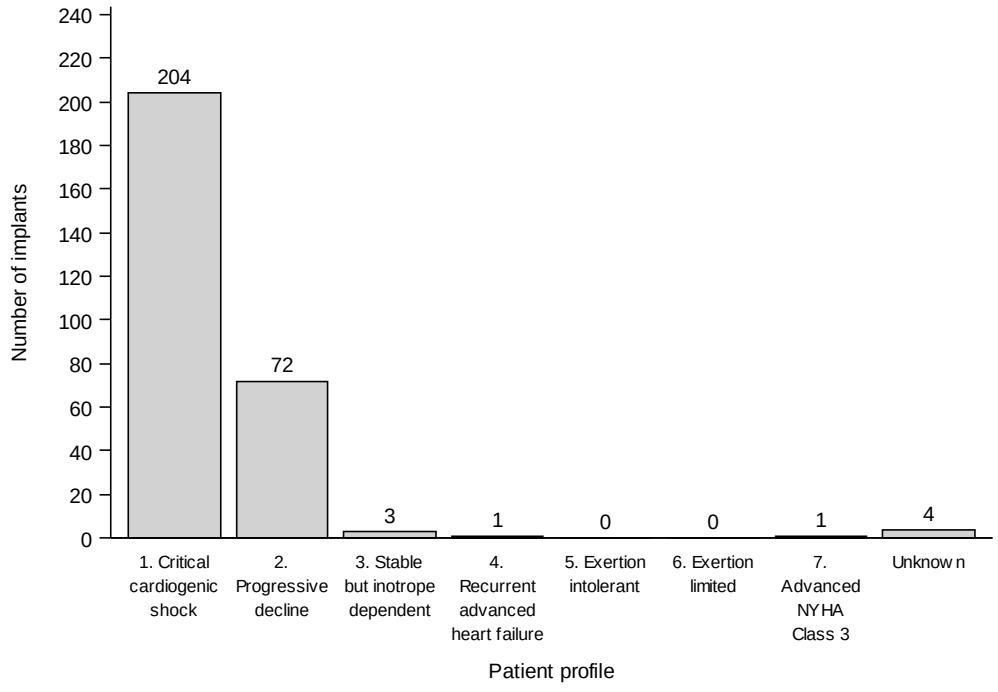


Table 5.1 shows the characteristics of patients who received a short-term device or ECMO by implant centre. Overall, the most frequently reported cardiothoracic diseases were dilated cardiomyopathy (57%) and ischaemic heart disease (29%). The overall median age at implant was 42 years (inter-quartile range 29 - 51 years) and the majority of recipients were male (69%).

The device history for all short-term device patients is outlined in sequence in **Table 5.1**.

Unlike **Table 5.1**, which presents information on a per patient basis, **Table 5.2** presents characteristics on a per device basis. **Table 5.2** shows that the most frequently used devices were Centrimag (62%) and ECMO only (36%). Overall 43% received only one short-term device and 16% received only one ECMO only. 79% were on inotropes at time of VAD implant whilst 53% received an IABP prior to VAD implant.

Table 5.1 Characteristics of patients who received a short-term device or ECMO for bridging to heart transplantation, 1 April 2005 to 31 March 2015, by centre

		Newcastle N (%)	Harefield N (%)	Papworth N (%)	Manchester N (%)	Birmingham N (%)	Glasgow N (%)	Total N (%)
Number		12	65	42	41	48	37	**245**
Recipient sex	Male	7 (58)	49 (75)	34 (81)	28 (68)	32 (67)	18 (49)	**168 (69)**
	Female	5 (42)	16 (25)	8 (19)	13 (32)	16 (33)	19 (51)	**77 (31)**
Recipient age	Median (IQR)	51 (37-60)	41 (25-50)	43.5 (31-52)	39 (31-47)	40.5 (28-53)	41 (33-50)	**42 (29-51)**
	Missing	0	0	0	0	0	0	**0**
Cardiothoracic disease	Dilated cardiomyopathy	4 (33)	42 (65)	24 (57)	24 (59)	31 (65)	15 (41)	**140 (57)**
	Ischaemic heart disease	4 (33)	16 (25)	16 (38)	14 (34)	13 (27)	8 (22)	**71 (29)**
	Congenital heart disease	2 (17)	2 (3)	0 (0)	0 (0)	1 (2)	0 (0)	**5 (2)**
	Hypertrophic cardiomyopathy	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	3 (8)	**4 (2)**
	Restrictive cardiomyopathy	0 (0)	3 (5)	1 (2)	0 (0)	0 (0)	0 (0)	**4 (2)**
	Valvular heart disease	0 (0)	0 (0)	1 (2)	1 (2)	2 (4)	1 (3)	**5 (2)**
	Other	2 (17)	0 (0)	0 (0)	2 (5)	0 (0)	7 (19)	**11 (4)**
	Unknown	0 (0)	1 (2)	0 (0)	0 (0)	1 (2)	3 (8)	**5 (2)**
Device history	LT-LT-ST	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (0)**
	LT-LT-ST-LT	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (0)**
	LT-ST	1 (8)	3 (5)	0 (0)	0 (0)	0 (0)	0 (0)	**4 (2)**
	LT-ST-ECMO	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	**1 (0)**
	LT-ST-LT	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (0)**
	LT/LT-ECMO	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (0)**
	LT/LT-LT/ST	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (0)**
	LT/ST	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (0)**
	ST	5 (42)	25 (38)	19 (45)	19 (46)	17 (35)	21 (57)	**106 (43)**
	ST-LT	0 (0)	17 (26)	0 (0)	1 (2)	1 (2)	4 (11)	**23 (9)**
	ST-LT-LT	0 (0)	1 (2)	0 (0)	1 (2)	0 (0)	0 (0)	**2 (1)**
	ST-ST	0 (0)	0 (0)	0 (0)	0 (0)	3 (6)	0 (0)	**3 (1)**
	ST-ST-LT	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	**1 (0)**
	ECMO	2 (17)	0 (0)	9 (21)	5 (12)	17 (35)	7 (19)	**40 (16)**
	ECMO-ECMO	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	**1 (0)**
	ECMO-LT	2 (17)	8 (12)	4 (10)	3 (7)	3 (6)	1 (3)	**21 (9)**
	ECMO-ST	1 (8)	1 (2)	8 (19)	6 (15)	6 (13)	3 (8)	**25 (10)**
	ECMO-ST-LT	0 (0)	1 (2)	0 (0)	4 (10)	0 (0)	1 (3)	**6 (2)**
	ECMO-ST/LT	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (0)**
	ECMO-TAH	1 (8)	1 (2)	1 (2)	0 (0)	0 (0)	0 (0)	**3 (1)**
	ECMO/ECMO-ST	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	**1 (0)**
	ECMO/LT	0 (0)	1 (2)	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 immediately following explantation of a long-term device
LT/ST indicates that a patient had two episodes and received a long-term device which was explanted and then a short-term device after a period of no support

Table 5.2 Device type and history of patients who received a short-term device or ECMO for bridging, 1 April 2005 to 31 March 2015, by centre

		Newcastle N (%)	Harefield N (%)	Papworth N (%)	Manchester N (%)	Birmingham N (%)	Glasgow N (%)	Total N (%)
Number		13	68	52	53	58	41	**285**
INTERMACS patient profile	1. Critical cardiogenic shock	9 (69)	38 (56)	34 (65)	47 (89)	53 (91)	23 (56)	**204 (72)**
	2. Progressive decline	4 (31)	25 (37)	17 (33)	4 (8)	5 (9)	17 (41)	**72 (25)**
	3. Stable but inotrope dependent	0 (0)	1 (1)	1 (2)	0 (0)	0 (0)	1 (2)	**3 (1)**
	4. Recurrent advanced heart failure	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (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)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (0)**
	Unknown	0 (0)	2 (3)	0 (0)	2 (4)	0 (0)	0 (0)	**4 (1)**
Treatment history prior to short-term VAD or ECMO implant	None	1 (8)	2 (3)	4 (8)	0 (0)	4 (7)	1 (2)	**12 (4)**
	VAD/ECMO only	0 (0)	3 (4)	0 (0)	0 (0)	0 (0)	0 (0)	**3 (1)**
	IABP only	0 (0)	1 (1)	1 (2)	0 (0)	0 (0)	6 (15)	**8 (3)**
	Inotropes only	2 (15)	17 (25)	11 (21)	3 (6)	10 (17)	6 (15)	**49 (17)**
	VAD/ECMO+IABP	0 (0)	3 (4)	1 (2)	0 (0)	0 (0)	0 (0)	**4 (1)**
	VAD/ECMO+inotropes	2 (15)	8 (12)	2 (4)	0 (0)	5 (9)	0 (0)	**17 (6)**
	IABP,inotropes	4 (31)	18 (26)	21 (40)	18 (34)	27 (47)	13 (32)	**101 (35)**
	VAD/ECMO, IABP,inotropes	0 (0)	6 (9)	8 (15)	6 (11)	6 (10)	3 (7)	**29 (10)**
	Unknown	4 (31)	10 (15)	4 (8)	26 (49)	6 (10)	12 (29)	**62 (22)**
Device name	Impella	0 (0)	0 (0)	0 (0)	0 (0)	5 (9)	0 (0)	**5 (2)**
	Centrimag	7 (54)	54 (79)	28 (54)	33 (62)	26 (45)	29 (71)	**177 (62)**
	ECMO only	6 (46)	14 (21)	24 (46)	20 (38)	27 (47)	12 (29)	**103 (36)**

SHORT TERM DEVICES USED FOR BRIDGING

Patient Outcomes

This section considers patients whose first device was a short-term device or ECMO. However, outcomes for patients who received a long-term device following a short term VAD or ECMO are excluded from this section and presented in the Bridged to long-term device section. Patients who received a total artificial heart following a short-term VAD or ECMO are also excluded from this section.

Patient outcomes presented in this section are split into two groups based on devices received: short-term devices and ECMO only. 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 6.1a and **6.1b** show the final outcome of recipients, by centre, of short-term devices and ECMO only, respectively, over the ten year period. Nationally, 66 patients were transplanted, 27 survived explantation of the short-term device or ECMO, 74 died on support and 8 died shortly after explantation. When combining activity across the two device groups, the overall number of patients alive at time of analysis was 78 out of 175 (45%).

Table 6.1a **Outcome of short-term devices used for bridging to heart transplantation (excluding patients who only received ECMO), by implant centre, 1 April 2005 to 31 March 2015**

	Newcastle		Papworth		Harefield		Birmingham		Manchester		Glasgow		Total	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Alive (post transplant)	1	(17)	13	(48)	6	(24)	10	(38)	11	(44)	2	(8)	**43**	**(32)**
Alive (post explant)	0	(0)	0	(0)	4	(16)	3	(12)	1	(4)	7	(29)	**15**	**(11)**
Alive on VAD	0	(0)	0	(0)	0	(0)	0	(0)	0	(0)	0	(0)	**0**	**(0)**
Total alive	*1*	*(17)*	*13*	*(48)*	*10*	*(40)*	*13*	*(50)*	*12*	*(48)*	*9*	*(38)*	***58***	***(44)***
Died (post transplant)	0	(0)	2	(7)	1	(4)	3	(12)	3	(12)	2	(8)	**11**	**(8)**
Died (post explant)	1	(17)	1	(4)	2	(8)	1	(4)	0	(0)	2	(8)	**7**	**(5)**
Died with VAD	4	(67)	11	(41)	12	(48)	9	(35)	10	(40)	11	(46)	**57**	**(43)**
Total died	*5*	*(83)*	*14*	*(52)*	*15*	*(60)*	*13*	*(50)*	*13*	*(52)*	*15*	*(63)*	***75***	***(56)***
TOTAL	**6**	**(100)**	**27**	**(100)**	**25**	**(100)**	**26**	**(100)**	**25**	**(100)**	**24**	**(100)**	**133**	**(100)**

Table 6.1b **Outcome of ECMO only used for bridging to heart transplantation, by implant centre, 1 April 2005 to 31 March 2015**

	Newcastle		Papworth		Harefield		Birmingham		Manchester		Glasgow		Total	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Alive (post transplant)	0	(0)	2	(20)	0	(0)	4	(24)	1	(17)	1	(14)	**8**	**(19)**
Alive (post explant)	2	(100)	3	(30)	0	(0)	3	(18)	2	(33)	2	(29)	**12**	**(29)**
Alive on ECMO	0	(0)	0	(0)	0	(0)	0	(0)	0	(0)	0	(0)	**0**	**(0)**
Total alive	*2*	*(100)*	*5*	*(50)*	*0*	*(0)*	*7*	*(41)*	*3*	*(50)*	*3*	*(43)*	***20***	***(48)***
Died (post transplant)	0	(0)	0	(0)	0	(0)	4	(24)	0	(0)	0	(0)	**4**	**(10)**
Died (post explant)	0	(0)	0	(0)	0	(0)	0	(0)	0	(0)	1	(14)	**1**	**(2)**
Died with ECMO	0	(0)	5	(50)	0	(0)	6	(35)	3	(50)	3	(43)	**17**	**(40)**
Total died	*0*	*(0)*	*5*	*(50)*	*0*	*(0)*	*10*	*(59)*	*3*	*(50)*	*4*	*(57)*	***22***	***(52)***
TOTAL	**2**	**(100)**	**10**	**(100)**	**0**	**(0)**	**17**	**(100)**	**6**	**(100)**	**7**	**(100)**	**42**	**(100)**

Tables 6.2a and **6.2b** show the causes of death, by centre, for all patients who sadly died following implantation of a short-term device or ECMO, respectively. Deaths which occur more than one year post-transplant or more than one year post-explant are not referenced in these tables.

Table 6.2a Causes of death for patients who received a short-term device only, 1 April 2005 to 31 March 2015, by centre

	Newcastle N (%)	Harefield N (%)	Papworth N (%)	Manchester N (%)	Birmingham N (%)	Glasgow N (%)	Total N (%)
Number	5	15	14	13	13	15	**75**
	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	**1 (1)**
Cardiovascular	2 (40)	3 (20)	0 (0)	2 (15)	1 (8)	4 (27)	**12 (16)**
Haemorrhage	0 (0)	3 (20)	3 (21)	0 (0)	0 (0)	1 (7)	**7 (9)**
Infection	0 (0)	0 (0)	0 (0)	0 (0)	2 (15)	0 (0)	**2 (3)**
Pulmonary	0 (0)	0 (0)	1 (7)	0 (0)	1 (8)	0 (0)	**2 (3)**
Other	3 (60)	9 (60)	10 (71)	7 (54)	7 (54)	9 (60)	**45 (60)**
Post-explant	0 (0)	0 (0)	0 (0)	4 (31)	1 (8)	1 (7)	**6 (8)**

Table 6.2b Causes of death for patients who received ECMO only, 1 April 2005 to 31 March 2015, by centre

	Newcastle N (%)	Harefield N (%)	Papworth N (%)	Manchester N (%)	Birmingham N (%)	Glasgow N (%)	Total N (%)
Number	0 (0)	0 (0)	5	3	10	4	**22**
Cardiovascular	0 (0)	0 (0)	0 (0)	1 (33)	2 (20)	0 (0)	**3 (14)**
Infection	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	**1 (5)**
Other	0 (0)	0 (0)	5 (100)	1 (33)	7 (70)	3 (75)	**16 (73)**
Post-explant	0 (0)	0 (0)	0 (0)	1 (33)	0 (0)	1 (25)	**2 (9)**

Tables 6.3a and **6.3b** shows the duration of support, by centre, for short-term VADs and ECMO only, respectively. Across both device groups, the duration of support ranged between 0 and 175 days (under 6 months). Using the Kaplan-Meier estimation method, median duration of support across both device types was estimated to be 17 days (95% CI: 12, 22).

Table 6.3a Short-term device duration, by implant centre, 1 April 2005 to 31 March 2015

Hospital	No. of implants	No. missing	Range	Median	(95% confidence interval)
Newcastle	6	0	2 - 17	9	(1, 17)
Papworth	27	0	4 - 175	33	(18, 48)
Harefield	25	0	1 - 104	25	(15, 35)
Birmingham	26	0	1 - 51	15	(5, 25)
Manchester	25	0	2 - 123	29	(14, 44)
Glasgow	24	0	1 - 101	27	(22, 32)
All centres	**133**	**0**	**1 - 175**	**25**	**(20, 30)**

Table 6.3b ECMO duration, by implant centre, 1 April 2005 to 31 March 2015

Hospital	No. of implants	No. missing	Range	Median	(95% confidence interval)
Newcastle	2	0	4 - 13	4	(-)
Papworth	10	0	0 - 35	5	(0, 10)
Harefield	0	-	-	-	-
Birmingham	17	0	1 - 25	6	(3, 9)
Manchester	6	0	1 - 9	7	(5, 9)
Glasgow	7	0	0 - 10	5	(0, 13)
All centres	**42**	**0**	**0 - 35**	**5**	**(4, 6)**

Table 6.4 shows Kaplan-Meier estimates of patient survival from time of first ST device /ECMO implant to death by device group. Patients still alive were censored at the date of last follow-up. Other events such as device explantation or transplantation were not censored.

Table 6.4 Patient survival after implant of short-term device, by device group, 1 April 2005 to 31 March 2015

Device	No. at risk on day 0	% patient survival (95% confidence interval) 30 days		90 days		1 year		2 years		3 years	
ECMO only	42	57	(41 - 70)	52	(36 - 66)	48	(32 - 62)	48	(32 - 62)	48	(32 - 62)
ST only	133	66	(57 - 74)	53	(44 - 61)	43	(34 - 51)	41	(32 - 49)	41	(32 - 49)
Overall	**175**	**64**	**(56 - 71)**	**53**	**(45 - 60)**	**44**	**(37 - 52)**	**43**	**(35 - 50)**	**43**	**(35 - 50)**
Number at risk		113		92		64		52		36	

Table 6.5 shows patient survival during support by device group. Unlike the survival estimates presented in **Table 6.4**, survival was censored at time of device explantation or transplantation. Survival during support was lower than the overall patient survival, as survival post-transplant and explant are not considered. One-year, two year and three year survival estimates are not presented due to the small number of patients at risk. ECMO only support was typically very short; all but 5 of the 41 patients were on support for 15 days or less.

Table 6.5 Survival during short-term device support, by device group, 1 April 2005 to 31 March 2015

Device	No. at risk on day 0	% survival on a device (95% confidence interval) 30 days		90 days	
ECMO only	42	26	(5 - 54)	0	(-)
ST only	133	68	(58 - 76)	49	(35 - 61)
Overall	**175**	**63**	**(54 - 71)**	**43**	**(31 - 55)**
Number at risk		56		12	

SHORT TERM DEVICES USED POST-HEART TRANSPLANT

Activity

One hundred thirty-five patients received a short-term device or ECMO for primary graft dysfunction (PGD) at six adult implant centres in the UK between 1 April 2005 and 31 March 2015. Six patients received six devices at Newcastle, 38 at Harefield (38 devices), 22 at Papworth (22 devices), 16 at Birmingham (17 devices), 24 at Glasgow (30 devices) and 29 at Manchester (35 devices).

In addition to the 135 patients above, four patients received short-term devices or ECMO for rejection more than 30 days post-heart transplant. One patient who received a device for PGD subsequently received a device for rejection. One patient was at Papworth, two at Newcastle, one at Birmingham and one at Glasgow. Four of these 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 7.1 shows the cumulative number of short-term VADs/ ECMOs implanted each month, overall and by centre, whilst **Figure 7.2** shows the number of devices by financial year and centre. Short-term device/ ECMO activity has increased at most centres.

Figure 7.1 Cumulative short-term devices and ECMOs used for primary graft dysfunction, by month and implant centre, 1 April 2005 to 31 March 2015

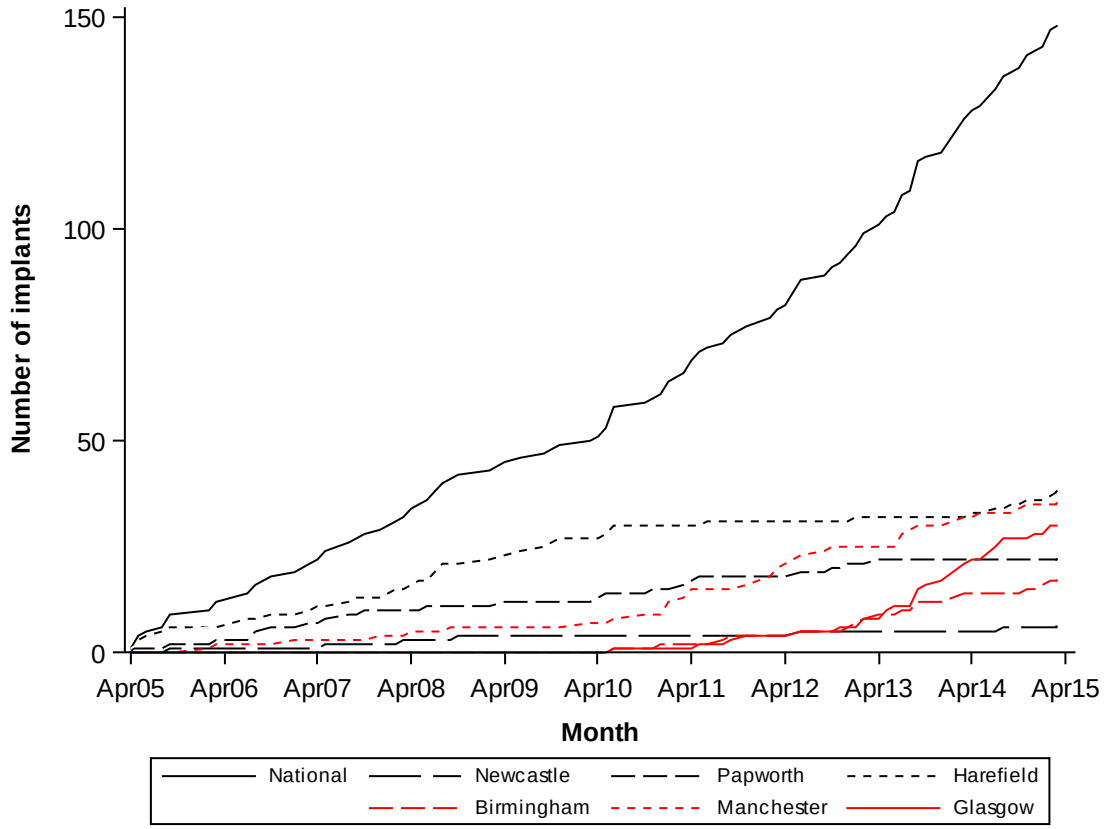


Figure 7.2 Short-term devices and ECMOs used for primary graft dysfunction, by financial year and implant centre, 1 April 2005 to 31 March 2015

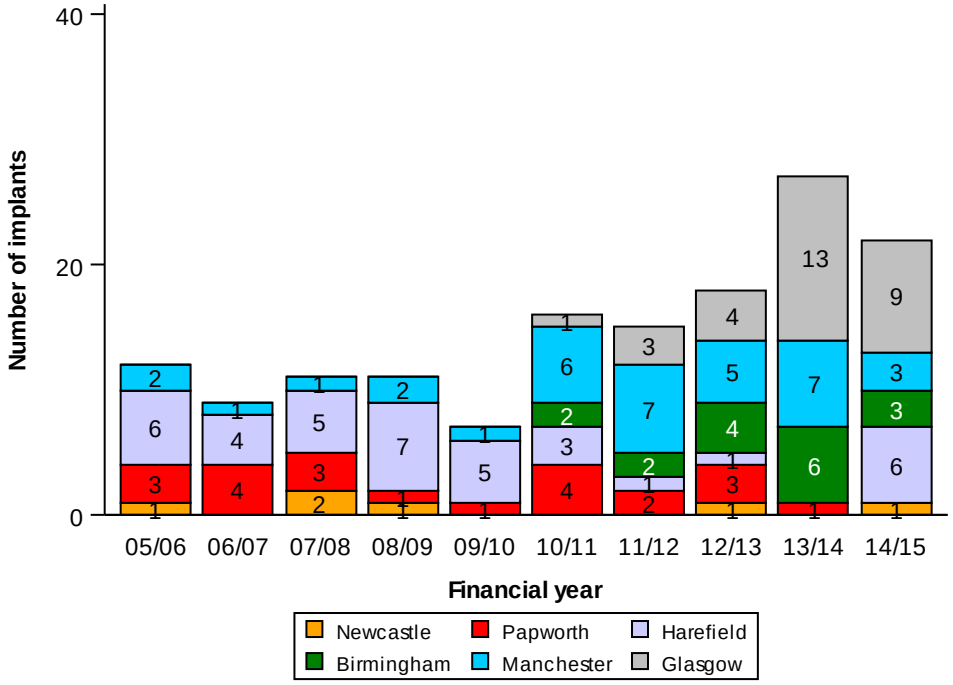


Table 7.1 shows the characteristics of patients who received short-term devices or ECMOs for primary graft dysfunction, by implant centre. Overall, the most frequently reported cardiothoracic diseases were dilated cardiomyopathy (53%) and ischaemic heart disease (21%). The overall median age at implant was 49 years (inter-quartile range 38 - 56 years) and the majority of recipients were male (74%). Overall 93% received only one short-term device.

Table 7.2 shows that the most frequently used devices were ECMO only (52%) and Centrimag (47%). 39% were on inotropes at time of VAD implant whilst 32% received an IABP prior to VAD implant.

Table 7.1 Characteristics of patients who received a short-term device or ECMO for primary graft dysfunction, 1 April 2005 to 31 March 2015, by centre

		Newcastle N (%)	Harefield N (%)	Papworth N (%)	Manchester N (%)	Birmingham N (%)	Glasgow N (%)	Total N (%)
Number		6	38	22	29	16	24	**135**
Recipient sex	Male	2 (33)	28 (74)	17 (77)	24 (83)	13 (81)	16 (67)	**100 (74)**
	Female	4 (67)	10 (26)	5 (23)	5 (17)	3 (19)	8 (33)	**35 (26)**
Recipient age	Median (IQR)	46 (42-48)	50 (35-56)	48.5 (40-54)	49 (41-57)	52 (36.5-58)	48 (37.5-52.5)	**49 (38-56)**
	Missing	0	0	0	0	0	0	**0**
Cardiothoracic disease	Dilated cardiomyopathy	1 (17)	32 (84)	8 (36)	13 (45)	7 (44)	10 (42)	**71 (53)**
	Ischaemic heart disease	2 (33)	1 (3)	6 (27)	11 (38)	4 (25)	4 (17)	**28 (21)**
	Congenital heart disease	1 (17)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	**2 (1)**
	Hypertrophic cardiomyopathy	1 (17)	1 (3)	3 (14)	1 (3)	2 (13)	2 (8)	**10 (7)**
	Restrictive cardiomyopathy	0 (0)	1 (3)	1 (5)	0 (0)	0 (0)	2 (8)	**4 (3)**
	Valvular heart disease	0 (0)	2 (5)	0 (0)	2 (7)	0 (0)	1 (4)	**5 (4)**
	Infiltrative heart muscle disease	0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	**1 (1)**
	Other	0 (0)	0 (0)	3 (14)	2 (7)	0 (0)	5 (21)	**10 (7)**
	Unknown	1 (17)	1 (3)	1 (5)	0 (0)	1 (6)	0 (0)	**4 (3)**
Device history	ST	4 (67)	31 (82)	11 (50)	5 (17)	5 (31)	5 (21)	**61 (45)**
	ST-ECMO	0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	**1 (1)**
	ECMO	2 (33)	7 (18)	11 (50)	19 (66)	10 (63)	14 (58)	**63 (47)**
	ECMO-ECMO-ST	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (4)	**1 (1)**
	ECMO-ST	0 (0)	0 (0)	0 (0)	4 (14)	0 (0)	1 (4)	**5 (4)**
	ECMO/ST	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (8)	**2 (1)**
	ECMO/ECMO	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (4)	**1 (1)**
	ECMO/ST-ECMO	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	**1 (1)**

ECMO-ST indicates that a patient received an ECMO and then a short-term device immediately following explantation of the ECMO
ECMO/ST indicates that a patient had two episodes and received an ECMO which was explanted and then a short-term device after a period of no support

Table 7.2	Device type and history of patients who received a short-term device or ECMO for primary graft dysfunction, 1 April 2005 to 31 March 2015, by centre							
		Newcastle N (%)	Harefield N (%)	Papworth N (%)	Manchester N (%)	Birmingham N (%)	Glasgow N (%)	Total N (%)
Number		6	38	22	35	17	30	**148**
INTERMACS patient profile	1. Critical cardiogenic shock	6 (100)	10 (26)	22 (100)	9 (26)	17 (100)	20 (67)	**84 (57)**
	2. Progressive decline	0 (0)	24 (63)	0 (0)	10 (29)	0 (0)	7 (23)	**41 (28)**
	3. Stable but inotrope dependent	0 (0)	0 (0)	0 (0)	2 (6)	0 (0)	3 (10)	**5 (3)**
	4. Recurrent advanced heart failure	0 (0)	2 (5)	0 (0)	10 (29)	0 (0)	0 (0)	**12 (8)**
	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 (6)	0 (0)	0 (0)	**3 (2)**
	Unknown	0 (0)	1 (3)	0 (0)	2 (6)	0 (0)	0 (0)	**3 (2)**
Treatment history prior to short-term VAD or ECMO implant	None	0 (0)	3 (8)	8 (36)	5 (14)	0 (0)	2 (7)	**18 (12)**
	VAD/ECMO only	0 (0)	5 (13)	1 (5)	0 (0)	1 (6)	0 (0)	**7 (5)**
	IABP only	0 (0)	0 (0)	0 (0)	3 (9)	2 (12)	2 (7)	**7 (5)**
	Inotropes only	0 (0)	2 (5)	6 (27)	2 (6)	7 (41)	1 (3)	**18 (12)**
	VAD/ECMO+IABP	2 (33)	2 (5)	0 (0)	0 (0)	0 (0)	2 (7)	**6 (4)**
	VAD/ECMO+inotropes	0 (0)	2 (5)	1 (5)	0 (0)	2 (12)	0 (0)	**5 (3)**
	IABP,inotropes	4 (67)	2 (5)	0 (0)	1 (3)	1 (6)	3 (10)	**11 (7)**
	VAD/ECMO, IABP,inotropes	0 (0)	3 (8)	2 (9)	0 (0)	3 (18)	4 (13)	**12 (8)**
	Unknown	0 (0)	19 (50)	4 (18)	24 (69)	1 (6)	16 (53)	**64 (43)**
Device name	Biomedicus	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	**1 (1)**
	Centrimag	4 (67)	31 (82)	11 (50)	9 (26)	6 (35)	9 (30)	**70 (47)**
	ECMO only	2 (33)	7 (18)	11 (50)	25 (71)	11 (65)	21 (70)	**77 (52)**

SHORT TERM DEVICES USED POST HEART TRANSPLANT

Patient Outcomes

Table 8.1 shows the outcome for the 135 patients who received a short-term device or ECMO for PGD. Nationally, 9 patients were re-transplanted, 49 survived explantation of the VAD or ECMO, 58 died on support and 19 died post device explantation (all within a month).

Table 8.1 Outcome of short-term devices or ECMOs used for primary graft dysfunction, by implant centre, 1 April 2005 to 31 March 2015

	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	(3)	0	(0)	**5**	**(4)**
Alive (post explant)	1	(17)	6	(27)	9	(24)	5	(31)	18	(62)	10	(42)	**49**	**(36)**
Alive with VAD/ECMO	0	(0)	0	(0)	0	(0)	0	(0)	0	(0)	0	(0)	**0**	**(0)**
Total alive	*1*	*(17)*	*9*	*(41)*	*10*	*(26)*	*5*	*(31)*	*19*	*(66)*	*10*	*(42)*	***54***	***(40)***
Died (post transplant)	0	(0)	0	(0)	2	(5)	1	(6)	0	(0)	1	(4)	**4**	**(3)**
Died (post explant)	1	(17)	1	(5)	7	(18)	7	(44)	0	(0)	3	(13)	**19**	**(14)**
Died with VAD/ECMO	4	(67)	12	(55)	19	(50)	3	(19)	10	(34)	10	(42)	**58**	**(43)**
Total died	*5*	*(83)*	*13*	*(59)*	*28*	*(74)*	*11*	*(69)*	*10*	*(34)*	*14*	*(58)*	***81***	***(60)***
TOTAL	**6**	**(100)**	**22**	**(100)**	**38**	**(100)**	**16**	**(100)**	**29**	**(100)**	**24**	**(100)**	**135**	**(100)**

Table 8.2 shows the grouped causes of death for all patients who sadly died after receiving a short-term device or ECMO for PGD.

Table 8.2 Causes of death for patients who received a short-term devices or ECMOs used for primary graft dysfunction, 1 April 2005 to 31 March 2015, by centre

	Newcastle N (%)	Harefield N (%)	Papworth N (%)	Manchester N (%)	Birmingham N (%)	Glasgow N (%)	Total N (%)
Number	**5**	**28**	**13**	**10**	**11**	**14**	**81**
	0 (0)	1 (4)	0 (0)	0 (0)	1 (9)	0 (0)	**2 (2)**
Cardiovascular	1 (20)	2 (7)	1 (8)	2 (20)	2 (18)	0 (0)	**8 (10)**
Haemorrhage	2 (40)	1 (4)	1 (8)	1 (10)	0 (0)	0 (0)	**5 (6)**
Infection	0 (0)	1 (4)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (1)**
Renal failure	0 (0)	1 (4)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (1)**
Pulmonary	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (7)	**1 (1)**
Other	2 (40)	17 (61)	11 (85)	6 (60)	7 (64)	13 (93)	**56 (69)**
Post-explant	0 (0)	5 (18)	0 (0)	1 (10)	1 (9)	0 (0)	**7 (9)**

Table 8.3 shows the short-term device or ECMO duration of support. Overall, the duration of support ranged between 0 and 76 days. Using the Kaplan-Meier estimation method, median duration of support for all patients was estimated to be 6 days (95% CI: 5, 7).

Table 8.3 Duration of short-term device or ECMO support for primary graft dysfunction, by implant centre, 1 April 2005 to 31 March 2015

Hospital	No. of implants	No. missing	Range	Median	(95% confidence interval)
Newcastle	6	0	2 - 15	4	(2, 6)
Papworth	22	0	1 - 26	8	(5, 11)
Harefield	38	0	1 - 45	10	(6, 14)
Birmingham	16	0	2 - 23	5	(3, 7)
Manchester	29	0	0 - 76	7	(4, 10)
Glasgow	24	0	0 - 53	5	(3, 7)
All centres	**135**	**0**	**0 - 76**	**6**	**(5, 7)**

Table 8.4 shows Kaplan-Meier estimates of patient survival from time of implant of a short-term device or ECMO 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 wide confidence intervals. Patient survival during short-term device or ECMO support is not presented due to all patients being on support for less than 90 days.

Table 8.4 Patient survival after implant of short-term devices or ECMOs used for primary graft dysfunction, by implant centre, 1 April 2005 to 31 March 2015

Centre	No. at risk on day 0	% patient survival (95% confidence interval) 30 days	90 days	1 year	2 years	3 years
Birmingham	16	56 (30 - 76)	56 (30 - 76)	31 (11 - 54)	31 (11 - 54)	31 (11 - 54)
Glasgow	24	50 (29 - 68)	50 (29 - 68)	41 (21 - 60)	35 (16 - 55)	(-)
Harefield	38	50 (33 - 65)	32 (18 - 46)	26 (14 - 41)	26 (14 - 41)	26 (14 - 41)
Manchester	29	72 (52 - 85)	66 (45 - 80)	66 (45 - 80)	66 (45 - 80)	61 (41 - 76)
Newcastle	6	17 (1 - 52)	17 (1 - 52)	17 (1 - 52)	17 (1 - 52)	17 (1 - 52)
Papworth	22	45 (24 - 64)	41 (21 - 60)	41 (21 - 60)	41 (21 - 60)	41 (21 - 60)
Overall	**135**	**53 (45 - 61)**	**46 (37 - 54)**	**40 (32 - 48)**	**39 (31 - 47)**	**37 (29 - 45)**
Number at risk		72	62	51	43	30

APPENDIX

A1: METHODS

Data are collected for all long-term devices used for the purposes of bridging to transplant 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 from this report. Results are reported for implants between 1 April 2005 and 31 March 2015.

This report presents both patient survival and survival on support. Patient survival describes survival from VAD/ECMO implant to death, regardless of intervening events such as transplantation or device explantation. Survival on support describes survival only while on a device and is therefore time from VAD/ECMO 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 2015, 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.

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

Survival on support is calculated as follows in each section:

Section	Start point	End point
Long-term	First long-term implant	Death on support
Bridged to Long-term	First long-term implant	Death on support
Short-term bridging	First short-term implant	Death on support
Short-term PGD	First short-term implant	Death on support

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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