NHS
Blood and Transplant

ANNUAL REPORT ON MECHANICAL CIRCULATORY SUPPORT RELATED TO HEART TRANSPLANTATION

REPORT FOR 2019/2020
(1 APRIL 2010 – 31 MARCH 2020)

PUBLISHED OCTOBER 2020

PRODUCED IN COLLABORATION WITH NHS ENGLAND

CONTENTS

Contents

EXECUTIVE SUMMARY

1 Executive Summary

This report summarises key information about mechanical circulatory support (MCS) used in patients in the UK as a bridge to heart transplantation or for post-transplant support. MCS in this context includes long-term ventricular assist devices (VADs), short-term VADs, total artificial hearts (TAH) and veno-arterial extracorporeal membrane oxygenation (ECMO). The period reported covers 10 years of MCS activity, from 1 April 2010 to 31 March 2020, however paediatric data are only available since 1 April 2013. Data were obtained from the UK VAD Database held by NHS Blood and Transplant as at 21 August 2020. Results are generally presented separately for adult and paediatric patients, for long-term and short-term devices and for bridging and post-transplant strategies.

Key findings

Long-term bridging devices in adults:

- During 2019/2020 there were 85 long-term device implantations, comprising 84 long-term VADs and 1 TAH. The number of implants has fallen compared to previous years.
- Almost all patients implanted were INTERMACS profile 1 to 4 with the most common group INTERMACS 3 (stable but inotrope dependent) representing 40% of all patients.
- At 1-year post-implant, 71% of patients remained on support, 5% had received a heart transplant and 4% were explanted without transplant. 21% died on support.
- The national 1-year patient survival rate from the point of first long-term VAD implant, irrespective of subsequent intervention (not censored at transplant or explant for recovery) was 77.1%. The 3-year survival rate was 60.1%, which has improved over the last 3 years (58.4% in 2018/2019; 52.1% in 2017/2018).
- The current median duration of long-term VAD support was 978 days (2.7 years).

Short-term bridging devices in adults:

- During 2019/2020 there were 114 short-term device implantations into 86 patients, comprising 68 VADs and 46 ECMO procedures; a 23% increase from the previous year.
- The majority (69%) of implantations last year were into INTERMACS profile 1 patients (critical cardiogenic shock).
- The median duration on short-term support was 11 days.
- At 30 days post-implant, 25% of patients remained on short term support, 14% had been transplanted, 17% transferred to a long-term device and 17% were explanted without transplant. 28% had died on support.
- The 1-year patient survival rate from the point of first short-term VAD implant (excluding those bridged to long-term support) was 46.0% (not censored for transplant/explant).

Short-term devices used for Primary Graft Dysfunction (PGD) in adults:

- During 2019/2020 there were 35 short-term device implantations into 28 PGD patients, comprising 26 ECMO procedures and 9 short term VADs. This was a 29% decrease from the previous year.
- The 1-year patient survival rate for patients requiring MCS for PGD was 55.0%.
- On average, patients spent 5 days on support

Bridging devices used in paediatrics:

- During 2019/2020 there were 19 device implantations into 19 paediatric patients.
- On average, patients spent 68 days on support.
- 35% of patients received a transplant within 90 days of implantation and the 1-year patient survival rate from the point of implant was 76.2%.

Use of the contents of this report should be acknowledged as follows:
Annual Report on Mechanical Circulatory Support Related to Heart Transplantation 2019/2020, NHS Blood and Transplant

INTRODUCTION

2 Introduction

In the United Kingdom, mechanical circulatory support (MCS) therapy is commissioned as a bridge to heart transplantation or for post-transplant support due to primary graft dysfunction (PGD) or rejection. MCS in this context includes long-term ventricular assist devices (VADs), short-term VADs, total artificial hearts (TAH) and veno-arterial extracorporeal membrane oxygenation (ECMO). The seven centres that provide this service are those that also provide heart transplantation: Birmingham Queen Elizabeth Hospital, Harefield Hospital, Manchester Wythenshawe Hospital, Newcastle Freeman Hospital, Royal Papworth Hospital, Great Ormond Street Hospital and Glasgow Golden Jubilee Hospital. Great Ormond Street Hospital provide a paediatric (age less than 16 years) service only, Newcastle provide both adult and paediatric services, and the remaining centres provide adult services only.

All centres are required to submit data to the national database hosted by NHS Blood and Transplant, known as the VAD Database. The database collects extensive data prior to and at time of device implant, explant, transplant and death along with follow-up at various time points post-implant and post-explant. These data are audited and reported annually in this report in order to provide centres, commissioners and patients with relevant and transparent information about the UK MCS service. The report also incorporates data from the UK Transplant Registry on listing for heart transplantation and survival after transplant for patients receiving MCS.

The cohort covered in this report is from 1 April 2010 to 31 March 2020, however paediatric data are only presented for the period 1 April 2013 to 31 March 2020 since before 2013 there was no national data capture for paediatric MCS therapy. Data were obtained from the database as at 21 August 2020 by which date it was expected that most devices used during the audit period had been reported to the database.

Prior to the introduction of the General Data Protection Regulation (GDPR) in May 2018, consent had to be gained from patients to record their data on the VAD Database. During this time 16 patients refused consent and so these patients are excluded from this report. From May 2018, patient data are recorded lawfully without explicit consent under Section 6(1)e of the GDPR. Use of Section 6(1)e requires a specific exemption and the patient data is being collected and processed under Section 9(2)h “management of healthcare”.

The report is split into four main parts:

- Adult long-term devices used for bridging (long-term VADs and TAH)
- Adult short-term devices used for bridging (short-term VADs and ECMO)
- Adult short-term devices used post-heart transplant (short-term VADs and ECMO)
- Paediatric devices used for bridging (VAD and ECMO)

Each part includes an activity section where data are analysed on a per-implant basis and a patient outcome section where data are analysed on a per-patient basis. Activity is analysed over the decade whilst outcomes are typically analysed for patients receiving MCS in a recent 4 year period (1 April 2015 – 31 March 2019 for this report). See Appendix A1 for a breakdown of the number of observations analysed in each section and notes on classifications and limitations.

Methods used to produce the report are described in Appendix A2.

Patient survival is analysed in two ways; from the point of first device implant to death, irrespective of subsequent intervention, and survival on support which is time from short-term or long-term VAD implant to death on support where explant or transplant events are censored. The reader should note that in both cases the results are not adjusted for potential differences in risk between patients treated at different centres. Such differences in "case-mix" may explain any variation in the centre-specific survival rates, thus no conclusions can be made about differences in the standard of care between centres. Further work is needed to identify the relevant risk-factors to adjust for to calculate risk-adjusted survival rates.

2.1 Overview

Figure 2.1 shows the number of bridging implants reported in the last ten years, split by device type for adult patients. Up to 2015/2016, long-term implant activity increased steadily to a peak of 124 devices but has since decreased to 85 in 2019/2020. Short-term device usage has increased over the decade, with 114 devices in 2019/2020. **Figure 2.2** shows a breakdown of paediatric bridging implants in the last seven years. VAD activity fell from a peak in 31 in 2014/2015 to 19 in 2019/2020. ECMO usage in paediatric patients has remained rare in the period.

In total there were 1,839 bridging implants reported across the decade in 1,474 patients; 1,171 (79%) patients had a single device implant, 252 (17%) had two implants, 41 (3%) had three, 9 (0.6%) had four, and 1 (0.1%) had five (see **Table A1.4** in Appendix A1 for details of device histories).

Figure 2.1 Total number of adult bridging device implants in the UK, by device type and financial year, 1 April 2010 to 31 March 2020

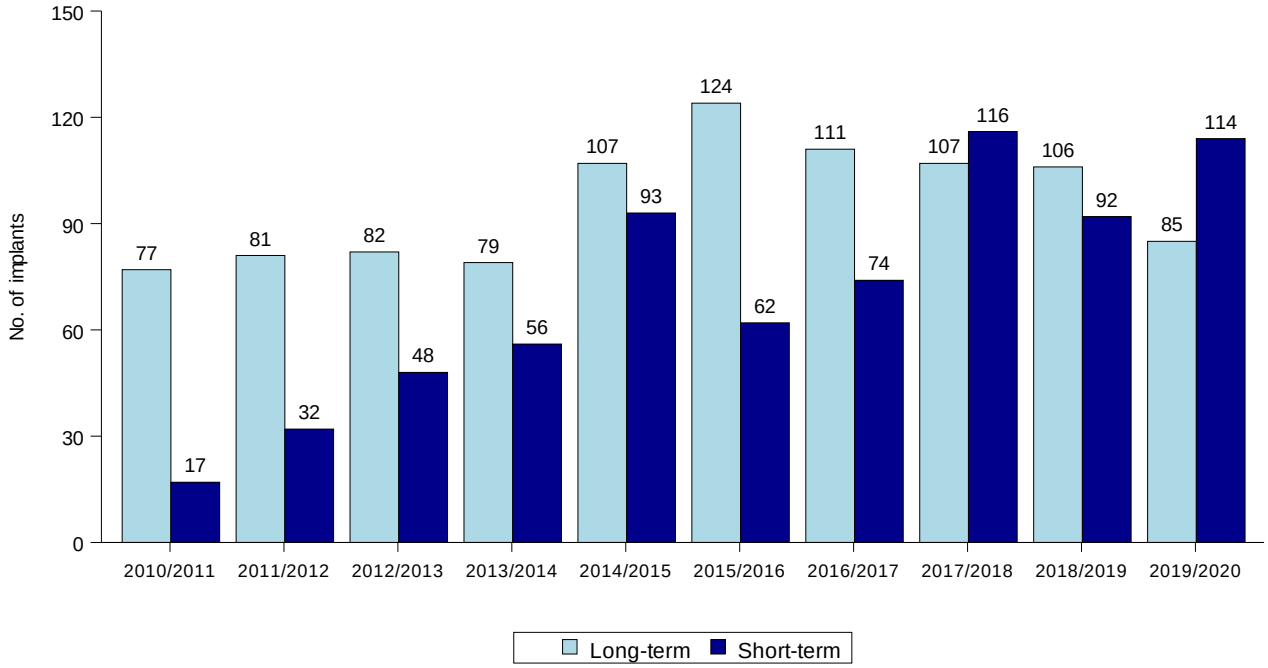


Figure 2.2 Total number of paediatric bridging device implants in the UK, by device type and financial year, 1 April 2013 to 31 March 2020

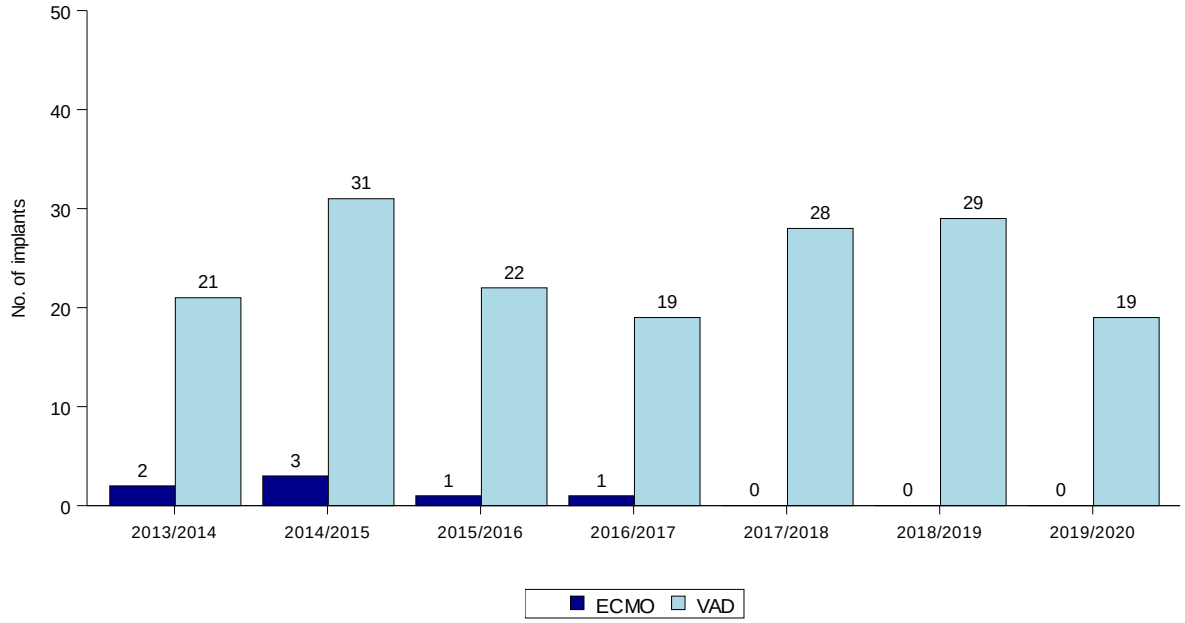


Figure 2.3 shows the number of post-heart transplant implants reported in the last ten years, split by primary graft dysfunction and rejection (short-term implants beyond 30 days post-transplant) strategies for adult patients. The number of implants for PGD has increased over the period, reaching 51 in 2018/2019 but fallen in the last year to 36. Devices used for rejection remain relatively rare, with one performed in 2019/2020. In total there were 331 post-transplant implants across the decade in 278 patients; 231 (83%) patients had a single device implant, 39 (14%) had two implants, 6 (2%) had three and 1 (0.4%) had four (see **Table A1.4** Appendix A1 for details of device histories).

Figure 2.3 Total number of adult post-transplant device implants in the UK, by strategy and financial year, 1 April 2010 to 31 March 2020

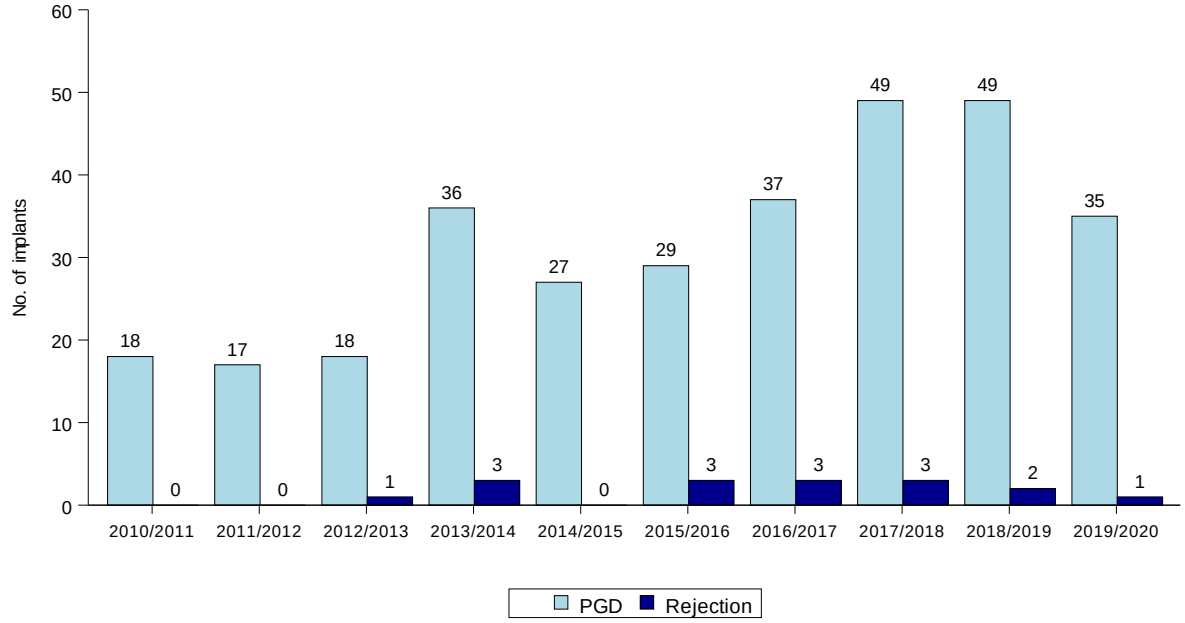


Figure 2.4 shows the number of adult patients reported as alive on bridging support as at 31 March 2020 by centre and device type. In total, there were 308 patients alive on a long-term device and 8 alive on short-term support, with Harefield and Birmingham having the highest number of patients on support. **Figure 2.5** shows the same information but for paediatric patients. There were 11 paediatric patients alive on support on 31 March 2020, all on VAD support.

Figure 2.4 Number of adult patients alive on bridging support at 31 March 2020, by device type and centre

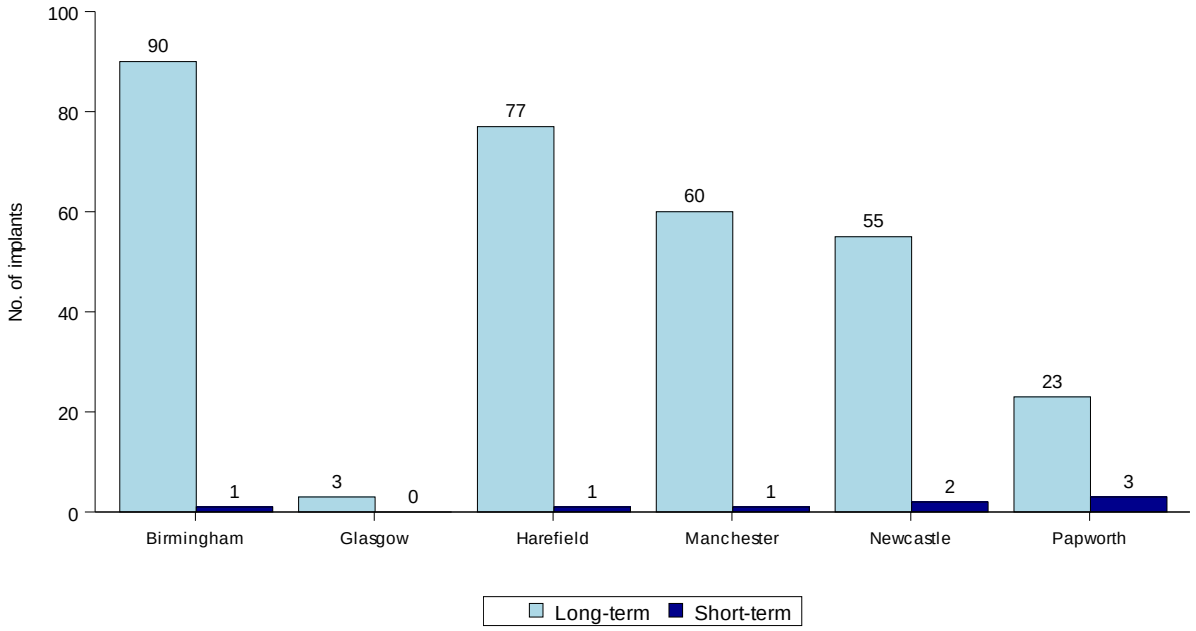
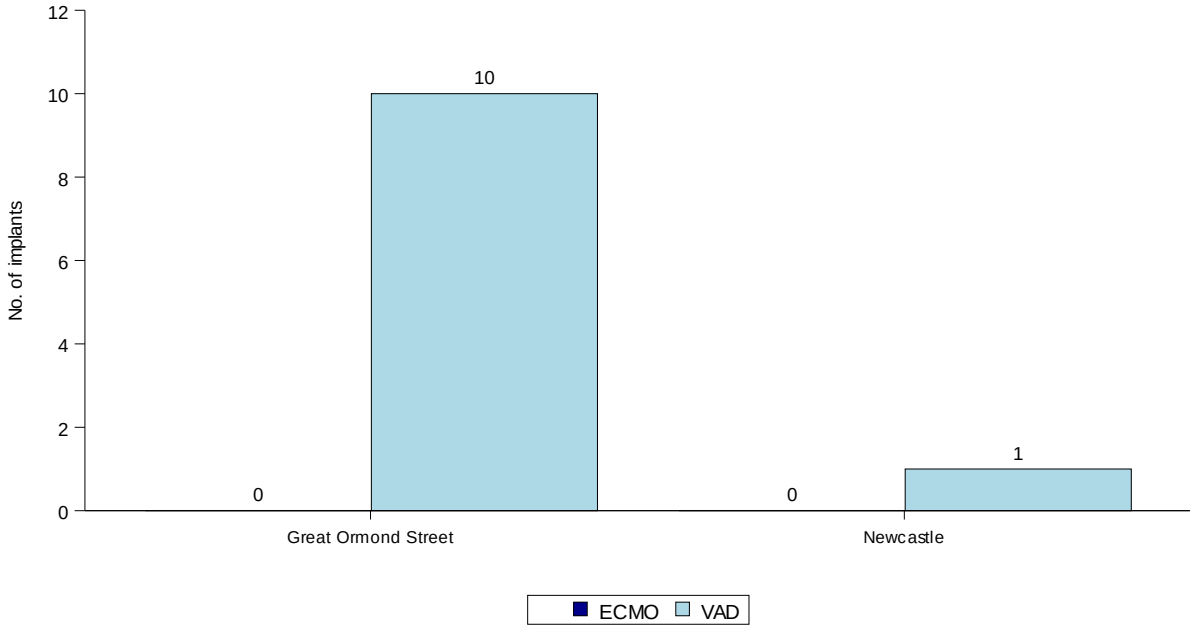


Figure 2.5 Number of paediatric patients alive on bridging support at 31 March 2020, by device type and centre



Tables 2.1 and **2.2** summarise the number of patients and implants that have been reported to the VAD Database by centres for the period 1 April 2010 to 31 March 2020 and separately for the most recent year, 1 April 2019 to 31 March 2020. **Table 2.1** reflects the adult data while **Table 2.2** reflects the paediatric data. No post-transplant devices have been reported in paediatric patients.

Table 2.1 Number of adult patients receiving devices and number of implants, by strategy and centre, during the decade and the most recent year

Strategy	Centre	1 April 2010 - 31 March 2020						1 April 2019 - 31 March 2020					
		No. implants	Type of device				No. patients	No. implants	Type of device				No. patients
			LT VAD	TAH	ST VAD*	ECMO			LT VAD	TAH	ST VAD*	ECMO	
Bridging	Birmingham	**304**	151	0	104	49	235	**45**	19	0	23	3	32
	Glasgow	**104**	23	0	46	35	89	**10**	2	0	3	5	10
	Harefield	**480**	281	23	91	85	341	**60**	13	1	24	22	36
	Manchester	**243**	118	0	81	44	203	**21**	10	0	9	2	20
	Newcastle	**326**	252	1	9	64	284	**38**	26	0	1	11	36
	Papworth	**206**	108	2	64	32	174	**25**	14	0	8	3	22
	Total	**1663**	**933**	**26**	**395**	**309**	**1326**	**199**	**84**	**1**	**68**	**46**	**156**
		1 April 2010 - 31 March 2020						**1 April 2019 - 31 March 2020**					
		No. implants	Type of device				No. patients	No. implants	Type of device				No. patients
			LT VAD	TAH	ST VAD*	ECMO			LT VAD	TAH	ST VAD*	ECMO	
Post-transplant	Birmingham	**69**	0	0	23	46	52	**11**	0	0	5	6	6
	Glasgow	**45**	0	0	14	31	35	**2**	0	0	0	2	2
	Harefield	**57**	0	0	5	52	51	**7**	0	0	0	7	6
	Manchester	**68**	0	0	9	59	60	**3**	0	0	0	3	3
	Newcastle	**54**	0	0	3	51	48	**6**	0	0	0	6	6
	Papworth	**38**	0	0	12	26	31	**7**	0	0	4	3	6
	Total	**331**	**0**	**0**	**66[1]**	**265[1]**	**277**	**36**	**0**	**0**	**9**	**27[2]**	**29**

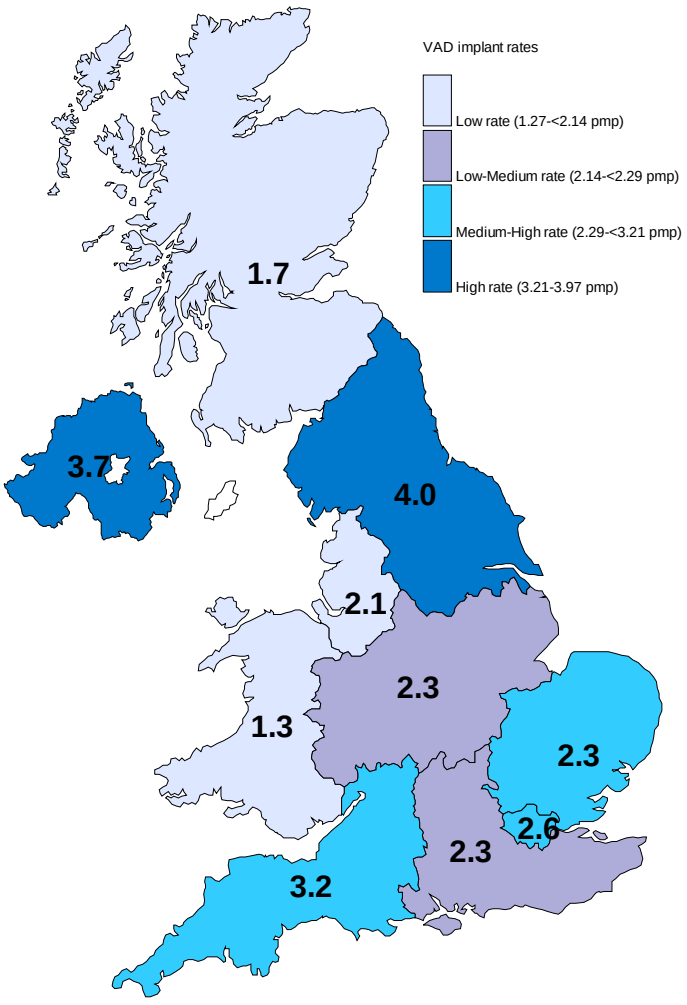
* Includes Berlin Heart devices
[1] Includes 6 ST VAD and 10 ECMO used for rejection which are excluded from the rest of the report
[2] Includes 1 ECMO used for rejection which is excluded from the rest of the report

Table 2.2	**Number of paediatric patients receiving devices and number of implants, by strategy and centre, during the decade and the most recent year**								
Strategy	**Centre**	**1 April 2013 - 31 March 2020**				**1 April 2019 - 31 March 2020**			
		No. implants	Type of device		No. patients	No. implants	Type of device		No. patients
			VAD	ECMO			VAD	ECMO	
Bridging	Great Ormond Street	**82**	76	6	73	**11**	11	0	11
	Newcastle	**94**	93	1	75	**8**	8	0	8
	Total	**176**	**169**	**7**	**148**	**19**	**19**	**0**	**19**
Post-transplant	Great Ormond Street	**0**	0	0	0	**0**	0	0	0
	Newcastle	**0**	0	0	0	**0**	0	0	0
	Total	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**

Figure 2.6 shows the number of patients receiving MCS as a bridge to heart transplant per million population (pmp) between 1 April 2019 and 31 March 2020, by country/NHS region of patient residence. No adjustments have been made for potential demographic differences in populations. Note that this analysis only considered NHS Group 1 patients. Overall, the number of patients receiving MCS was 2.6 pmp of the UK.

Since there will inevitably be some random variation in rates between areas, the systematic component of variation (SCV) was used to identify if the variation is more (or less) than a random effect for the different NHS regions in England only. The larger the SCV the greater the evidence of a high level of systematic variation between areas. The implant rate yielded an SCV of 0.01 (p-value = 0.259). The p-value shows the probability that an SCV of this size (or higher) would be observed by chance if only random variation existed and therefore, no evidence of geographical variation beyond what would be expected at random. No adjustment has been made for area-specific demographic characteristics that may impact the rates of implantation such as age and sex. Therefore, these results should be interpreted with caution.

Figure 2.6 Number of patients receiving MCS as a bridge to heart transplantation per million population (pmp) in the UK, 1 April 2019 – 31 March 2020, by country/NHS region of patient residence



Country/NHS region	Number of patients receiving bridging devices (pmp)	
North East and Yorkshire	34	(4.0)
North West	15	(2.1)
Midlands	24	(2.3)
East of England	15	(2.3)
London	23	(2.6)
South East	20	(2.3)
South West	18	(3.2)
England	**149**	**(2.7)**
Isle of Man	**0**	**(0.0)**
Channel Islands	**1**	**(6.3)**
Wales	**4**	**(1.3)**
Scotland	**9**	**(1.7)**
Northern Ireland	**7**	**(3.7)**
TOTAL[1]	**173**	**(2.6)**

[1] Implants include 3 recipients whose postcode was unknown and excludes 2 NHS Group 2 patients

ADULT LONG-TERM DEVICES USED FOR BRIDGING

Activity

3 Long-term bridging devices in adults

This section considers all patients who received a long-term device as a bridge to heart transplantation. All figures and tables in this section present information on a per implant basis as opposed to per patient, so if a single patient had more than one long-term device implantation in the time period, each is included. If a patient had a previous short-term device, their long-term device is included.

Figure 3.1 shows the total number of long-term bridging device implants in the last ten years nationally by device type (long-term VAD or TAH). During 2019/2020 there were 85 implantations; 21 fewer than 2018/2019. In total there were 26 TAH implantations. **Figure 3.2** shows the trend per centre, with Birmingham and Manchester having the most marked increases in implantations over the decade but have fallen in recent years. Last year's activity is shown by centre and device type in **Figure 3.3**. The highest number of implantations last year was performed by Newcastle, followed by Birmingham.

Figure 3.1 Number of adult long-term bridging device implants in the UK, by financial year and device type, 1 April 2010 to 31 March 2020

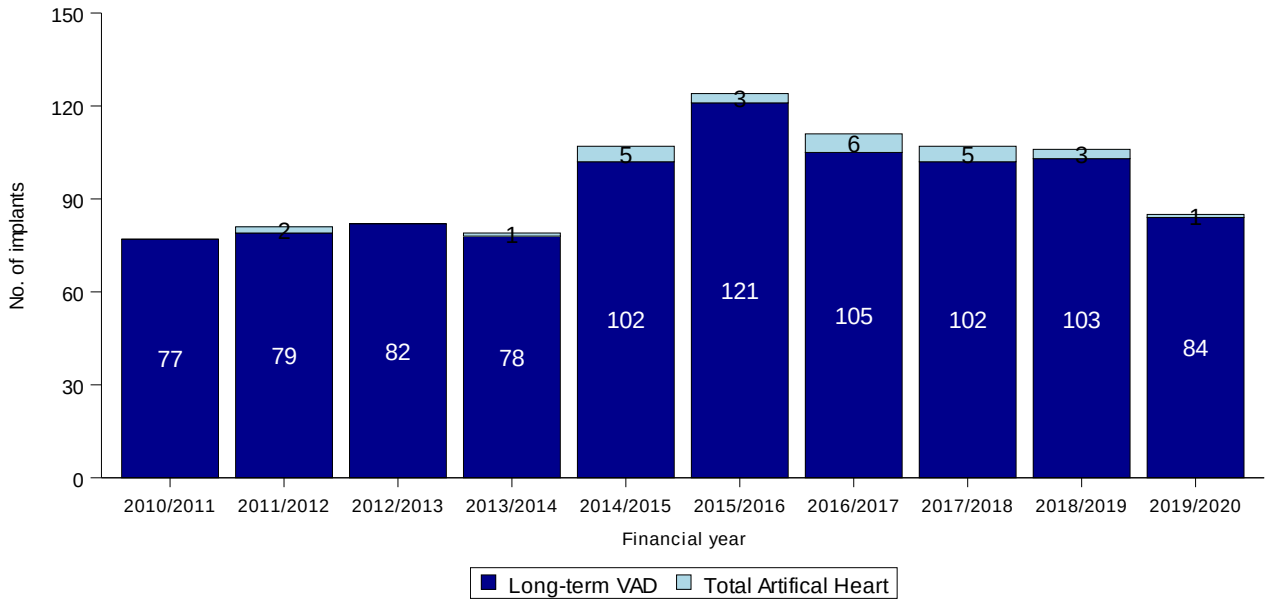


Figure 3.2 Number of adult long-term bridging device implants in the UK, by financial year, centre and device type, 1 April 2010 to 31 March 2020

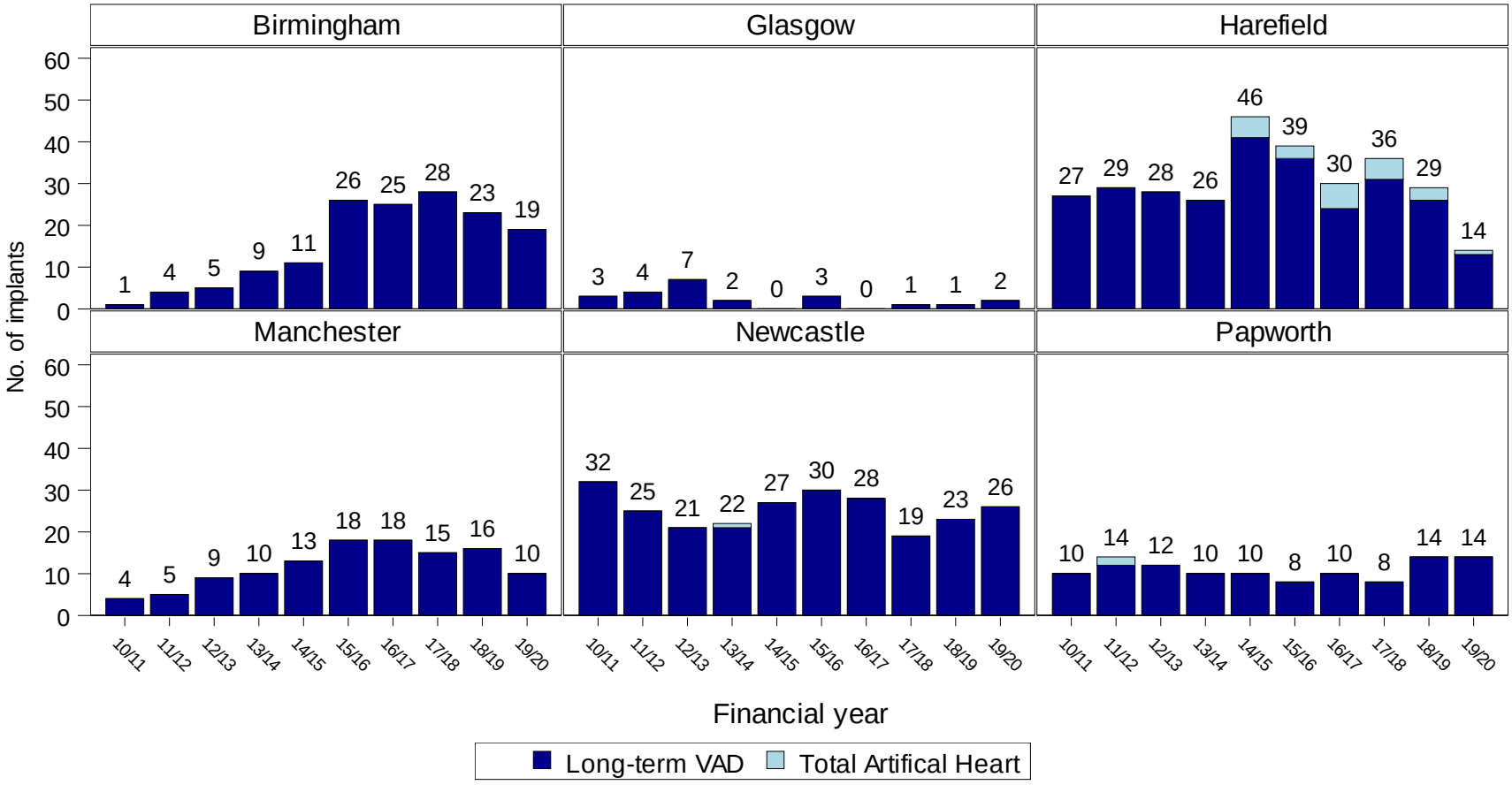


Figure 3.3 Number of adult long-term bridging device implants in the UK, by centre and device type, 1 April 2019 to 31 March 2020

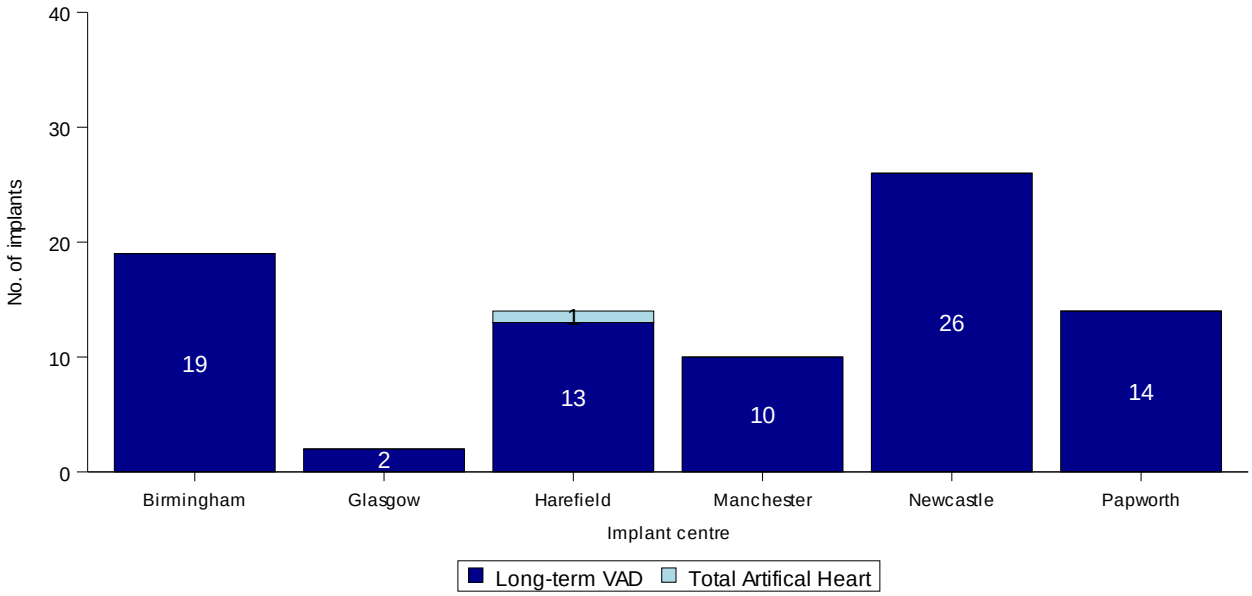
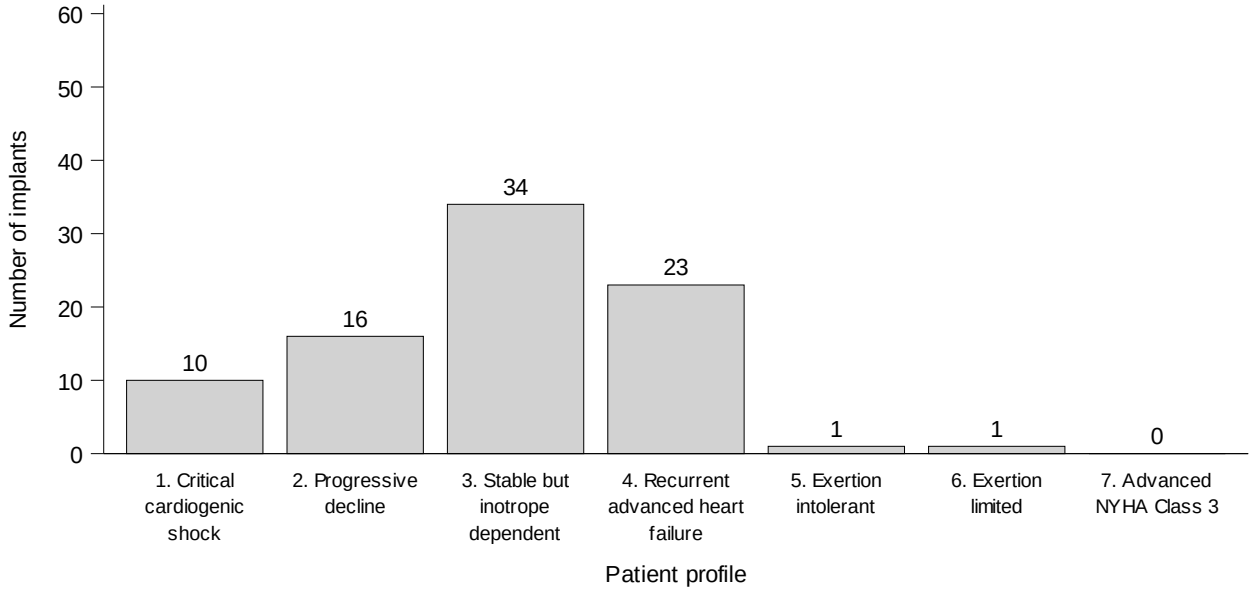


Figure 3.4 shows the INTERMACS patient profile at time of long-term VAD implantation for patients implanted during 2019/2020. Level 3 (stable but inotrope dependent) was the most common, followed by level 4 (recurrent advanced heart failure) and level 2 (progressive decline).

Figure 3.4 INTERMACS patient profile of adult patients receiving long-term bridging device implants during 1 April 2019 – 31 March 2020



ADULT LONG-TERM DEVICES USED FOR BRIDGING

Patient Outcomes

4 Outcomes for adult patients with long-term bridging devices

This section only considers patients whose first long-term device was a continuous-flow long-term VAD. Patients who received prior short-term support are included in this section. Patients with no follow-up information available are excluded from this section as we cannot assume information about their time on support (one patient, as detailed in **Table A1.3** in Appendix A1). Patients who received a Total Artificial Heart are considered separately in Section 4.7. Patients are analysed on a per-patient basis.

4.1 Demographic characteristics

The demographic characteristics of the 403 patients analysed in this section are shown below in **Table 4.1** by centre and overall. Nationally, 81% of patients were male, the median age was 54 years and 55% of patients received a Heartware HVAD device. For some characteristics, due to rounding, percentages may not add up to 100.

Table 4.1 Characteristics of patients in the long-term bridging VAD patient outcomes section, by centre

		Birmingham N (%)	Glasgow N (%)	Harefield N (%)	Manchester N (%)	Newcastle N (%)	Papworth N (%)	**Total N (%)**
Number of patients		93	5	110	66	90	39	**403**
Age at implant (years)	Median (IQR)	56 (50-62)	54 (51-56)	52 (40-58)	53 (43-59)	56 (45-61)	55 (49-59)	**54 (45-60)**
	Missing	0	0	0	0	0	0	**0**
Sex	Male	75 (81)	5 (100)	82 (75)	53 (80)	78 (87)	33 (85)	**326 (81)**
	Female	18 (19)	0 (0)	28 (25)	13 (20)	12 (13)	6 (15)	**77 (19)**
Primary disease	Dilated cardiomyopathy	46 (49)	3 (60)	71 (65)	39 (59)	45 (50)	18 (46)	**222 (55)**
	Ischaemic heart disease	35 (38)	0 (0)	33 (30)	17 (26)	33 (37)	18 (46)	**136 (34)**
	Congenital heart disease	1 (1)	0 (0)	1 (1)	1 (2)	9 (10)	0 (0)	**12 (3)**
	Hypertrophic cardiomyopathy	0 (0)	1 (20)	3 (3)	1 (2)	1 (1)	3 (8)	**9 (2)**
	Restrictive cardiomyopathy	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	**1 (0)**
	Valvular heart disease	2 (2)	0 (0)	0 (0)	3 (5)	0 (0)	0 (0)	**5 (1)**
	Infiltrative heart muscle disease	2 (2)	0 (0)	1 (1)	0 (0)	1 (1)	0 (0)	**4 (1)**
	Other	7 (8)	0 (0)	0 (0)	3 (5)	0 (0)	0 (0)	**10 (2)**
	Unknown	0 (0)	1 (20)	0 (0)	2 (3)	1 (1)	0 (0)	**4 (1)**

Table 4.1 Characteristics of patients in the long-term bridging VAD patient outcomes section, by centre

		Birmingham N (%)	Glasgow N (%)	Harefield N (%)	Manchester N (%)	Newcastle N (%)	Papworth N (%)	**Total N (%)**
INTERMACS patient profile	1. Critical cardiogenic shock	18 (19)	0 (0)	31 (28)	6 (9)	9 (10)	0 (0)	**64 (16)**
	2. Progressive decline	26 (28)	4 (80)	50 (45)	19 (29)	20 (22)	14 (36)	**133 (33)**
	3. Stable but inotrope dependent	47 (51)	0 (0)	24 (22)	24 (36)	26 (29)	17 (44)	**138 (34)**
	4. Recurrent advanced heart failure	2 (2)	0 (0)	4 (4)	12 (18)	34 (38)	6 (15)	**58 (14)**
	5. Exertion intolerant	0 (0)	0 (0)	0 (0)	5 (8)	1 (1)	0 (0)	**6 (1)**
	6. Exertion limited	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (5)	**2 (0)**
	7. Advanced NYHA Class 3	0 (0)	1 (20)	1 (1)	0 (0)	0 (0)	0 (0)	**2 (0)**
Pre-implant BMI (kg/m^2)	Median (IQR)	28 (24-30)	25 (24-26)	25 (23-30)	26 (23-29)	26 (23-30)	26 (24-29)	**26 (23-30)**
	Missing	13	0	28	14	29	15	**99**
Pre-implant serum creatinine (umol/l)	Median (IQR)	109 (89-152)	91 (78-116)	100 (79-121)	87 (71-128)	119 (104-154)	120 (92-140)	**109 (81-134)**
	Missing	5	0	0	0	18	4	**27**
Pre-implant serum bilirubin (umol/l)	Median (IQR)	15 (10-25)	10 (7-21)	20 (13-29)	20 (11-28)	17 (11-36)	14 (7-19)	**17 (11-29)**
	Missing	8	0	3	8	26	11	**56**
First VAD device name	Heartmate II	16 (17)	1 (20)	0 (0)	9 (14)	0 (0)	0 (0)	**26 (6)**
	Heartware	0 (0)	4 (80)	107 (97)	0 (0)	88 (98)	24 (62)	**223 (55)**
	Heartware MVAD	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)	0 (0)	**2 (0)**
	HeartMate III	77 (83)	0 (0)	0 (0)	57 (86)	0 (0)	15 (38)	**149 (37)**
	Reliant Heart aVAD	0 (0)	0 (0)	3 (3)	0 (0)	0 (0)	0 (0)	**3 (1)**
Long-term device configuration	LVAD	93 (100)	5 (100)	110 (100)	66 (100)	87 (97)	39 (100)	**400 (99)**
	RVAD	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)	0 (0)	**3 (1)**
	BiVAD	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**0 (0)**
Conjunction ST RVAD support	No	85 (91)	5 (100)	103 (94)	57 (86)	73 (81)	36 (92)	**359 (89)**
	Yes	8 (9)	0 (0)	7 (6)	9 (14)	17 (19)	3 (8)	**44 (11)**
Previous transplant	No	93 (100)	5 (100)	110 (100)	66 (100)	90 (100)	39 (100)	**403 (100)**
	Yes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**0 (0)**
Previous ST support	No	80 (86)	5 (100)	90 (82)	59 (89)	83 (92)	37 (95)	**354 (88)**
	Yes	13 (14)	0 (0)	20 (18)	7 (11)	7 (8)	2 (5)	**49 (12)**

4.2 Duration on support

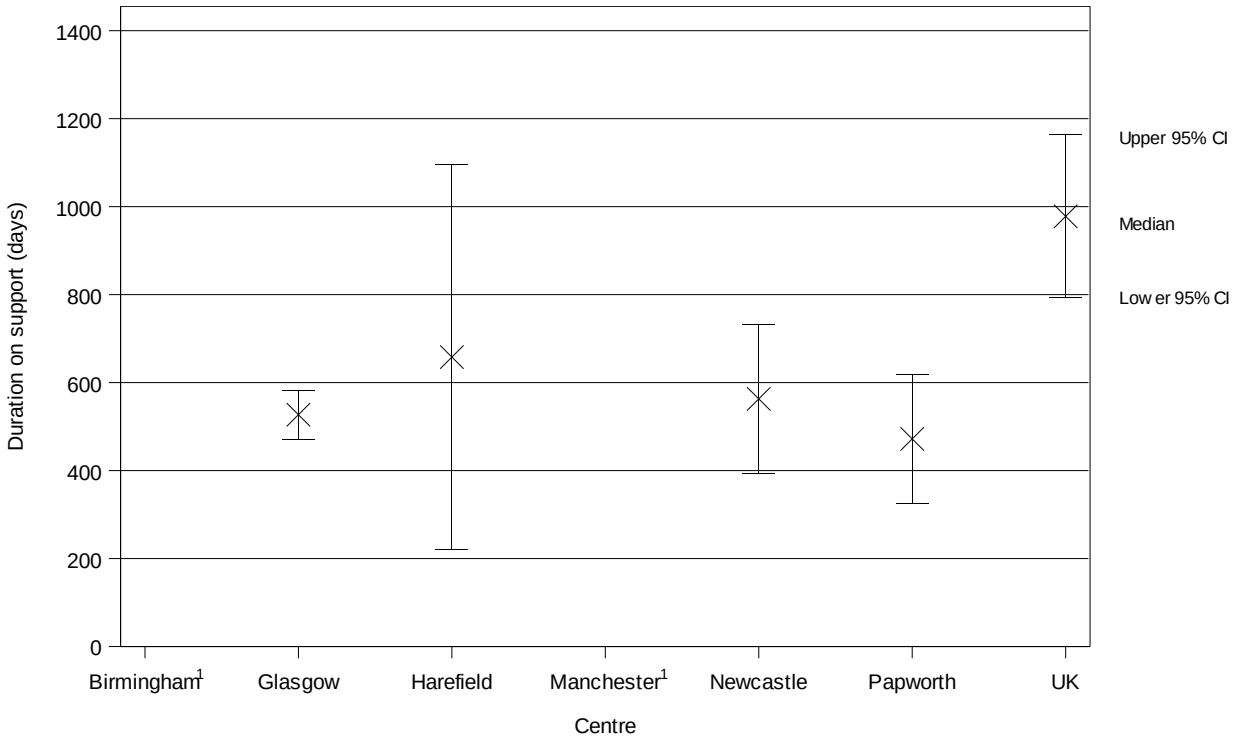
Table 4.2 shows the median duration on long-term VAD support for patients implanted in a recent four year period, both nationally and by centre. The medians and confidence intervals are estimated using the Kaplan-Meier method since not all patients have come to the end of their support and this method allows these (censored) patients to be included in the analysis. Transplant, explant or death signify end of support. If a patient was subsequently given a short-term device, only time on the long-term device is counted. Nationally, the median time on long-term support was 978 days and ranged from 472 days at Papworth to 658 days at Harefield (log-rank p<0.0001) with estimates not able to be obtained for Birmingham and Manchester.

Table 4.2 Median duration on long-term VAD support for adult patients implanted between 1 April 2015 and 31 March 2019, by centre

Centre	Number of patients	Time on support (days) Median	(95% confidence interval)
Birmingham[1]	93	-	-
Glasgow	5	527	471 - 583
Harefield	110	658	220 - 1096
Manchester[1]	66	-	-
Newcastle	90	563	394 - 732
Papworth	39	472	326 - 618
Overall	**403**	**978**	**793 - 1163**

[1] Median duration on support cannot be estimated as not enough patients have come to the end of support

Figure 4.1 Median duration on long-term VAD support for adult patients implanted between 1 April 2015 and 31 March 2019



[1] Median duration on support cannot be estimated as not enough patients have come to the end of support

4.3 Rate of transplant listing

Figure 4.2 and **Table 4.3** show the rate of transplant listing for patients first implanted between 1 April 2015 and 31 March 2019, by centre. This includes listing on the super-urgent, urgent or non-urgent heart transplant lists (whichever occurred first). Overall, 27% of patients were on the list at implant, but this proportion ranged significantly across centres (chi-squared p<0.0001), however Glasgow's figures are based on a small number of patients. The proportion still on a VAD at one year and not listed was 25% overall and ranged from 4% at Newcastle to 44% at Birmingham (chi-squared p<0.0001).

Figure 4.2 Heart transplant listing status with respect to long-term VAD implantation for adult patients receiving a first device 1 April 2015 – 31 March 2019, by centre and overall

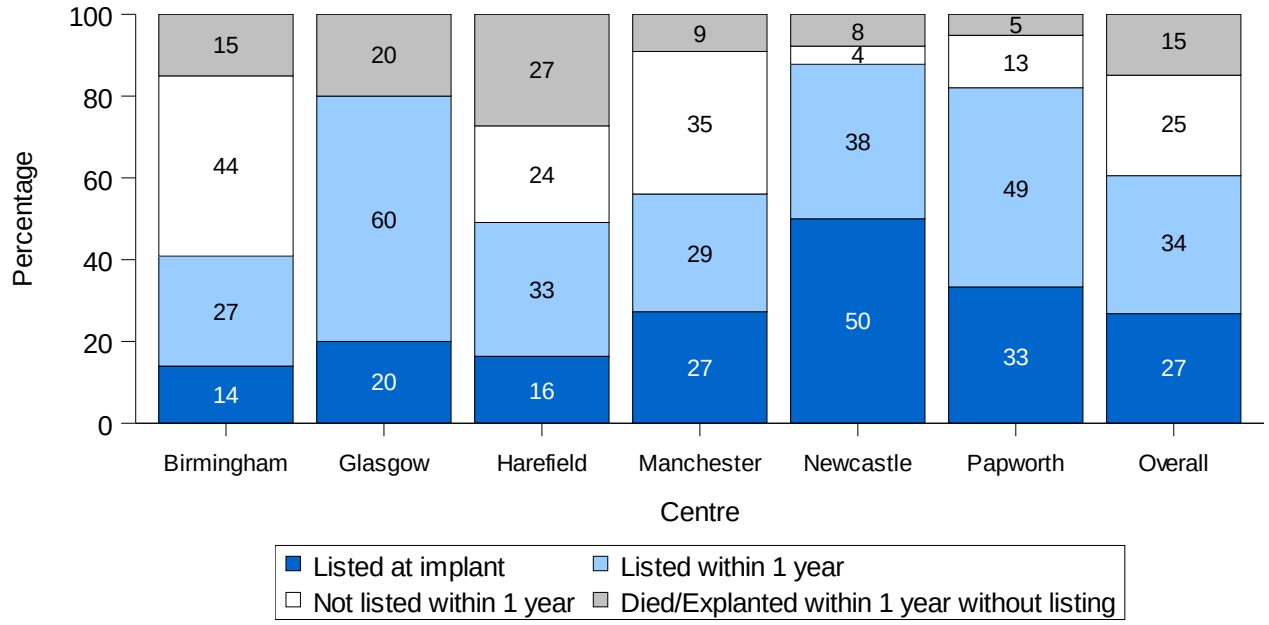


Table 4.3 Heart transplant listing status with respect to long-term VAD implantation for adult patients receiving a first device 1 April 2015 – 31 March 2019, by centre and overall

Centre	Number of patients	Listed at VAD implant	Listed within 1 year	Not listed within 1 year	Died/explanted within 1 year without listing
	N	N (%)	N (%)	N (%)	N (%)
Birmingham	93	13 (14)	25 (27)	41 (44)	14 (15)
Glasgow	5	1 (20)	3 (60)	0 (0)	1 (20)
Harefield	110	18 (16)	36 (33)	26 (24)	30 (27)
Manchester	66	18 (27)	19 (29)	23 (35)	6 (9)
Newcastle	90	45 (50)	34 (38)	4 (4)	7 (8)
Papworth	39	13 (33)	19 (49)	5 (13)	2 (5)
Overall	**403**	**108 (27)**	**136 (34)**	**99 (25)**	**60 (15)**

4.4 Competing outcomes

Whilst on VAD support, patients are susceptible to different outcomes. Death on support, transplant, and explant without transplant (with or without recovery) are all possible outcomes. **Figure 4.3** shows the cumulative incidence of each of these outcomes occurring from time of implantation, for the cohort of patients receiving a first long-term device between 1 April 2015 and 31 March 2019. This is calculated using the Aalen-Johansen method to account for competing outcomes. At time zero, 100% of patients are on support and as time passes, patients either experience death on support, transplant or explant without transplant. At any time point, the proportion alive on support plus the proportions experiencing each outcome will add up to 100%. Deaths after transplant are not counted and these patients are classed simply as transplanted. Patients who were explanted and died within 30 days of explant are counted as deaths at time of explant. Any subsequent VAD support post-explant is not counted and any such patients are classed simply as explanted. If a patient is moved from one long-term device to another without a period free of support, they are counted as still on support. Patients who receive a subsequent short-term device are counted as explanted at time of short-term implant.

For this cohort, at one year post- long-term implant, 71% of patients remained alive on support, 21% died on support, 5% received a heart transplant and 4% had their device explanted. At two years, the incidence of transplantation rose to 11%, however so did the incidence of death, to 28%, with the remaining 55% of patients still alive on support and 7% explanted. At three years, the incidence of death on support rose to 35%, the incidence of transplant rose to 14%, 8% had been explanted and 44% remained alive on support.

Figure 4.3 Cumulative incidence of transplant, death and explant for adult patients implanted with a first long-term VAD, 1 April 2015 to 31 March 2019

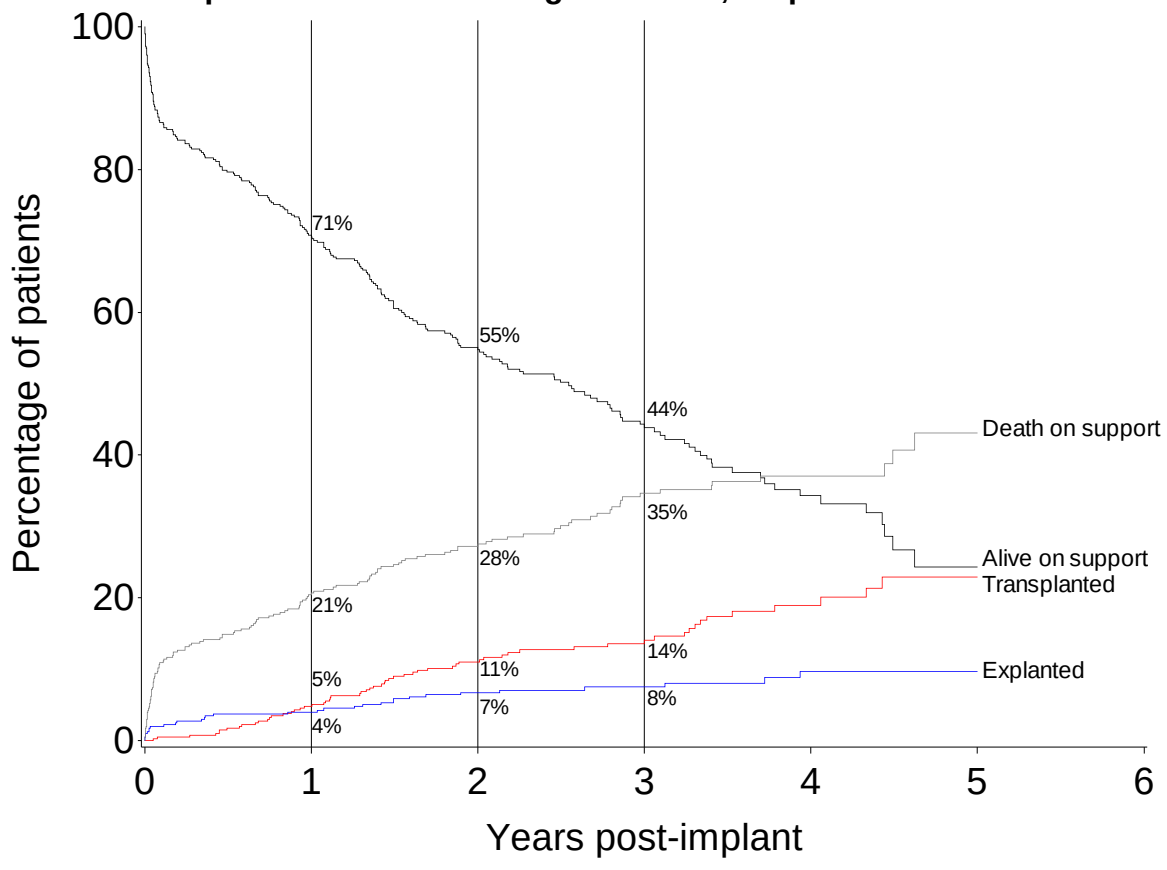


Table 4.4a and **Table 4.4b** shows the centre-specific one-year and three-year estimates for each competing outcome, respectively. The incidence of each outcome varies across centres.

Table 4.4a Cumulative incidence of each outcome at 1 year, by centre, for adult patients implanted with a first long-term VAD, 1 April 2015 to 31 March 2019

Centre	Number of patients	Transplanted %	Explanted %	Alive on support %	Death on support %
Birmingham	93	2	4	80	14
Glasgow	5	0	0	80	20
Harefield	110	8	7	56	29
Manchester	66	0	0	91	9
Newcastle	90	8	3	62	27
Papworth	39	17	3	64	16
Overall	**403**	**5**	**4**	**71**	**21**

Table 4.4b Cumulative incidence of each outcome at 3 years, by centre, for adult patients implanted with a first long-term VAD, 1 April 2015 to 31 March 2019

Centre	Number of patients	Transplanted %	Explanted %	Alive on support %	Death (before transplant) %
Birmingham	93	3	6	69	21
Glasgow	5	60	0	20	20
Harefield	110	9	10	42	40
Manchester	66	9	6	65	19
Newcastle	90	15	7	22	55
Papworth	39	54	6	12	29
Overall	**403**	**14**	**8**	**44**	**35**

4.5 Survival on support

This section presents Kaplan-Meier estimates of patient survival during long-term VAD support. All patients who received a long-term VAD were included, whether this was their first VAD or after a short-term VAD. Survival time is calculated as the time on long-term VAD support only, and death on long-term support (including patients who died within 30 days of explant) is the only event considered. Times were censored if the patient had their long-term VAD explanted, received a transplant from support, or were alive on support at last report. This differs from the analysis in Section 4.6 which considers a patient's overall survival from the point of implant and includes time after explant or transplant, as well as time on other subsequent devices.

Figure 4.4 shows the unadjusted survival curve on long-term support. **Table 4.5** shows the unadjusted centre-specific survival on support rates at 30 days, 1 year and 3 years respectively. The national survival on support rates were 90.0%, 78.7%, and 61.5% at 30

days, 1 year, and 3 years respectively. There was a significant difference between unadjusted survival on support at 3 years between centres (log-rank p<0.001).

Figure 4.4 Patient survival during long-term VAD support for adult patients implanted 1 April 2015 – 31 March 2019

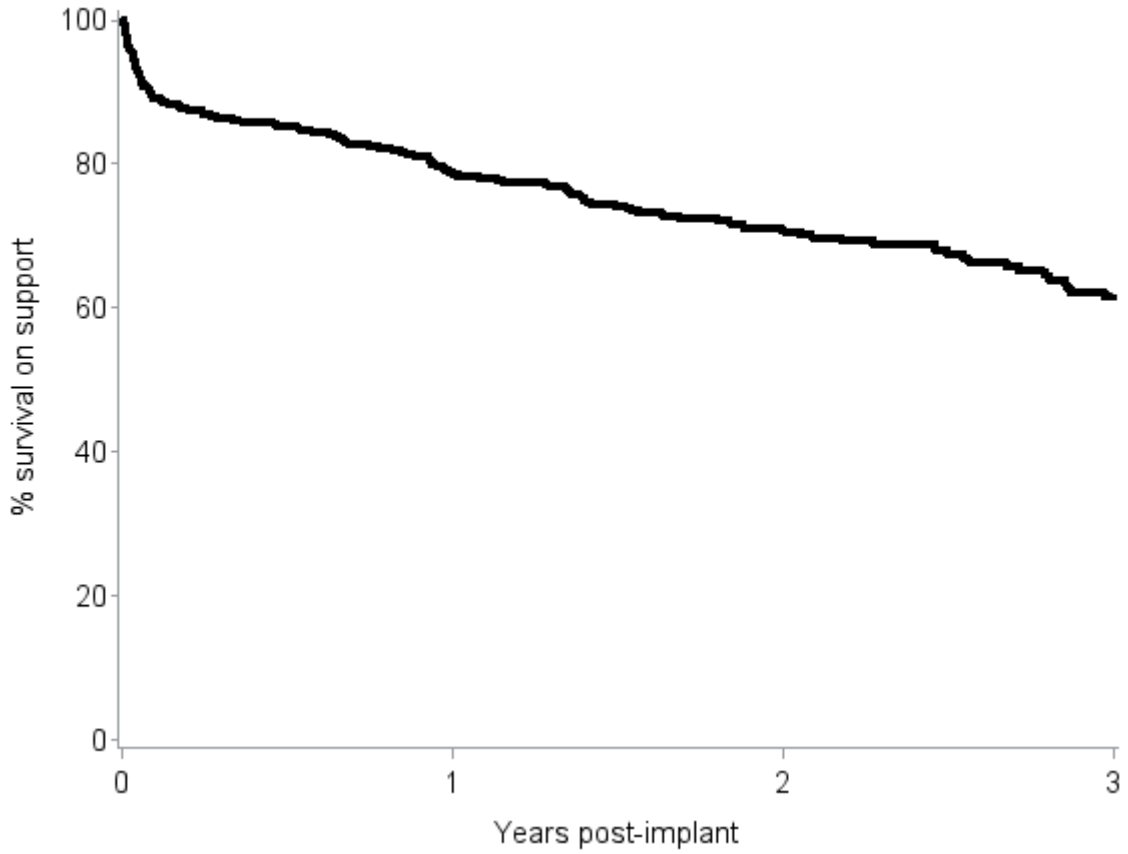


Table 4.5 Unadjusted survival during long-term VAD support, by centre, 1 April 2015 to 31 March 2019

Centre	No. of patients	% 30 day survival (95% CI)		% 1 year survival (95% CI)		% 3 year survival (95% CI)	
Birmingham	93	90.2	(82.1 - 94.8)	84.7	(75.6 - 90.7)	78.6	(67.8 - 86.1)
Glasgow[1]	5	-	-	-	-	-	-
Harefield	110	83.4	(75.0 - 89.2)	69.6	(59.8 - 77.5)	57.0	(46.0 - 66.5)
Manchester	66	95.5	(86.6 - 98.5)	90.9	(80.9 - 95.8)	78.6	(62.0 - 88.6)
Newcastle	90	89.9	(81.5 - 94.6)	71.7	(60.7 - 80.1)	34.1	(21.7 - 46.9)
Papworth	39	97.4	(83.2 - 99.6)	82.6	(65.0 - 91.9)	46.3	(9.8 - 77.5)
Number at risk		356		284		94	
Log-rank p-value		**0.04**		**<0.001**		**<0.001**	
UK	**403**	**90.0**	**(86.6 - 92.6)**	**78.7**	**(74.3 - 82.4)**	**61.5**	**(55.4 - 67.1)**

[1] Survival rates for groups with fewer than 10 patients are not presented due to small numbers

4.6 Patient survival from implant

Overall survival rates from the point of first long-term VAD implant, not censored for transplant or explant, are presented in this section. Survival data from the UK Transplant Registry were incorporated, as was any additional survival time recorded on the VAD Database for patients who were explanted. Time on additional devices is also counted, so for example if a patient had a period of long-term support, then a period of short-term support, all this time is included. Times are censored if the patient was still alive at last known event or follow-up.

Survival rates are calculated using the Kaplan-Meier method and are based on those patients recorded as receiving a first device between 1 April 2015 and 31 March 2019 where information on survival post-implant is known.

In **Tables 4.6**-**4.8** and **Figures 4.5**-**4.7** the centre-specific survival rates for implants are presented for 30 days, 1 year and 3 years respectively. The national survival rates were 89.1%, 77.1%, and 60.1% at 30 days, 1 year, and 3 years respectively.

The centre-specific rates are not adjusted for differences in risk between patients treated at different centres. These differences can be seen at the start of this section in **Table 4.1** which displays the baseline characteristics of the 403 patients included in this analysis (including the number of patients who received prior short-term support). The survival rates are compared with the national rate and the uncertainty around this rate using funnel plots where outliers appear outside of the funnels; rates above the funnel are significantly high while rates below the funnel are significantly low. Rates for Glasgow are not included due to low numbers.

The unadjusted centre-specific 30-day survival rates for patients implanted in the recent period are shown in **Table 4.6** and **Figure 4.5**. The rate for Papworth was 97.4% and exceeded the upper 99.8% confidence limit, indicating a higher unadjusted rate than the national rate. There was some evidence that the rate for Manchester was higher than average and some evidence that the rate for Harefield was lower than average.

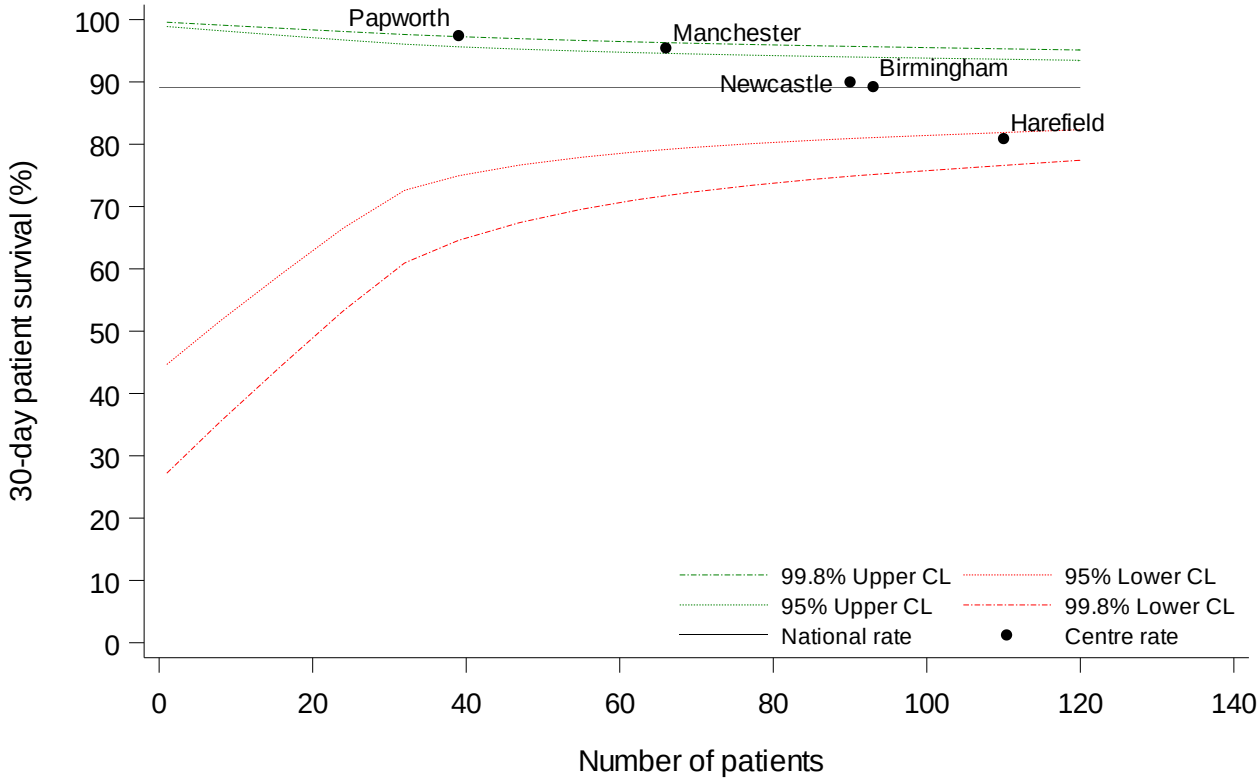
Table 4.6 30-day patient survival rates after long-term VAD implant for adult patients implanted 1 April 2015 – 31 March 2019, by centre

Centre	Number of patients	% 30-day survival (95% CI) Unadjusted	
Birmingham	93	89.2	(80.9 - 94.1)
Glasgow[1]	5	-	-
Harefield	110	80.9	(72.2 - 87.1)
Manchester	66	95.5	(86.6 - 98.5)
Newcastle	90	90.0	(81.7 - 94.7)
Papworth	39	97.4	(83.2 - 99.6)
UK	**403**	**89.1**	**(85.6 - 91.8)**

Centre has reached the lower 99.8% confidence limit
Centre has reached the lower 95% confidence limit
Centre has reached the upper 95% confidence limit
Centre has reached the upper 98.8% confidence limit

[1] Survival rates for groups with fewer than 10 patients are not presented due to small numbers

Figure 4.5 Unadjusted 30-day patient survival rates after long-term VAD implant for adult patients implanted 1 April 2015 – 31 March 2019, by centre



The unadjusted centre-specific 1-year survival rates are shown in **Table 4.7** and **Figure 4.6**. The centre-specific rates varied between 65.4% and 90.9% with Manchester having a higher unadjusted rate than the national rate, and there being some difference of a lower than average rate at Harefield.

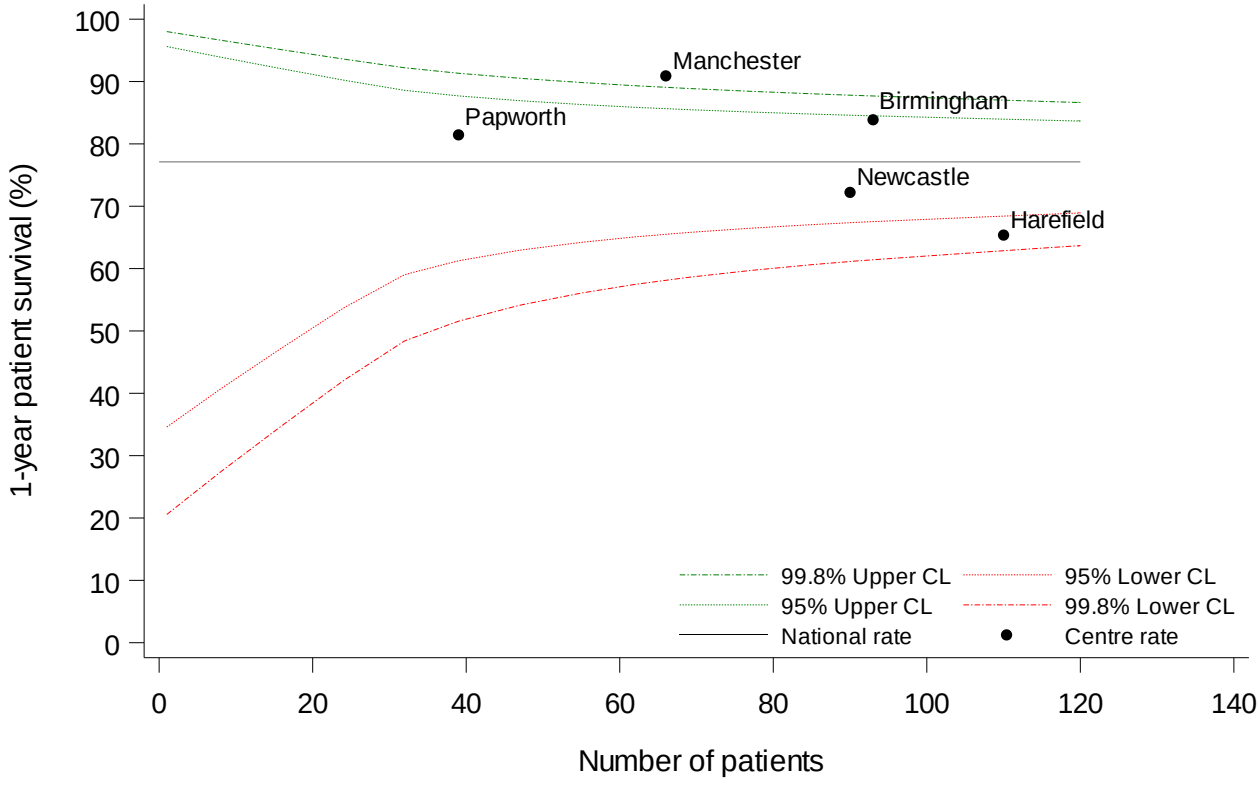
Table 4.7 1-year patient survival rates after long-term VAD implant for adult patients implanted 1 April 2015 – 31 March 2019, by centre

Centre	Number of patients	% 1-year survival (95% CI) Unadjusted	
Birmingham	93	83.9	(74.7 - 89.9)
Glasgow[1]	5	-	-
Harefield	110	65.4	(55.7 - 73.5)
Manchester	66	90.9	(80.9 - 95.8)
Newcastle	90	72.2	(61.7 - 80.3)
Papworth	39	81.4	(64.9 - 90.7)
UK	**403**	**77.1**	**(72.7 - 80.9)**

Centre has reached the lower 99.8% confidence limit
Centre has reached the lower 95% confidence limit
Centre has reached the upper 95% confidence limit
Centre has reached the upper 98.8% confidence limit

1 Survival rates for groups with fewer than 10 patients are not presented due to small numbers

Figure 4.6 Unadjusted 1-year patient survival rates after long-term VAD implant for adult patients implanted 1 April 2015 – 31 March 2019, by centre



The unadjusted centre-specific 3-year survival rates are shown in **Table 4.8** and **Figure 4.7**. The rate for Newcastle exceeded the lower 99.8% confidence limit, indicating that their unadjusted rate was lower than the national rate. The rates for Birmingham and Manchester exceeded the upper 99.8% confidence limit, indicating a higher unadjusted rate than the national rate.

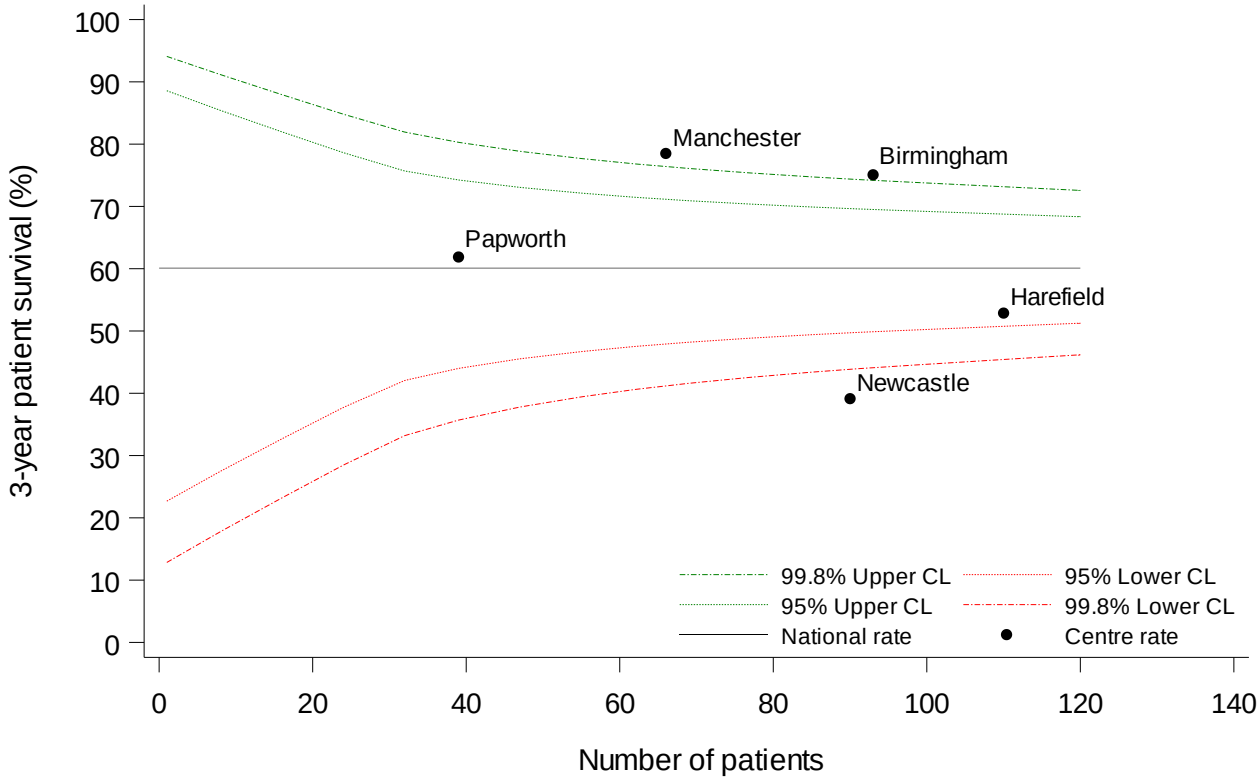
Table 4.8 3-year patient survival rates after long-term VAD implant for adult patients implanted 1 April 2015 – 31 March 2019, by centre

Centre	Number of patients	% 3-year survival (95% CI) Unadjusted	
Birmingham	93	75.1	(63.9 - 83.2)
Glasgow[1]	5	-	-
Harefield	110	52.9	(42.7 - 62.0)
Manchester	66	78.5	(63.4 - 87.9)
Newcastle	90	39.1	(27.6 - 50.5)
Papworth	39	61.9	(40.3 - 77.6)
UK	**403**	**60.1**	**(54.6 - 65.2)**

Centre has reached the lower 99.8% confidence limit
Centre has reached the lower 95% confidence limit
Centre has reached the upper 95% confidence limit
Centre has reached the upper 98.8% confidence limit

1 Survival rates for groups with fewer than 10 patients are not presented due to small numbers

Figure 4.7 Unadjusted 3-year patient survival rates after long-term VAD implant for adult patients implanted 1 April 2015 – 31 March 2019, by centre



4.7 TAH outcomes

Table 4.9 shows the outcomes of the 26 patients who received a TAH as a bridge to transplant in the time period. All patients are considered, including those who received other MCS prior to the TAH and those who received a TAH post-transplant. Three centres have used TAH in the time period. **Table 4.10** shows the national 30-day and 1-year post-implant survival rates for these patients. The 30-day rate was 68.8% and fell to 17.2% at 1-year, however care should be used when interpreting this rate due to the small cohort the numbers are based on.

Table 4.9 Outcomes of TAH recipients, by implant centre, 1 April 2010 to 31 March 2020

Centre	Number of patients N	Alive on support N (%)	Died not on list N (%)	Died on list N (%)	Survived to transplant N (%)
Harefield	23	1 (4)	9 (39)	3 (13)	10 (43)
Newcastle	1	0 (0)	0 (0)	1 (100)	0 (0)
Papworth	2	0 (0)	1 (50)	0 (0)	1 (50)
Overall	**26**	**1 (4)**	**10 (38)**	**4 (15)**	**11 (42)**

Table 4.10 Patient survival rates after TAH implant, 1 April 2010 to 31 March 2020

Number of patients	% 30-day survival (95% CI)	% 1-year survival (95% CI)
26	68.8 (47.2 - 83.0)	17.2 (5.4 - 34.6)

ADULT SHORT-TERM DEVICES USED FOR BRIDGING

Activity

5 Short-term bridging devices in adults

This section considers all patients who received short-term support as a bridge to heart transplantation. All figures and tables present information on a per implant basis as opposed to per patient, so if a single patient had more than one short-term device implant in the time period, each one is included.

Figure 5.1 shows the total number of short-term bridging device implants in the last ten years nationally by device type (ECMO or short-term VAD). During 2019/2020 there were 114 implantations; 22 more than 2018/2019. Since 2014/2015 there have been more short-term VAD implants than ECMO procedures. **Figure 5.2** shows the trend per centre, with Birmingham and Harefield showing an increasing trend over the decade. Last year's implant activity is shown by centre and device type in **Figure 5.3**. The highest number of short-term VAD implants were performed by Harefield.

Figure 5.1 Number of adult short-term bridging device implants in the UK, by financial year and device type, 1 April 2010 to 31 March 2020

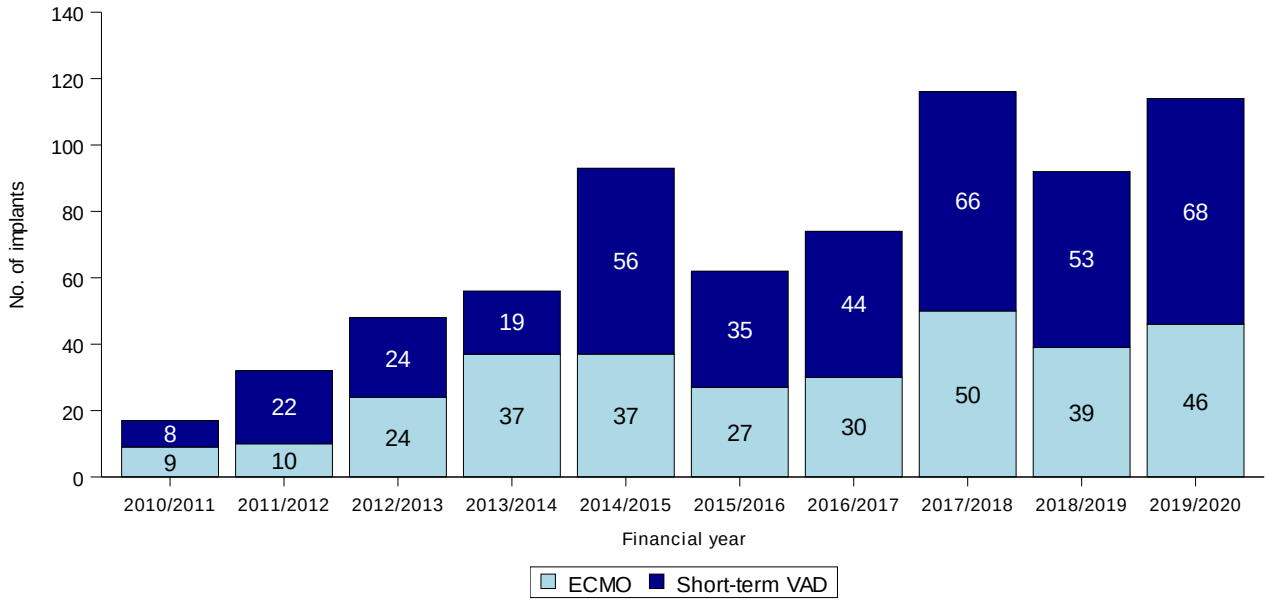


Figure 5.2 Number of adult short-term bridging device implants in the UK, by financial year, centre and device type, 1 April 2010 to 31 March 2020

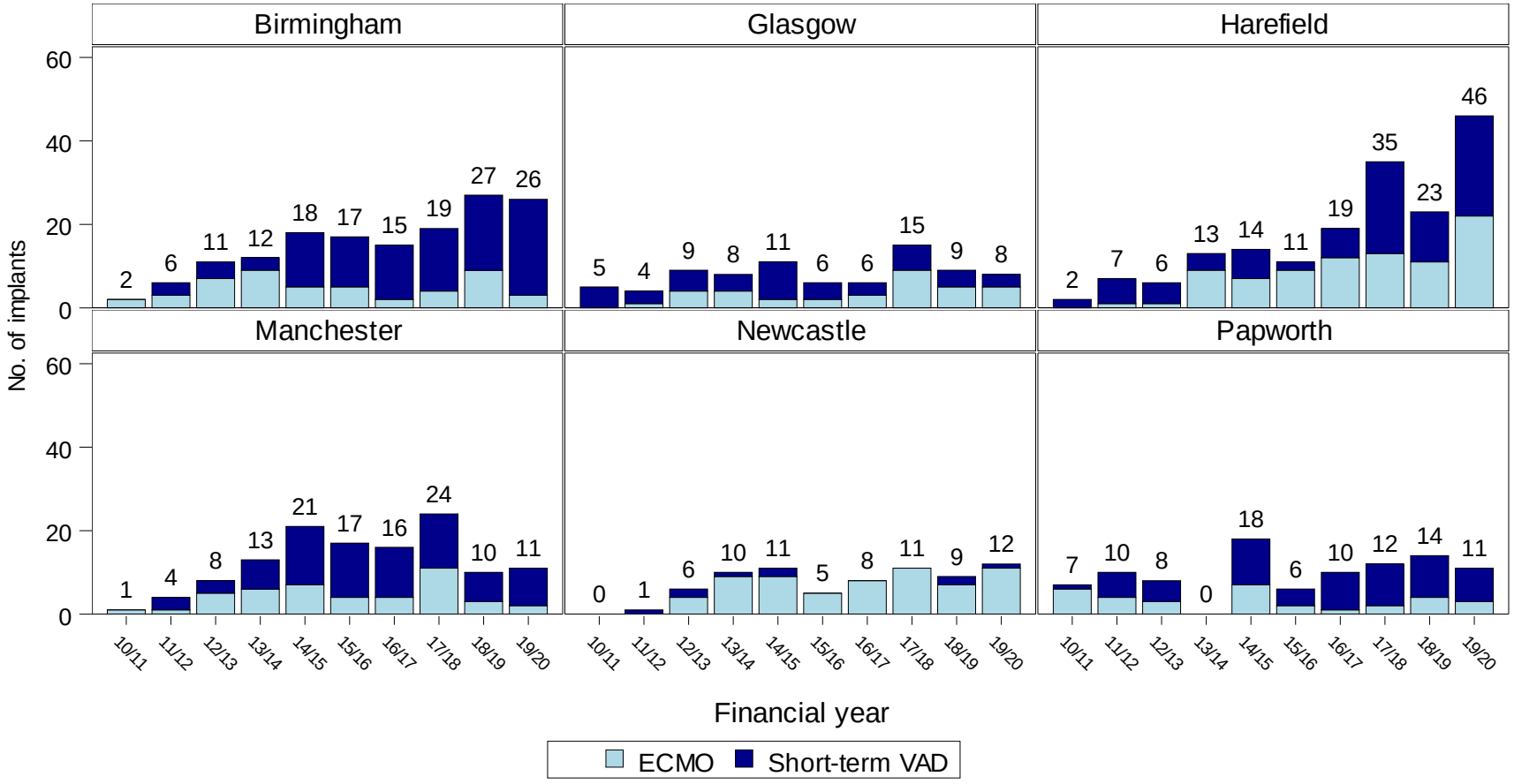


Figure 5.3 Number of adult short-term bridging device implants in the UK, by centre and device type, 1 April 2019 to 31 March 2020

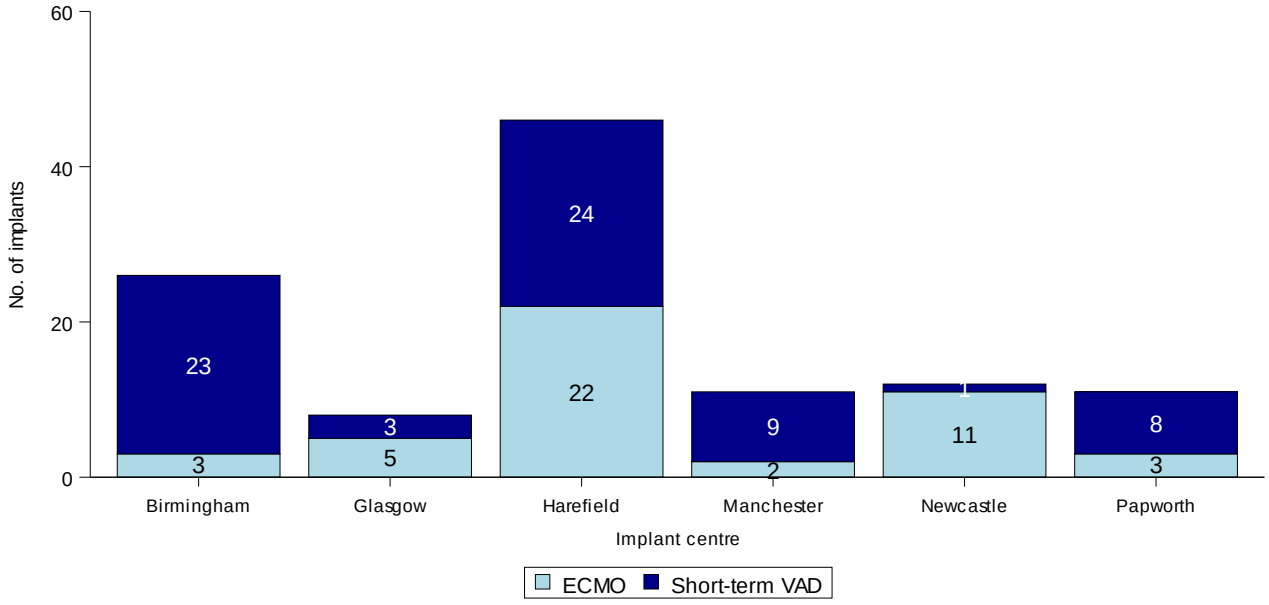
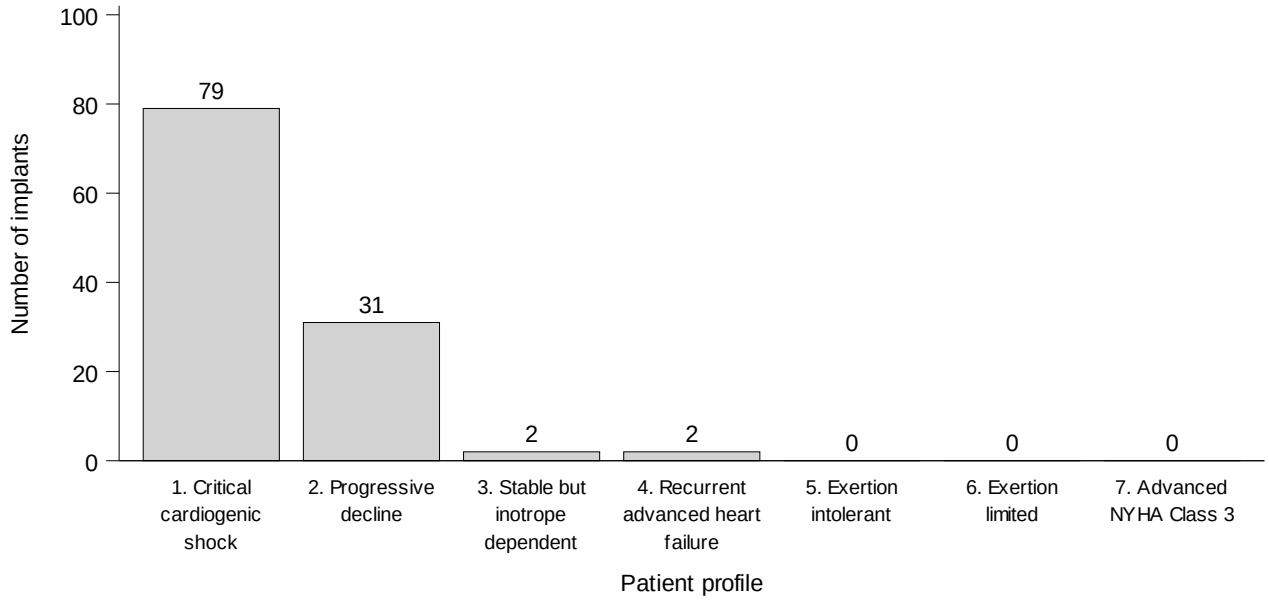


Figure 5.4 shows the INTERMACS patient profile at receipt of short-term support for patients implanted during 2019/2020. Most patients were profile 1 (critical cardiogenic shock).

Figure 5.4 INTERMACS patient profile for all short-term bridging device implants in adult patients in the UK, 1 April 2019 to 31 March 2020



ADULT SHORT TERM DEVICES USED FOR BRIDGING

Patient Outcomes

6 Outcomes of adult patients receiving short-term bridging devices

This section only considers patients who received a short-term device (including ECMO) as a bridge to transplant. Patients who received prior long-term support are included, apart from in Section 6.6 which considers patients who received short-term support only. Patients are analysed on a per-patient basis, as opposed to per implant.

6.1 Demographic characteristics

The demographic characteristics of the 284 patients analysed in **Sections 6.2**-**6.5** are shown below in **Table 6.1** by centre and overall. Nationally, 69% of patients were male, the median age was 48 years, 39% of patients received ventricular assist devices and 20% were bridged to a long-term device. For some characteristics, due to rounding, percentages may not add up to 100.

Table 6.1 Characteristics of patients in the short-term bridging outcomes section, by centre

		Birmingham N (%)	Glasgow N (%)	Harefield N (%)	Manchester N (%)	Newcastle N (%)	Papworth N (%)	**Total N (%)**
Number of patients		62	31	69	59	32	31	**284**
Age at implant (years)	Median (IQR)	49 (33-57)	49 (40-57)	45 (32-57)	44 (31-53)	48 (33-58)	46 (30-53)	**48 (32-56)**
	Missing	0	0	0	0	0	0	**0**
Recipient sex	Male	39 (63)	24 (77)	49 (71)	39 (66)	21 (66)	24 (77)	**196 (69)**
	Female	23 (37)	7 (23)	20 (29)	20 (34)	11 (34)	7 (23)	**88 (31)**
Primary disease	Dilated cardiomyopathy	34 (55)	10 (32)	40 (58)	31 (53)	20 (63)	15 (48)	**150 (53)**
	Ischaemic heart disease	16 (26)	12 (39)	22 (32)	18 (31)	6 (19)	11 (35)	**85 (30)**
	Congenital heart disease	2 (3)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	**3 (1)**
	Hypertrophic cardiomyopathy	1 (2)	0 (0)	2 (3)	0 (0)	0 (0)	2 (6)	**5 (2)**
	Restrictive cardiomyopathy	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	**1 (0)**
	Valvular heart disease	0 (0)	2 (6)	1 (1)	2 (3)	0 (0)	0 (0)	**5 (2)**
	Infiltrative heart muscle disease	3 (5)	0 (0)	0 (0)	1 (2)	1 (3)	0 (0)	**5 (2)**
	Other	4 (6)	5 (16)	2 (3)	6 (10)	3 (9)	2 (6)	**22 (8)**
	Unknown	2 (3)	2 (6)	0 (0)	1 (2)	2 (6)	1 (3)	**8 (3)**

Table 6.1 Characteristics of patients in the short-term bridging outcomes section, by centre

		Birmingham N (%)	Glasgow N (%)	Harefield N (%)	Manchester N (%)	Newcastle N (%)	Papworth N (%)	**Total N (%)**
INTERMACS patient profile	1. Critical cardiogenic shock	43 (69)	24 (77)	62 (90)	50 (85)	19 (59)	18 (58)	**216 (76)**
	2. Progressive decline	17 (27)	7 (23)	7 (10)	9 (15)	12 (38)	11 (35)	**63 (22)**
	3. Stable but inotrope dependent	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (6)	**2 (1)**
	4. Recurrent advanced heart failure	1 (2)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	**2 (1)**
	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	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (0)**
Type of support	Percutaneous VAD	12 (19)	0 (0)	23 (33)	0 (0)	2 (6)	0 (0)	**37 (13)**
	Ventricular assist (Centrimag)	32 (52)	12 (39)	6 (9)	39 (66)	0 (0)	22 (71)	**111 (39)**
	Peripheral ECMO	11 (18)	17 (55)	34 (49)	12 (20)	27 (84)	7 (23)	**108 (38)**
	Central ECMO	7 (11)	2 (6)	6 (9)	8 (14)	3 (9)	2 (6)	**28 (10)**
Previous long-term support	No	59 (95)	31 (100)	61 (88)	59 (100)	29 (91)	30 (97)	**269 (95)**
	Yes	3 (5)	0 (0)	8 (12)	0 (0)	3 (9)	1 (3)	**15 (5)**
Bridged to long-term support	No	49 (79)	31 (100)	40 (58)	52 (88)	25 (78)	29 (94)	**226 (80)**
	Yes	13 (21)	0 (0)	29 (42)	7 (12)	7 (22)	2 (6)	**58 (20)**
Pre-implant serum creatinine (umol/l)	Median (IQR)	125 (105-193)	124 (91-164)	120 (80-169)	118 (90-135)	137 (84-221)	109 (94-161)	**122 (90-166)**
	Missing	5	6	1	16	28	6	**62**
Pre-implant serum bilirubin (umol/l)	Median (IQR)	33 (16-49)	13 (9-19)	25 (14-40)	28 (14-42)	-	21 (10-35)	**24 (12-42)**
	Missing	5	7	3	22	32	12	**81**
Pre-implant lactate (mmol/l)	Median (IQR)	6 (3-8)	5 (2-8)	4 (2-8)	5 (2-8)	-	-	**5 (2-8)**
	Missing	46	26	43	57	32	31	**235**
Pre-implant cardiac arrest	No	49 (79)	19 (61)	58 (84)	47 (80)	24 (75)	27 (87)	**224 (79)**
	Yes	13 (21)	12 (39)	11 (16)	12 (20)	8 (25)	4 (13)	**60 (21)**
Pre-implant intubation and ventilation	No	42 (68)	21 (68)	35 (51)	36 (61)	13 (41)	27 (87)	**174 (61)**
	Yes	20 (32)	10 (32)	34 (49)	23 (39)	19 (59)	4 (13)	**110 (39)**
Pre-implant renal replacement therapy	No	54 (87)	30 (97)	58 (84)	49 (83)	21 (66)	18 (58)	**230 (81)**
	Yes	8 (13)	1 (3)	11 (16)	10 (17)	11 (34)	13 (42)	**54 (19)**

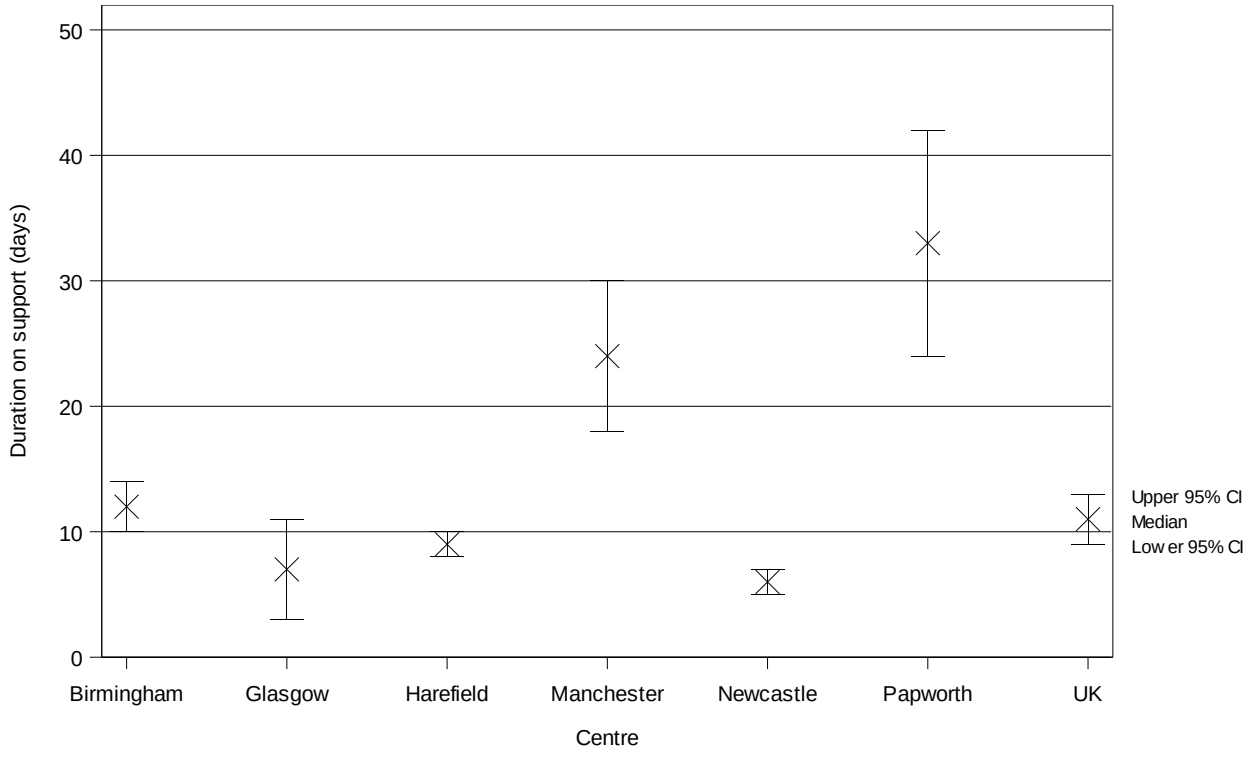
6.2 Duration on support

Table 6.2 shows the median duration on short-term support for patients implanted in a recent four year period, both nationally and by centre. The medians and confidence intervals are estimated using the Kaplan-Meier method. Transplant, explant, death or transfer to a long-term device signify end of short-term support. If a patient went from ECMO to short-term VAD, all this time is counted. Nationally, the median time on support was 11 days and ranged from 6 days at Newcastle to 33 days at Papworth (log-rank p< 0.0001).

Table 6.2 Median duration on short-term bridging device support for adult patients implanted between 1 April 2015 and 31 March 2019, by centre

Centre	Number of patients	Time on support (days) Median	(95% confidence interval)
Birmingham	62	12	10 - 14
Glasgow	31	7	3 - 11
Harefield	69	9	8 - 10
Manchester	59	24	18 - 30
Newcastle	32	6	5 - 7
Papworth	31	33	24 - 42
Overall	**284**	**11**	**9 - 13**

Figure 6.1 Median duration on short-term bridging device support for adult patients implanted between 1 April 2015 and 31 March 2019



6.3 Rate of transplant listing

Figure 6.2 and **Table 6.3** show the rate of transplant listing for patients first implanted between 1 April 2015 and 31 March 2019, by centre. This includes listing on the super-urgent, urgent or non-urgent heart transplant lists (whichever occurred first) and considers time on long-term support if bridged to a long-term device. Overall, 15% of patients were on the list at short-term implant, which was a smaller proportion than that observed for long-term implants (27%). This proportion ranged between 7% at Manchester to 22% at Newcastle (chi-squared p=0.48). The proportion that died or were explanted within 1 month without listing was 42% overall and ranged significantly across centres (chi-squared p=0.004).

Figure 6.2 Heart transplant listing status with respect to short-term device implantation for adult patients receiving a first bridging device 1 April 2015 – 31 March 2019, by centre and overall

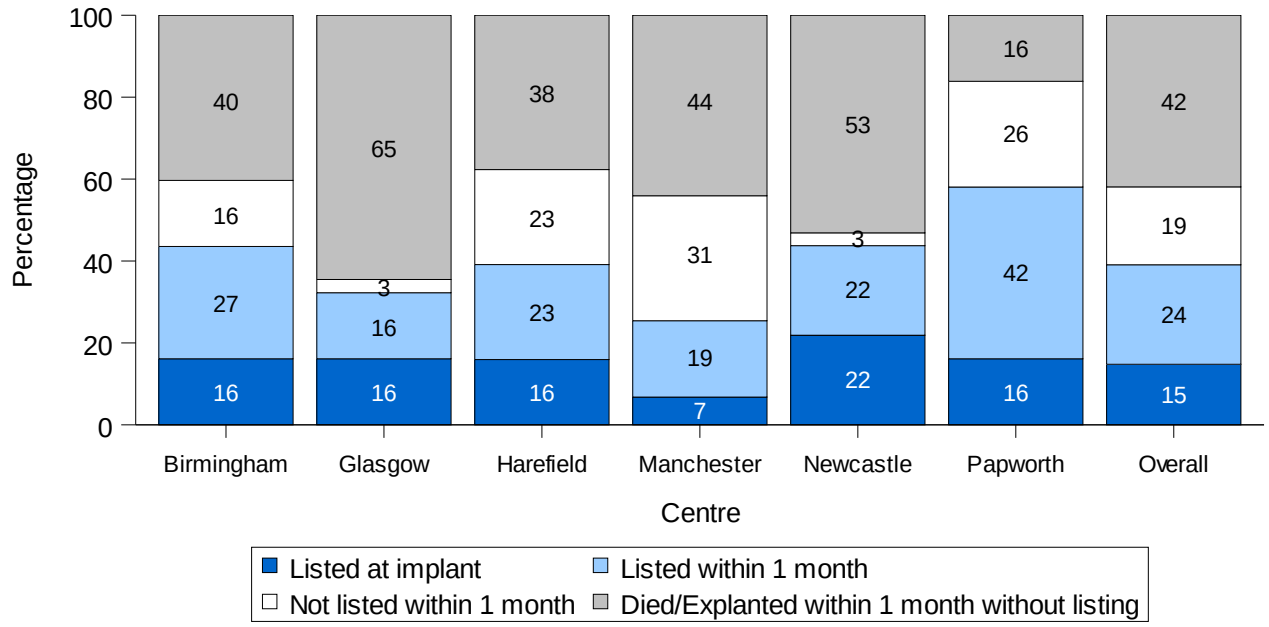


Table 6.3 Heart transplant listing status with respect to short-term device implantation for adult patients receiving a first bridging device 1 April 2015 – 31 March 2019, by centre and overall

Centre	Number of patients N	Listed before VAD N (%)	Listed within 1 month N (%)	Not listed within 1 month N (%)	Died/explanted within 1 month without listing N (%)
Birmingham	62	10 (16)	17 (27)	10 (16)	25 (40)
Glasgow	31	5 (16)	5 (16)	1 (3)	20 (65)
Harefield	69	11 (16)	16 (23)	16 (23)	26 (38)
Manchester	59	4 (7)	11 (19)	18 (31)	26 (44)
Newcastle	32	7 (22)	7 (22)	1 (3)	17 (53)
Papworth	31	5 (16)	13 (42)	8 (26)	5 (16)
Overall	**284**	**42 (15)**	**69 (24)**	**54 (19)**	**119 (42)**

6.4 Competing outcomes

Whilst on short-term support, patients are susceptible to different outcomes. Death on support, transplant, transfer to long-term support and explant without transplant are all possible outcomes. **Figure 6.3** shows the cumulative incidence of each of these outcomes occurring from time of implantation, for the cohort of adult patients receiving a first short-term device between 1 April 2015 and 31 March 2019. This is calculated using the Aalen-Johansen method to account for competing outcomes. At time zero, 100% of patients are on support and as time passes, patients either experience death on support, transplant, transferral to long-term support or explant without transplant. At any time point, the proportion alive on support plus the proportions experiencing each outcome will add up to 100%. Deaths after transplant are not counted and these patients are classed simply as transplanted. Patients who were explanted and died within 30 days of explant are counted as deaths at time of explant. Any subsequent VAD support post-explant is not counted and any such patients are classed simply as explanted. If a patient is moved from one short-term device to another without a period free of support, they are counted as still on support.

For this cohort, one month after receipt of a short-term device, 17% of patients were explanted, 28% died on short-term support, 25% remained alive on support, 14% received a transplant, and 17% were transferred to a long-term device. At two months, there was a small increase in the incidence of each of these events, leading to a reduction in the proportion that remained alive on support, down to 7%.

Figure 6.3 Cumulative incidence of transplant, death, transferral to long-term device and explant for adult patients implanted with a first short-term bridging device, 1 April 2015 to 31 March 2019

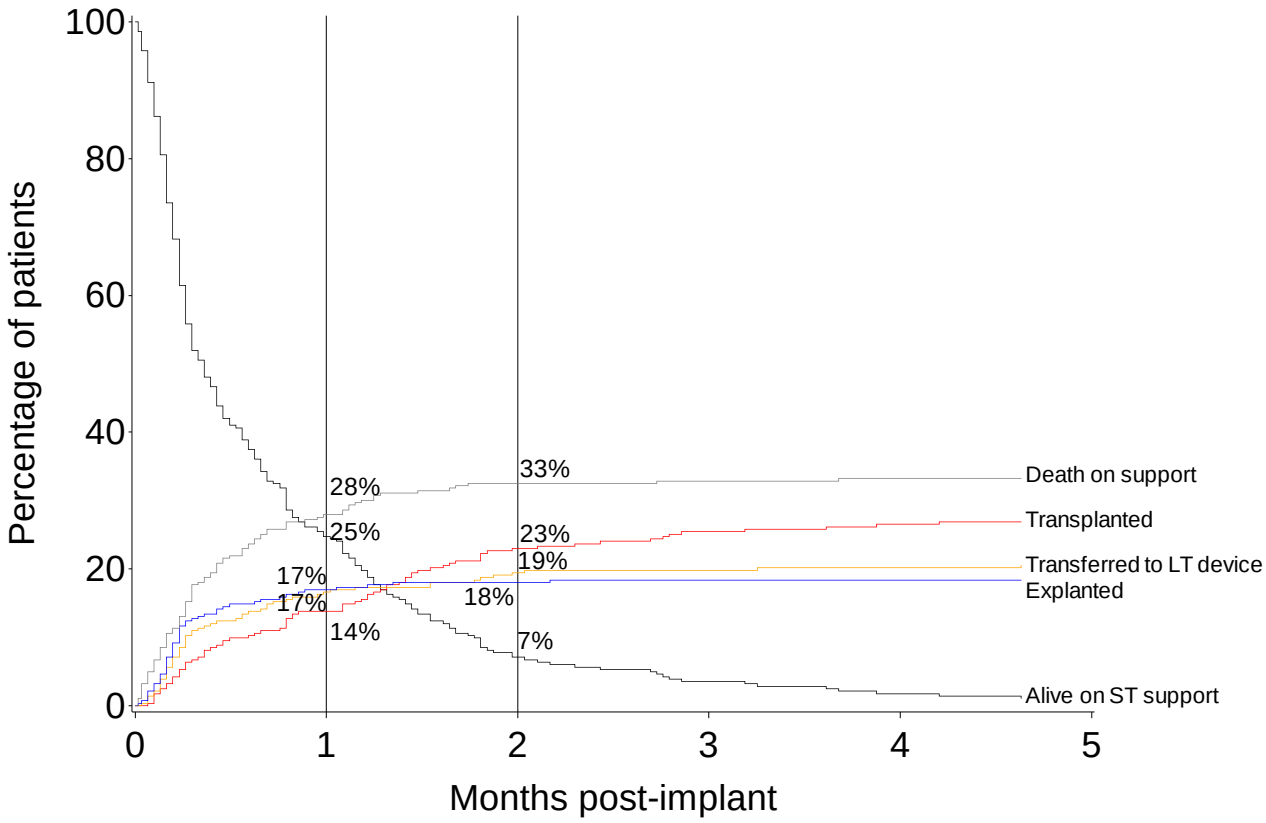


Table 6.4 shows the centre-specific 30-day estimates for each competing outcome. The incidence of each outcome varies across centres.

Table 6.4 Cumulative incidence of each outcome at 30 days, by centre, for adult patients implanted with a first short-term bridging device, 1 April 2015 to 31 March 2019

Centre	Number of patients	Transplanted %	Transferred to LT device %	Explanted %	Alive on support %	Death on support %
Birmingham	62	18	19	10	18	35
Glasgow	31	6	0	35	23	35
Harefield	69	13	35	7	19	26
Manchester	59	12	7	15	39	27
Newcastle	32	6	23	52	0	19
Papworth	31	26	0	3	52	19
Overall	**291**	**13**	**16**	**17**	**25**	**28**

6.5 Survival on support

This section presents Kaplan-Meier estimates of patient survival during short-term VAD support. All patients who received a short-term VAD were included, whether this was their first VAD or not. Patients who received short-term support as a bridge to long-term support are included. Survival time is calculated as the time on short-term VAD support only, and death on short-term support (including patients who died within 30 days of explant) is the only event considered. Times were censored if the patient had their short-term VAD explanted, received a transplant from support, or were alive on support at last report. This differs from the analysis in Section 6.6 which considers a patient's overall survival from short-term implant and includes time after explant or transplant, as well as time on other subsequent devices.

The cohort analysed is those patients who received a first short-term device between 1 April 2015 and 31 March 2019. **Figure 6.4** shows the unadjusted survival curve on short-term support. **Table 6.5** shows the unadjusted centre-specific survival on support rates at 30 days and 90 days respectively. The national survival on support rates were 61.6% and 41.5% at 30 days and 90 days respectively. There was no significant difference between unadjusted survival on support between centres at 30 and 90 days (log-rank p=0.2 and 0.3 respectively).

Figure 6.4 Patient survival during short-term bridge to transplant support for adult patients implanted 1 April 2015 – 31 March 2019

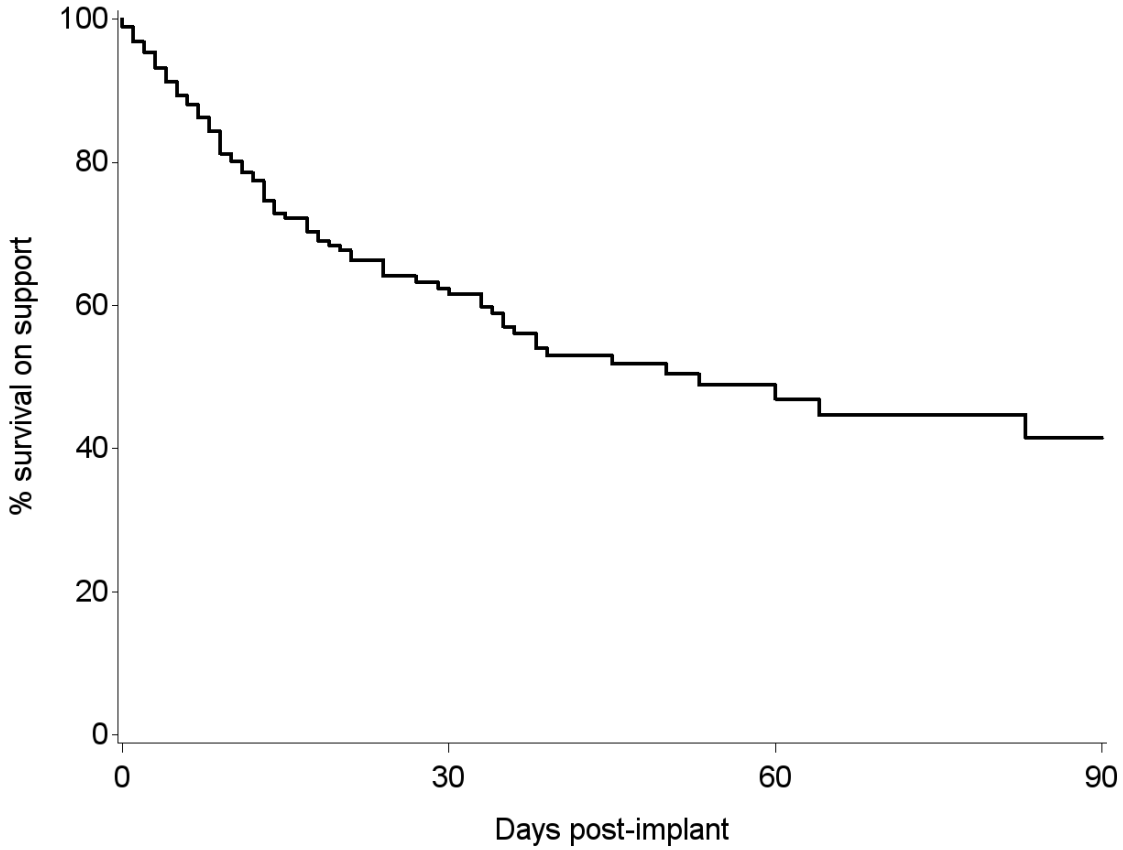


Table 6.5 Unadjusted survival during short-term bridge to transplant support, by centre, 1 April 2015 to 31 March 2019

Hospital	No. of patients	Thirty day			Ninety day		
		Survival rate (95% CI)		Number at risk[1]	Survival rate (95% CI)		Number at risk[1]
Birmingham	62	48.7	(31.2 - 64.1)	11	29.9	(11.2 - 51.4)	2
Glasgow	31	43.8	(20.7 - 65.0)	7	37.6	(16.0 - 59.3)	2
Harefield	69	61.9	(44.7 - 75.1)	13	35.5	(12.2 - 60.0)	3
Manchester	59	71.1	(56.4 - 81.6)	25	40.3	(15.8 - 63.9)	2
Newcastle[2]	32	26.1	(1.1 - 67.0)	1	-	-	0
Papworth	31	77.7	(56.2 - 89.5)	15	65.2	(40.2 - 81.9)	1
Log-rank p-value		**0.19**			**0.29**		
UK	**284**	**61.6**	**(53.9 - 68.3)**	**73**	**41.5**	**(30.6 - 52.0)**	**10**

[1] Number of patients with reported follow-up beyond this time point
[2] 90 day survival rate is not presented for Newcastle as there were no patients on support after day 31

6.6 Patient survival from implant

Overall survival rates from the point of first short-term VAD implant, not censored for transplant or explant, are presented in this section. Survival data from the UK Transplant Registry were incorporated, as was any additional survival time recorded on the VAD Database for patients who were explanted. Patients who received a short-term device as a bridge to long-term support are excluded from this analysis and instead included in Section 4.6 (as are patients who received prior long-term support). Times are censored if the patient was still alive at last known event or follow-up.

Survival rates are calculated using the Kaplan-Meier method and are based on those patients recorded as receiving a first device between 1 April 2015 and 31 March 2019 where information on survival post-implant is known.

In **Tables 6.7**-**6.9** and **Figures 6.5**-**6.7** the centre-specific survival rates for implants are presented for 30 days, 90 days and 1 year respectively. The centre-specific rates are not adjusted for potential differences in risk between patients treated at different centres. These differences can be seen in **Table 6.6** which displays the baseline characteristics of the 211 patients included in this analysis. The survival rates are compared with the national rate and the uncertainty around this rate using funnel plots where outliers appear outside of the funnels; rates above the funnel are significantly high while rates below the funnel are significantly low.

The demographic characteristics of the 211 patients in this analysis are shown below in **Table 6.6** by centre and overall. Nationally, 68% of patients were male, the median age was 48 years and 46% of patients received ventricular assist devices. For some characteristics, due to rounding, percentages may not add up to 100.

Table 6.6 Characteristics of patients in the short-term bridging survival from implant analysis, by centre

		Birmingham N (%)	Glasgow N (%)	Harefield N (%)	Manchester N (%)	Newcastle N (%)	Papworth N (%)	**Total N (%)**
Number of patients		46	31	32	52	22	28	**211**
Age at implant (years)	Median (IQR)	46 (32-55)	49 (40-57)	52 (35-58)	45 (31-53)	48 (34-60)	49 (30-54)	**48 (32-55)**
	Missing	0	0	0	0	0	0	**0**
Recipient sex	Male	27 (59)	24 (77)	23 (72)	35 (67)	13 (59)	22 (79)	**144 (68)**
	Female	19 (41)	7 (23)	9 (28)	17 (33)	9 (41)	6 (21)	**67 (32)**
Primary disease	Dilated cardiomyopathy	29 (63)	10 (32)	20 (63)	30 (58)	12 (55)	14 (50)	**115 (55)**
	Ischaemic heart disease	6 (13)	12 (39)	10 (31)	14 (27)	5 (23)	10 (36)	**57 (27)**
	Congenital heart disease	2 (4)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**2 (1)**
	Hypertrophic cardiomyopathy	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	1 (4)	**2 (1)**
	Valvular heart disease	0 (0)	2 (6)	0 (0)	2 (4)	0 (0)	0 (0)	**4 (2)**
	Infiltrative heart muscle disease	3 (7)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	**4 (2)**
	Other	4 (9)	5 (16)	2 (6)	5 (10)	3 (14)	2 (7)	**21 (10)**
	Unknown	1 (2)	2 (6)	0 (0)	0 (0)	2 (9)	1 (4)	**6 (3)**
INTERMACS patient profile	1. Critical cardiogenic shock	30 (65)	24 (77)	26 (81)	43 (83)	15 (68)	17 (61)	**155 (73)**
	2. Progressive decline	14 (30)	7 (23)	6 (19)	9 (17)	7 (32)	10 (36)	**53 (25)**
	3. Stable but inotrope dependent	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (4)	**1 (0)**
	4. Recurrent advanced heart failure	1 (2)	0 (0)	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	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (0)**
Type of support	Percutaneous VAD	5 (11)	0 (0)	17 (53)	0 (0)	2 (9)	0 (0)	**24 (11)**
	Ventricular assist (Centrimag)	28 (61)	12 (39)	1 (3)	37 (71)	0 (0)	20 (71)	**98 (46)**
	Peripheral ECMO	9 (20)	17 (55)	13 (41)	7 (13)	18 (82)	6 (21)	**70 (33)**
	Central ECMO	4 (9)	2 (6)	1 (3)	8 (15)	2 (9)	2 (7)	**19 (9)**
Pre-implant serum creatinine (umol/l)	Median (IQR)	124 (100-184)	124 (91-164)	148 (85-172)	118 (97-133)	179 (95-263)	109 (94-161)	**124 (95-163)**
	Missing	3	6	1	16	20	5	**51**

Table 6.6	**Characteristics of patients in the short-term bridging survival from implant analysis, by centre**							
		Birmingham N (%)	Glasgow N (%)	Harefield N (%)	Manchester N (%)	Newcastle N (%)	Papworth N (%)	**Total** **N (%)**
Pre-implant serum bilirubin (umol/l)	Median (IQR) Missing	35 (17-50) 3	13 (9-19) 7	26 (14-45) 2	28 (14-47) 21	- 22	21 (10-31) 11	**25 (12-44)** **66**
Pre-implant bilirubin (mmol/l)	Median (IQR) Missing	5 (3-8) 35	5 (2-8) 26	4 (3-6) 20	5 (2-8) 50	- 22	- 28	**4 (3-8)** **181**
Pre-implant cardiac arrest	No Yes	38 (83) 8 (17)	19 (61) 12 (39)	26 (81) 6 (19)	40 (77) 12 (23)	17 (77) 5 (23)	24 (86) 4 (14)	**164 (78)** **47 (22)**
Pre-implant intubation and ventilation	No Yes	33 (72) 13 (28)	21 (68) 10 (32)	17 (53) 15 (47)	29 (56) 23 (44)	7 (32) 15 (68)	25 (89) 3 (11)	**132 (63)** **79 (37)**
Pre-implant renal replacement therapy	No Yes	42 (91) 4 (9)	30 (97) 1 (3)	26 (81) 6 (19)	42 (81) 10 (19)	14 (64) 8 (36)	16 (57) 12 (43)	**170 (81)** **41 (19)**

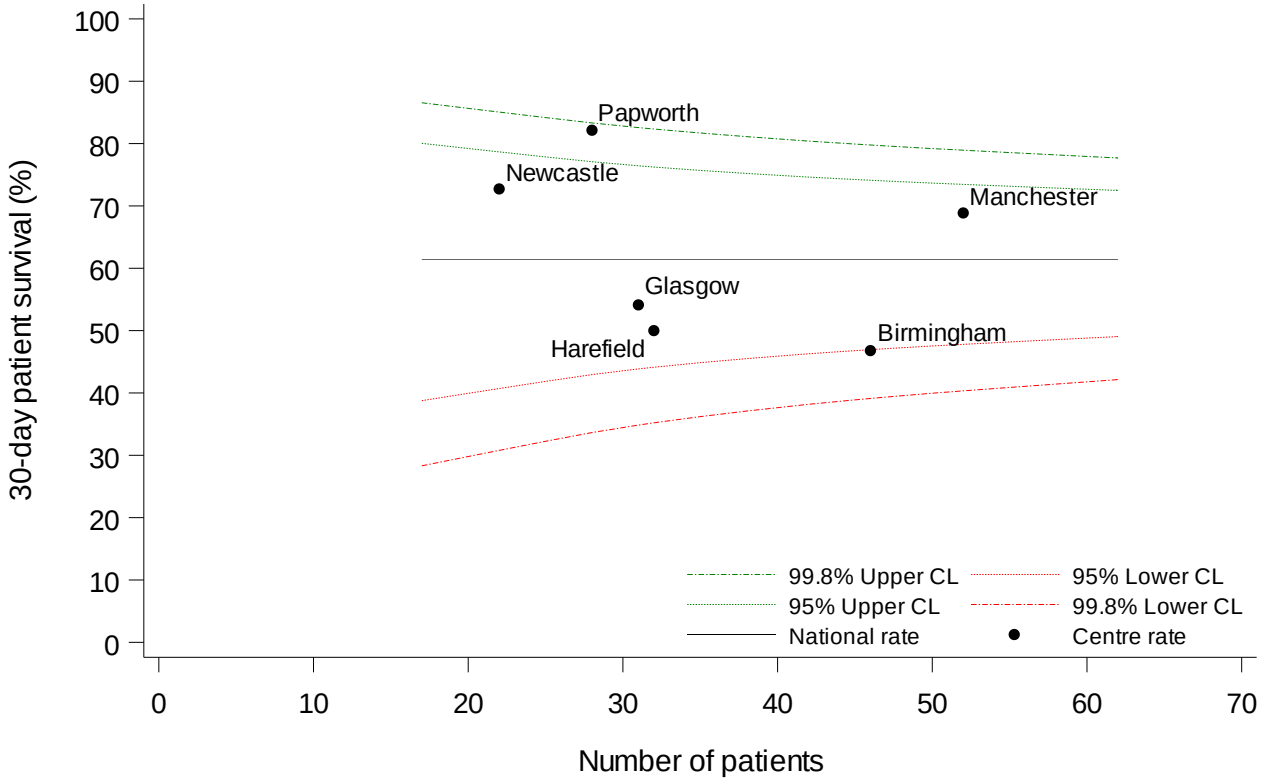
The unadjusted centre-specific 30-day survival rates for patients in the recent era are shown in **Table 6.7** and **Figure 6.5**. There was some evidence that Birmingham have a rate lower than the national rate of 61.4%. The rate for Papworth exceeded the upper 95% confidence limit, indicating some evidence of a significantly higher unadjusted rate.

Table 6.7 30-day patient survival rates after short-term bridging device implant for adult patients implanted 1 April 2015 – 31 March 2019, by centre

Centre	Number of patients	% 30-day survival (95% CI) Unadjusted	
Birmingham	46	46.8	(31.8 - 60.4)
Glasgow	31	54.1	(31.9 - 71.9)
Harefield	32	50.0	(31.9 - 65.7)
Manchester	52	68.9	(54.3 - 79.6)
Newcastle	22	72.7	(49.1 - 86.7)
Papworth	28	82.1	(62.3 - 92.1)
UK	**211**	**61.4**	**(54.3 - 67.8)**

Centre has reached the lower 99.8% confidence limit
Centre has reached the lower 95% confidence limit
Centre has reached the upper 95% confidence limit
Centre has reached the upper 98.8% confidence limit

Figure 6.5 Unadjusted 30-day patient survival rates after short-term bridging device implant for adult patients implanted 1 April 2015 – 31 March 2019, by centre



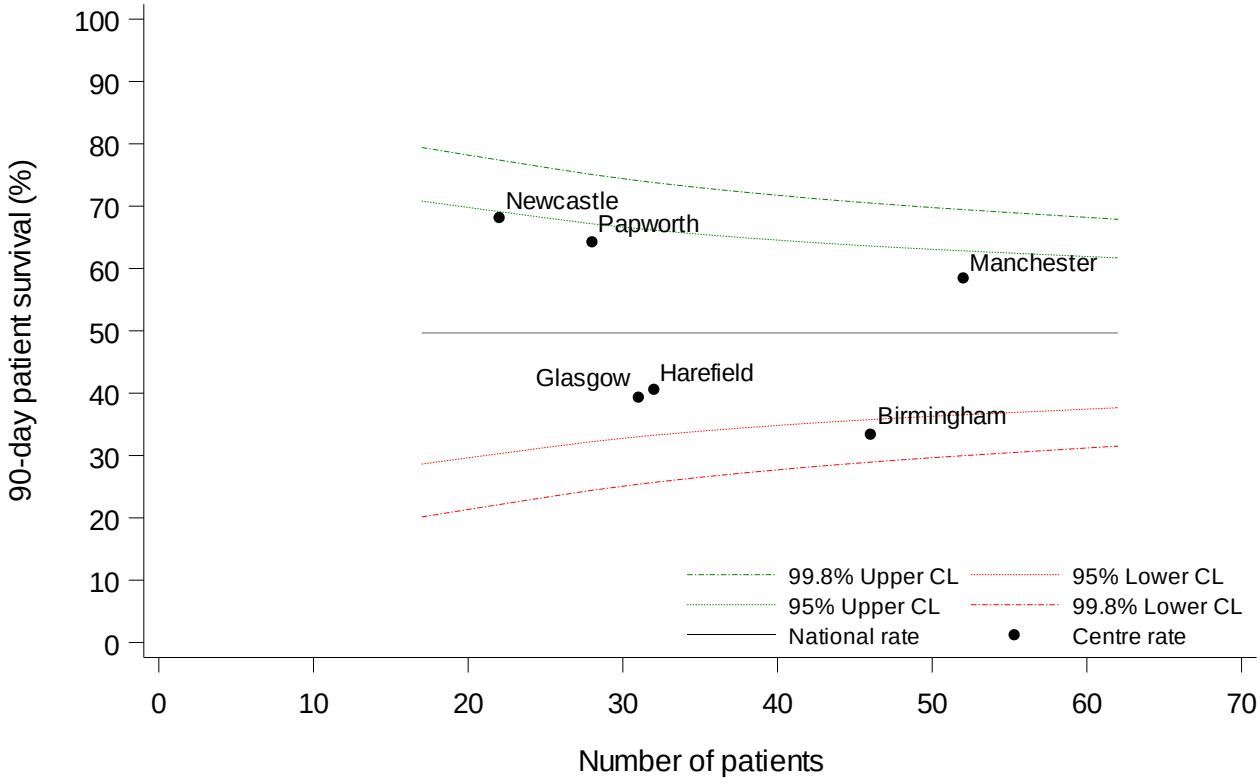
The unadjusted centre-specific 90-day survival rates are shown in **Table 6.8** and **Figure 6.6**. The national rate of survival was 49.7%, and apart from Birmingham for whom there was some evidence of a lower rate, all rates were consistent with the national rate.

Table 6.8 90-day patient survival rates after short-term bridging device implant for adult patients implanted 1 April 2015 – 31 March 2019, by centre

Centre	Number of patients	% 90-day survival (95% CI) Unadjusted	
Birmingham	46	33.4	(20.3 - 47.1)
Glasgow	31	39.4	(19.4 - 58.8)
Harefield	32	40.6	(23.8 - 56.8)
Manchester	52	58.5	(43.7 - 70.7)
Newcastle	22	68.2	(44.6 - 83.4)
Papworth	28	64.3	(43.8 - 78.9)
UK	**211**	**49.7**	**(42.5 - 56.4)**

Centre has reached the lower 99.8% confidence limit
Centre has reached the lower 95% confidence limit
Centre has reached the upper 95% confidence limit
Centre has reached the upper 98.8% confidence limit

Figure 6.6 Unadjusted 90-day patient survival rates after short-term bridging device implant for adult patients implanted 1 April 2015 – 31 March 2019, by centre



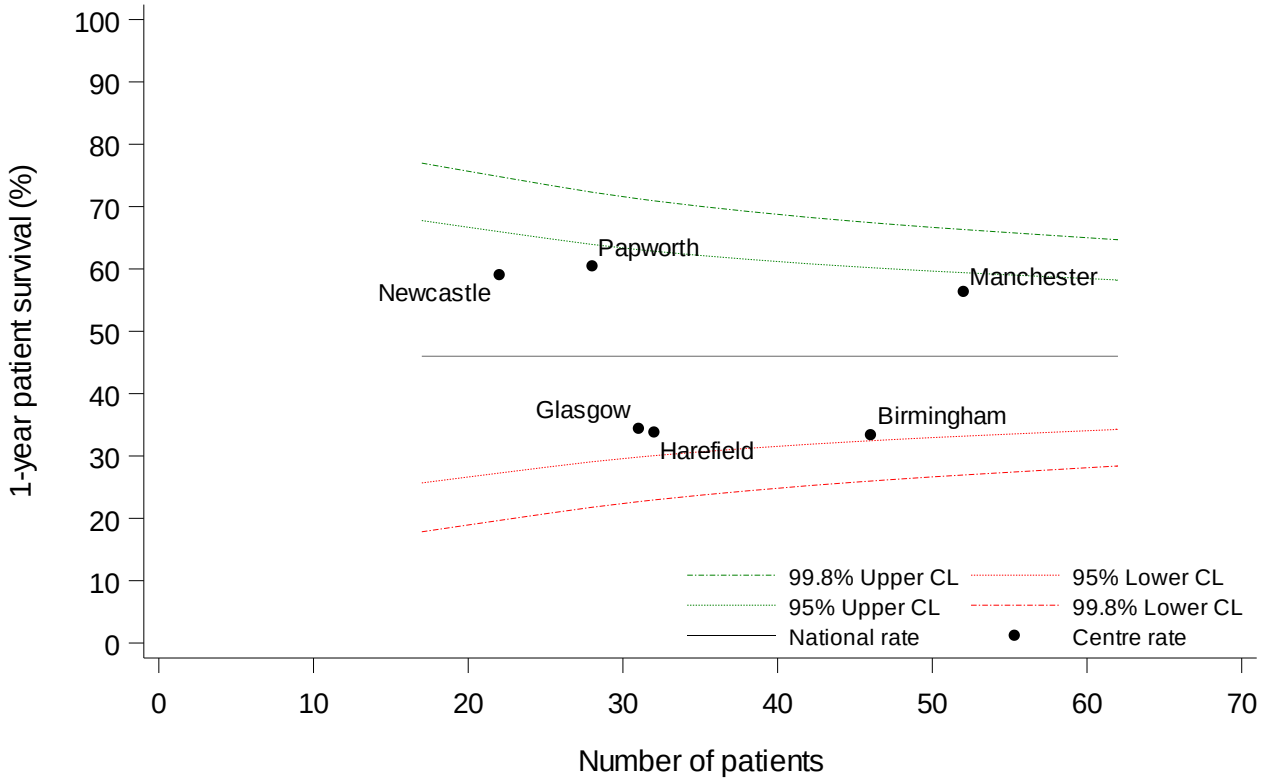
The unadjusted centre-specific 1-year survival rates are shown in **Table 6.9** and **Figure 6.7**. All centres were consistent with the national rate of 46.0%.

Table 6.9 1-year patient survival rates after short-term bridging device implant for adult patients implanted 1 April 2015 – 31 March 2019, by centre

Centre	Number of patients	% 1-year survival (95% CI) Unadjusted	
Birmingham	46	33.4	(20.3 - 47.1)
Glasgow	31	34.4	(15.7 - 54.1)
Harefield	32	33.9	(18.2 - 50.2)
Manchester	52	56.4	(41.6 - 68.8)
Newcastle	22	59.1	(36.1 - 76.2)
Papworth	28	60.5	(40.1 - 75.9)
UK	**211**	**46.0**	**(39.0 - 52.8)**

Centre has reached the lower 99.8% confidence limit
Centre has reached the lower 95% confidence limit
Centre has reached the upper 95% confidence limit
Centre has reached the upper 98.8% confidence limit

Figure 6.7 Unadjusted 1-year patient survival rates after short-term bridging device implant for adult patients implanted 1 April 2015 – 31 March 2019, by centre



ADULT SHORT TERM DEVICES USED POST-HEART TRANSPLANT

Activity

7 Short-term post-transplant devices in adults

This section considers all adult patients who received short-term support for primary graft dysfunction (PGD). All figures and tables in this section present information on a per implant basis as opposed to per patient; if a single patient had more than one short-term device implant for PGD each implant is included. Short-term devices used more than 30 days post-heart transplant (rejection) are excluded (16 recorded in the time period) as are long-term devices used post-transplant (counted as bridging devices). Three Berlin Hearts used by Newcastle for PGD are included.

Figure 7.1 shows the total number of short-term device implants for PGD in the last ten years nationally by device type (ECMO or short-term VAD). During 2019/2020 there were 35 implantations, 14 fewer than 2018/2019 and 1.9 times higher than in 2010/2011. Over the decade, ECMO has been more common than short-term VADs for treatment of PGD. **Figure 7.2** shows the trend per centre and **Figure 7.3** shows last year's activity by centre and device type, indicating that Birmingham, Harefield, and Papworth implanted the most devices for PGD in 2019/2020.

Figure 7.1 Number of adult short-term device implants for PGD in the UK, by financial year and device type, 1 April 2010 to 31 March 2020

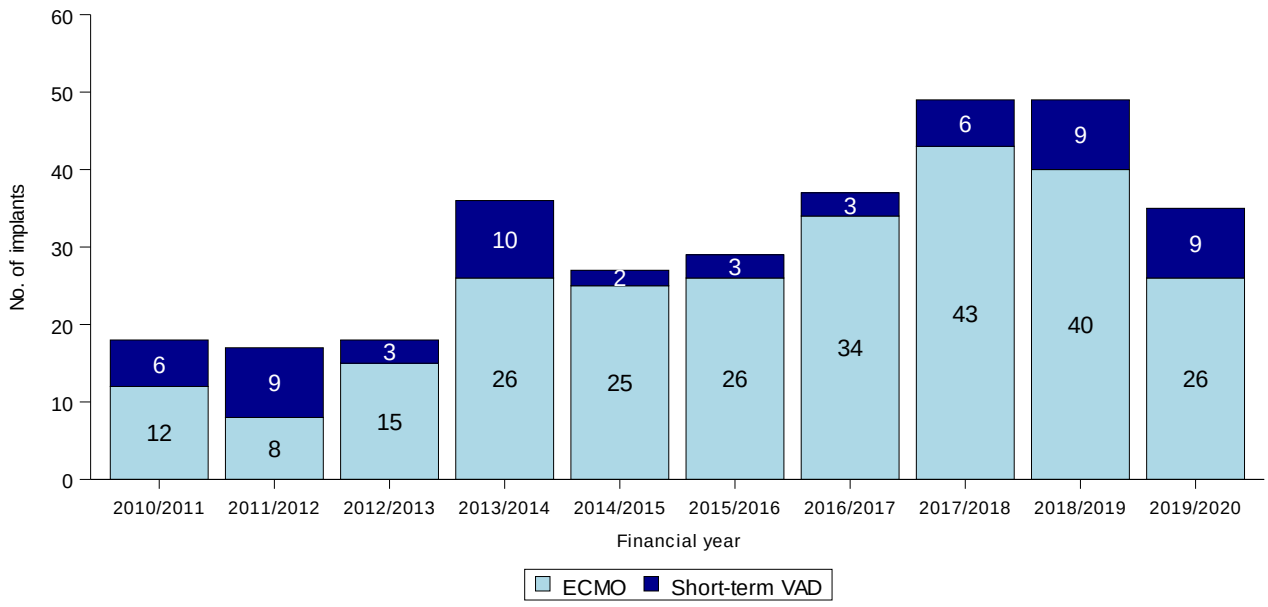


Figure 7.2 Number of adult short-term device implants for PGD in the UK, by financial year, centre and device type, 1 April 2010 to 31 March 2020

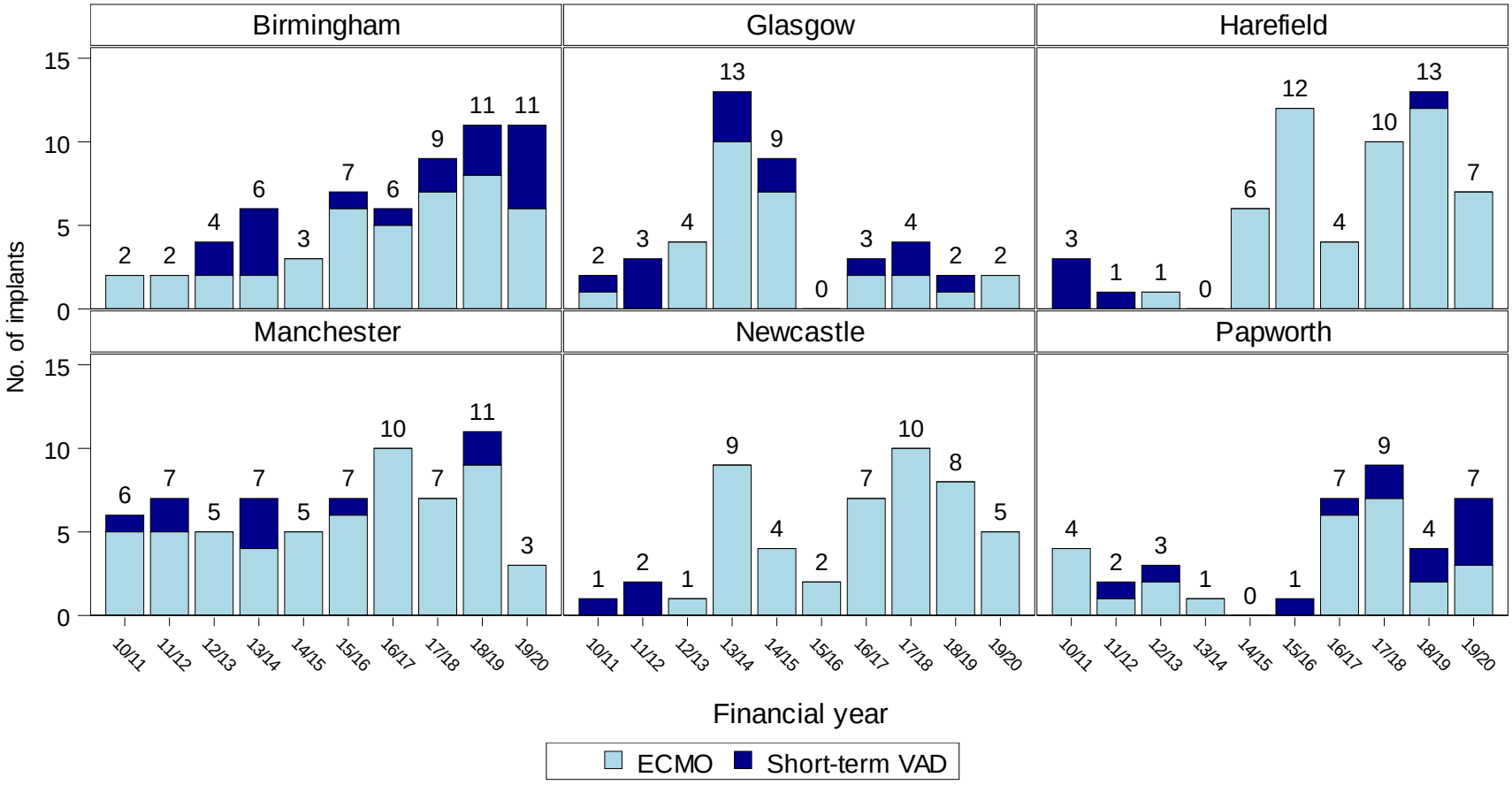
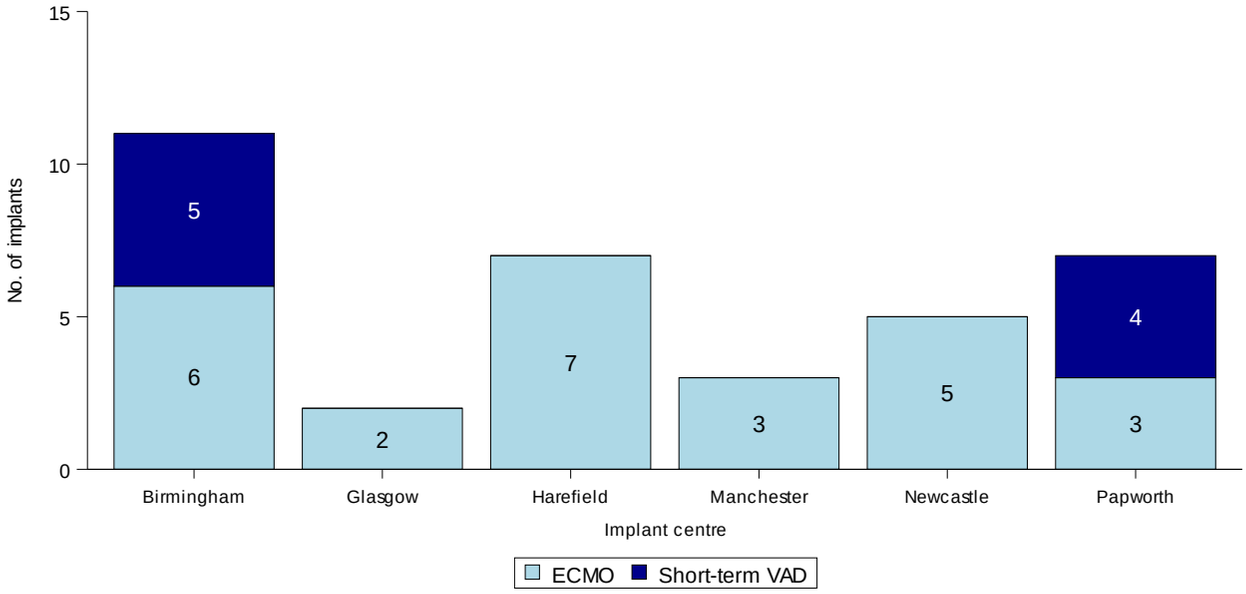


Figure 7.3 Number of adult short-term device implants for PGD in the UK, by centre and device type, 1 April 2019 to 31 March 2020



ADULT SHORT-TERM DEVICES USED POST-HEART TRANSPLANT

Patient Outcomes

8 Outcomes of adult patients receiving short-term devices for PGD

This section analyses patients on a per-patient basis, as opposed to per implant. If a patient was moved from one short-term device to another, this is counted as one observation.

8.1 Demographics characteristics

The transplant characteristics (as reported on the UKTR and VAD database) of the 140 patients analysed in this section are shown in **Table 8.1** by centre and overall. Nationally, 74% of patients were in hospital pre-transplant, the median age was 47 years and 64% of patients received central ECMO. The median ischaemia time was 3.5 hours. For some characteristics, due to rounding, percentages may not add up to 100.

Table 8.1 Characteristics of patients at time of transplant in the short-term PGD outcomes section, by centre

		Birmingham N (%)	Glasgow N (%)	Harefield N (%)	Manchester N (%)	Newcastle N (%)	Papworth N (%)	**Total N (%)**
Number of patients		28	7	34	33	23	15	**140**
Urgency at transplant	Non-urgent	3 (11)	2 (29)	5 (15)	4 (12)	5 (22)	6 (40)	**25 (18)**
	Urgent	22 (79)	3 (43)	25 (74)	22 (67)	15 (65)	5 (33)	**92 (66)**
	Super-urgent	3 (11)	2 (29)	4 (12)	7 (21)	3 (13)	4 (27)	**23 (16)**
Recipient age at transplant (years)	Median (IQR)	45 (35-55)	49 (40-53)	43 (30-55)	46 (37-54)	42 (32-52)	50 (35-56)	**47 (34-54)**
	Missing	0	0	0	0	0	0	**0**
Diabetes at registration	No	25 (89)	4 (57)	33 (97)	30 (91)	22 (96)	9 (60)	**123 (88)**
	Yes	3 (11)	0 (0)	1 (3)	3 (9)	1 (4)	5 (33)	**13 (9)**
	Missing	0 (0)	3 (43)	0 (0)	0 (0)	0 (0)	1 (7)	**4 (3)**
Recipient primary disease at registration	Coronary heart disease	0 (0)	2 (29)	7 (21)	8 (24)	0 (0)	5 (33)	**22 (16)**
	Cardiomyopathy	23 (82)	5 (71)	18 (53)	22 (67)	15 (65)	8 (53)	**91 (65)**
	Congenital heart disease	4 (14)	0 (0)	3 (9)	0 (0)	8 (35)	1 (7)	**16 (11)**
	Graft failure/Rejection	0 (0)	0 (0)	2 (6)	0 (0)	0 (0)	0 (0)	**2 (1)**
	Other	1 (4)	0 (0)	3 (9)	3 (9)	0 (0)	1 (7)	**8 (6)**
	Missing	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	**1 (1)**
Recipient BMI (kg/m^2)	Median (IQR)	26 (24-28)	26 (23-28)	26 (22-29)	25 (23-28)	26 (23-29)	27 (23-30)	**26 (23-28)**
	Missing	0	0	0	1	0	0	**1**

Table 8.1 Characteristics of patients at time of transplant in the short-term PGD outcomes section, by centre

		Birmingham N (%)	Glasgow N (%)	Harefield N (%)	Manchester N (%)	Newcastle N (%)	Papworth N (%)	**Total N (%)**
In hospital pre-transplant	No	6 (21)	2 (29)	6 (18)	4 (12)	10 (43)	7 (47)	**35 (25)**
	Yes	22 (79)	5 (71)	28 (82)	29 (88)	12 (52)	8 (53)	**104 (74)**
	Unknown	0 (0)	0 (0)	0 (0)	0 (0)	1 (4)	0 (0)	**1 (1)**
If in hospital, recipient on inotropes	No	6 (27)	2 (40)	6 (21)	14 (48)	1 (8)	4 (50)	**33 (32)**
	Yes	16 (73)	3 (60)	22 (79)	15 (52)	11 (92)	4 (50)	**71 (68)**
If in hospital, recipient on VAD	None	14 (64)	2 (40)	22 (79)	17 (59)	7 (58)	5 (63)	**67 (64)**
	LVAD	2 (9)	2 (40)	6 (21)	3 (10)	4 (33)	1 (13)	**18 (17)**
	RVAD	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**0 (0)**
	BiVAD	6 (27)	1 (20)	0 (0)	9 (31)	1 (8)	2 (25)	**19 (18)**
If in hospital, recipient on TAH	No	22 (100)	5 (100)	25 (89)	29 (100)	12 (100)	8 (100)	**101 (97)**
	Yes	0 (0)	0 (0)	3 (11)	0 (0)	0 (0)	0 (0)	**3 (3)**
If in hospital, recipient on ECMO	No	20 (91)	4 (80)	25 (89)	29 (100)	12 (100)	6 (75)	**96 (92)**
	Yes	2 (9)	1 (20)	3 (11)	0 (0)	0 (0)	2 (25)	**8 (8)**
If in hospital, recipient on IABP	No	21 (95)	3 (60)	28 (100)	26 (90)	11 (92)	8 (100)	**97 (93)**
	Yes	1 (5)	2 (40)	0 (0)	3 (10)	0 (0)	0 (0)	**6 (6)**
	Unknown	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	**1 (1)**
Recipient serum creatinine (umol/l)	Median (IQR)	118 (83-146)	98 (84-136)	95 (73-111)	90 (72-112)	131 (94-143)	110 (73-125)	**106 (80-131)**
	Missing	0	0	0	0	4	0	**4**
Donor cause of death	CVA	23 (82)	7 (100)	27 (79)	27 (82)	17 (74)	11 (73)	**112 (80)**
	Trauma	0 (0)	0 (0)	4 (12)	4 (12)	2 (9)	2 (13)	**12 (9)**
	Other	5 (18)	0 (0)	3 (9)	2 (6)	4 (17)	2 (13)	**16 (11)**
Donor age (years)	Median (IQR)	41 (32-54)	42 (32-53)	37 (26-47)	31 (24-47)	36 (25-46)	37 (29-48)	**38 (26-48)**
	Missing	0	0	0	0	0	0	**0**
Donor BMI (kg/m^2)	Median (IQR)	26 (23-29)	29 (22-31)	24 (22-28)	24 (23-28)	27 (25-30)	24 (23-29)	**25 (23-29)**
	Missing	0	0	0	0	0	0	**0**
Donor past smoker	No	13 (46)	5 (71)	15 (44)	15 (45)	8 (35)	6 (40)	**62 (44)**
	Yes	15 (54)	2 (29)	17 (50)	17 (52)	13 (57)	9 (60)	**73 (52)**
	Unknown	0 (0)	0 (0)	2 (6)	1 (3)	2 (9)	0 (0)	**5 (4)**

Table 8.1	**Characteristics of patients at time of transplant in the short-term PGD outcomes section, by centre**							
		Birmingham N (%)	Glasgow N (%)	Harefield N (%)	Manchester N (%)	Newcastle N (%)	Papworth N (%)	**Total N (%)**
Donor:Recipient sex mismatch	RF:DF	8 (29)	1 (14)	10 (29)	5 (15)	4 (17)	4 (27)	**32 (23)**
	RF:DM	2 (7)	0 (0)	4 (12)	3 (9)	3 (13)	1 (7)	**13 (9)**
	RM:DM	18 (64)	6 (86)	16 (47)	19 (58)	16 (70)	10 (67)	**85 (61)**
	RM:DF	0 (0)	0 (0)	4 (12)	6 (18)	0 (0)	0 (0)	**10 (7)**
Total ischaemia time (hours)	Median (IQR)	3.3 (2.3-3.5)	2.8 (2.5-3.1)	5.5 (4.7-6.3)	2.9 (2.5-3.3)	3.4 (3.1-4.0)	3.7 (3.0-4.0)	**3.5 (2.8-4.9)**
	Missing	1	0	0	0	2	0	**3**
Type of support	Ventricular assist (Centrimag)	3 (11)	2 (29)	0 (0)	1 (3)	0 (0)	1 (7)	**7 (5)**
	Peripheral ECMO	6 (21)	1 (14)	14 (41)	14 (42)	7 (30)	2 (13)	**44 (31)**
	Central ECMO	19 (68)	4 (57)	20 (59)	18 (55)	16 (70)	12 (80)	**89 (64)**

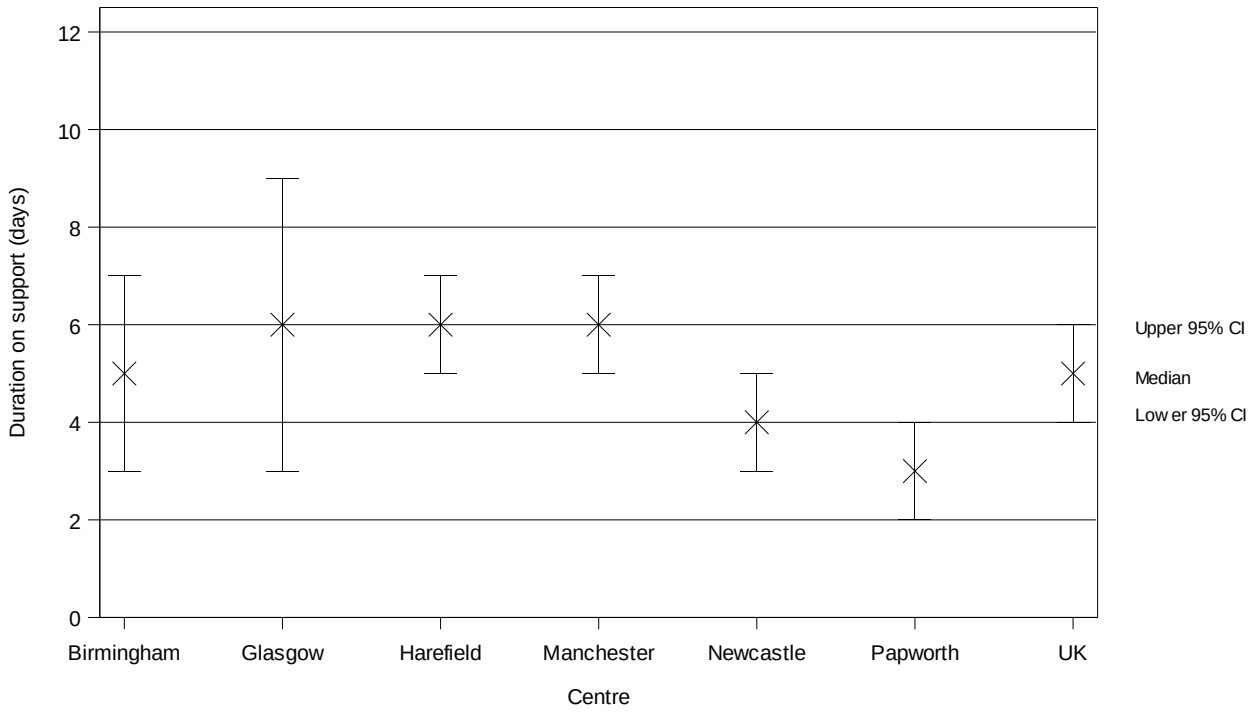
8.2 Duration on support

Table 8.2 shows the median duration on short-term support for patients implanted in a recent four year period, both nationally and by centre. The medians and confidence intervals are estimated using the Kaplan-Meier method. This includes time spent on any short-term device post-transplant so if a patient went from ECMO to short-term VAD, all this time is counted. Nationally, the median time on support was 5 days and was similar across all centres (log-rank p=0.7).

Table 8.2 Median duration on short-term device support for PGD for adult patients implanted between 1 April 2015 and 31 March 2019, by centre

Centre	Number of patients	Time of support (days) Median	(95% confidence interval)
Birmingham	28	5	3 - 7
Glasgow	7	6	3 - 9
Harefield	34	6	5 - 7
Manchester	33	6	5 - 7
Newcastle	23	4	3 - 5
Papworth	15	3	2 - 4
Overall	**140**	**5**	**4 - 6**

Figure 8.1 Median duration on short-term device support for PGD for adult patients implanted between 1 April 2015 and 31 March 2019



8.3 Patient survival from implant

This analysis looks at the rate of survival from the point of first short-term device implant for PGD. This uses data from the UK Transplant Registry (UKTR) on post-transplant survival. Survival rates are calculated using the Kaplan-Meier method where times are censored if the patient was still alive at last known follow-up. The rates are estimated at 30 days, 90 days and 1 year and are based on the 140 patients recorded as receiving a short-term device for PGD between 1 April 2015 and 31 March 2019 where information on survival post-implant is known. Survival rates are given nationally and for individual centres. Note that the centre-specific rates are unadjusted for potential differences in risk between patients treated at different centres.

The unadjusted 30-day, 90-day and 1-year survival rates for patients in the time period are shown in **Tables 8.3**, **8.4** and **8.5**, respectively. The national rates of survival were 72.1%, 62.1% and 55.0%, respectively.

Table 8.3 30-day patient survival rates after short-term device implant for PGD for adult patients implanted 1 April 2015 – 31 March 2019, by centre

Centre	Number of patients	Number of deaths	% 30-day survival (95% CI) Unadjusted	
Birmingham	28	9	67.9	(47.3 - 81.8)
Glasgow[1]	7	2	-	-
Harefield	34	10	64.7	(46.3 - 78.2)
Manchester	33	5	84.8	(67.4 - 93.4)
Newcastle	23	5	78.3	(55.4 - 90.3)
Papworth	15	4	66.7	(37.5 - 84.6)
UK	**140**	**35**	**72.1**	**(63.9 - 78.8)**

[1] Survival rates for groups with fewer than 10 patients are not presented due to small numbers

Table 8.4 90-day patient survival rates after short-term device implant for PGD for adult patients implanted 1 April 2015 – 31 March 2019, by centre

Centre	Number of patients	Number of deaths	% 90-day survival (95% CI) Unadjusted	
Birmingham	28	11	60.7	(40.4 - 76.0)
Glasgow[1]	7	3	-	-
Harefield	34	16	50.0	(32.4 - 65.3)
Manchester	33	8	75.8	(57.3 - 87.1)
Newcastle	23	8	65.2	(42.3 - 80.8)
Papworth	15	6	60.0	(31.8 - 79.7)
UK	**140**	**52**	**62.1**	**(53.6 - 69.6)**

[1] Survival rates for groups with fewer than 10 patients are not presented due to small numbers

Table 8.5 1-year patient survival rates after short-term device implant for PGD for adult patients implanted 1 April 2015 – 31 March 2019, by centre

Centre	Number of patients	Number of deaths	% 1-year survival (95% CI) Unadjusted	
Birmingham	28	12	57.1	(37.1 - 72.9)
Glasgow[1]	7	3	-	-
Harefield	34	20	41.2	(24.8 - 56.9)
Manchester	33	11	66.7	(47.9 - 80.0)
Newcastle	23	10	56.5	(34.3 - 73.8)
Papworth	15	7	53.3	(26.3 - 74.4)
UK	**140**	**63**	**55.0**	**(46.4 - 62.8)**

[1] Survival rates for groups with fewer than 10 patients are not presented due to small numbers

PAEDIATRIC DEVICES USED FOR BRIDGING

Activity

9 Mechanical circulatory support in paediatrics

This section considers all paediatric (age less than 16 years) patients who received mechanical circulatory support as a bridge to heart transplantation between 1 April 2013 and 31 March 2020. All figures and tables in this section present information on a per implant basis as opposed to per patient, so if a single patient had more than one implant in the period, each one is included (see **Tables A1.5** Appendix A1 for details of device histories).

Figure 9.1 shows the total number of bridging device implants each year nationally by device type (VAD and ECMO). During 2019/2020 there were 19 implantations; 10 fewer than 2018/2019. The highest activity was recorded in 2014/2015. Overall, there were 176 implants, with VAD implants making up 96%. **Figure 9.2** shows the trend per centre for the two paediatric centres. Last year's activity is shown by centre and device type in **Figure 9.3**.

Figure 9.1 Number of paediatric bridging device implants in the UK, by financial year and device type, 1 April 2013 to 31 March 2020

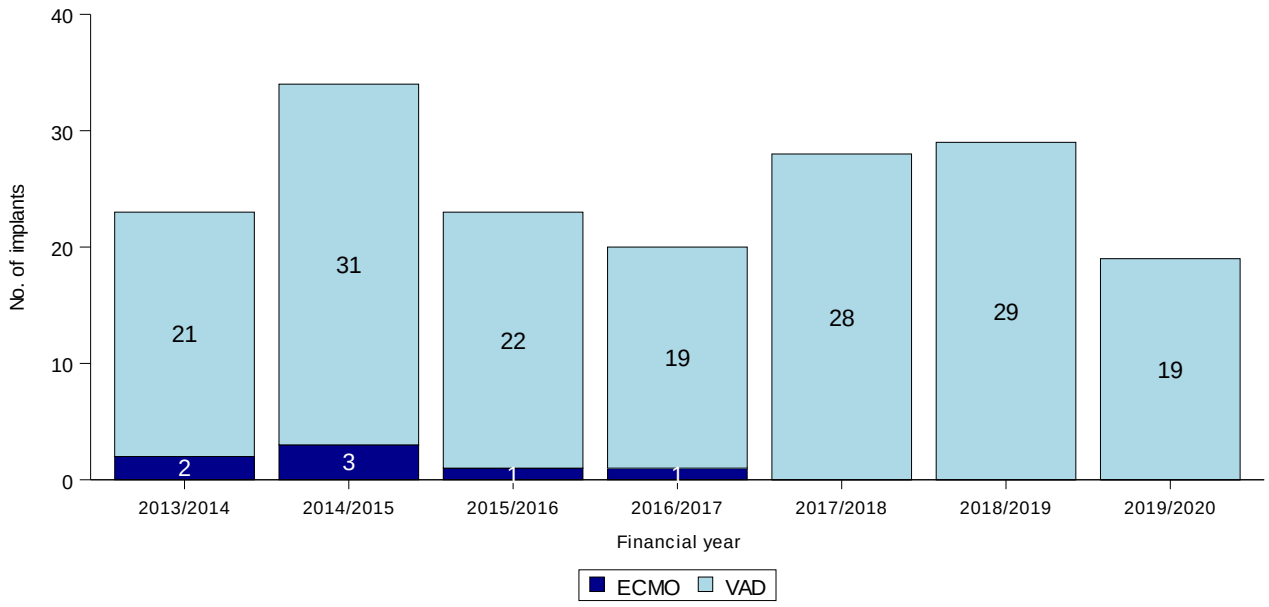


Figure 9.2 Number of paediatric bridging device implants in the UK, by financial year, centre and device type, 1 April 2013 to 31 March 2020

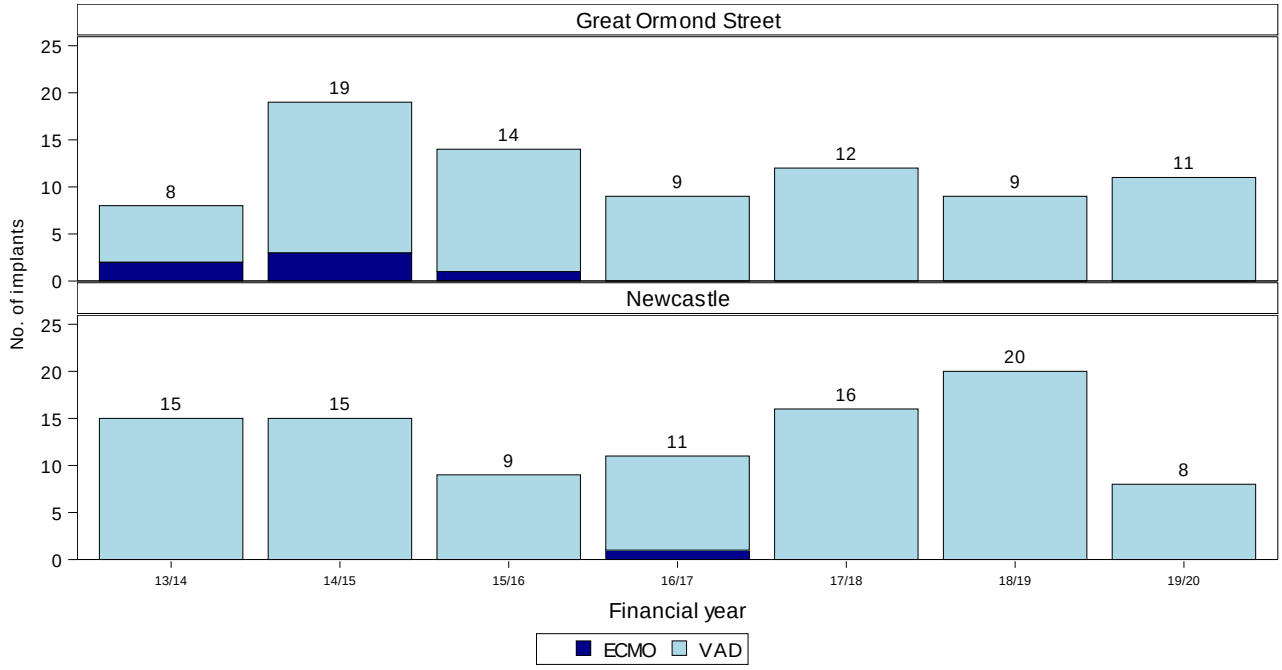


Figure 9.3 Number of paediatric bridging device implants in the UK, by centre and device type, 1 April 2019 to 31 March 2020

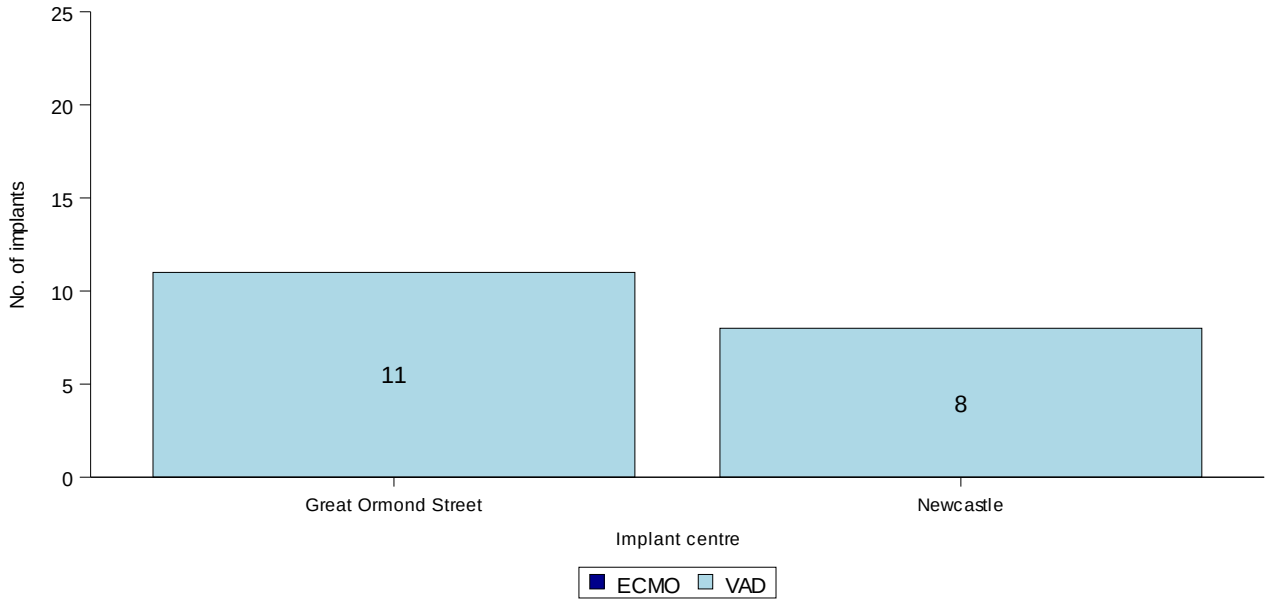
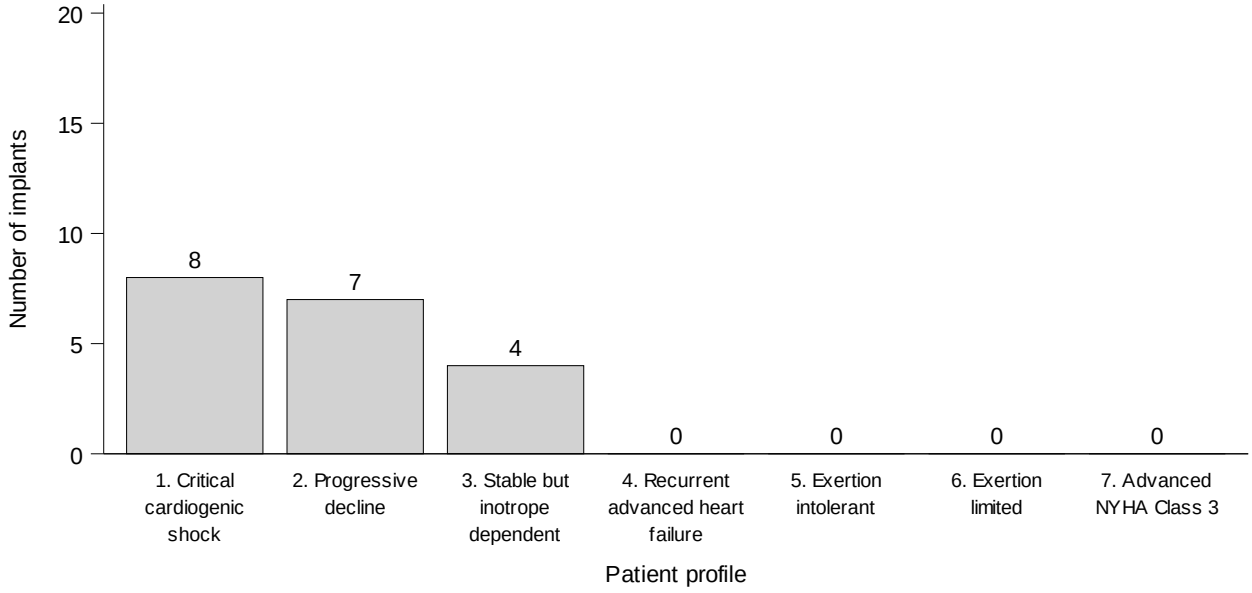


Figure 9.4 shows the INTERMACS patient profile at implant for paediatric patients implanted during 2019/2020. Most patients implanted were either level 1 (critical cardiogenic shock) or level 2 (progressive decline).

Figure 9.4 INTERMACS patient profile for all bridging devices used in paediatric patients in the UK, 1 April 2019 to 31 March 2020



PAEDIATRIC DEVICES USED FOR BRIDGING

Patient Outcomes

10 Outcomes of paediatric patients receiving bridging devices

This section considers all paediatric patients who received any type of support for bridging. Patients are analysed on a per-patient basis, as opposed to per implant. If a patient was moved from one device to a different device, the entire time they were on support is considered (see **Tables A1.5** Appendix A1 for details of device histories).

10.1 Demographic characteristics

The demographic characteristics of the 79 patients in the survival from implant analysis are shown below in **Table 10.1** by centre and overall. Nationally, 58% of patients were female, the median age was 4 years and the most common device was Heartware followed by Berlin Heart Excor. For some characteristics, due to rounding, percentages may not add up to 100.

Table 10.1 Characteristics of patients in the paediatric outcomes section, by centre

		Great Ormond Street N (%)	Newcastle N (%)	**Total** **N (%)**
Number of patients		41	38	**79**
Age at implant (years)	Median (IQR)	4 (3-11)	3 (0-10)	**4 (1-11)**
	Missing	0	0	**0**
Sex	Male	16 (39)	17 (45)	**33 (42)**
	Female	25 (61)	21 (55)	**46 (58)**
Primary disease	Dilated cardiomyopathy	27 (66)	30 (79)	**57 (72)**
	Congenital heart disease	1 (2)	5 (13)	**6 (8)**
	Hypertrophic cardiomyopathy	2 (5)	0 (0)	**2 (3)**
	Restrictive cardiomyopathy	6 (15)	0 (0)	**6 (8)**
	Valvular heart disease	1 (2)	0 (0)	**1 (1)**
	Other	3 (7)	3 (8)	**6 (8)**
	Unknown	1 (2)	0 (0)	**1 (1)**
INTERMACS patient profile	1. Critical cardiogenic shock	6 (15)	25 (66)	**31 (39)**
	2. Progressive decline	24 (59)	12 (32)	**36 (46)**
	3. Stable but inotrope dependent	7 (17)	1 (3)	**8 (10)**
	4. Recurrent advanced heart failure	2 (5)	0 (0)	**2 (3)**
	5. Exertion intolerant	1 (2)	0 (0)	**1 (1)**
	6. Exertion limited	1 (2)	0 (0)	**1 (1)**
	7. Advanced NYHA Class 3	0 (0)	0 (0)	**0 (0)**
Height (cm)	Median (IQR)	102 (86-145)	91 (71-110)	**102 (85-144)**
	Missing	5	36	**41**
Weight (kg)	Median (IQR)	14 (11-31)	12 (6-16)	**14 (10-30)**
	Missing	4	32	**36**
Body surface area (m^2)	Median (IQR)	0.61 (0.48-1.19)	0.56 (0.36-0.76)	**0.61 (0.48-1.17)**
	Missing	5	36	**41**
First VAD device name	Berlin Heart Excor	20 (49)	1 (3)	**21 (27)**
	Heartware	15 (37)	10 (26)	**25 (32)**
	Centrimag	6 (15)	11 (29)	**17 (22)**
	Centrimag with BH cannulae	0 (0)	15 (39)	**15 (19)**
	ECMO only	0 (0)	1 (3)	**1 (1)**

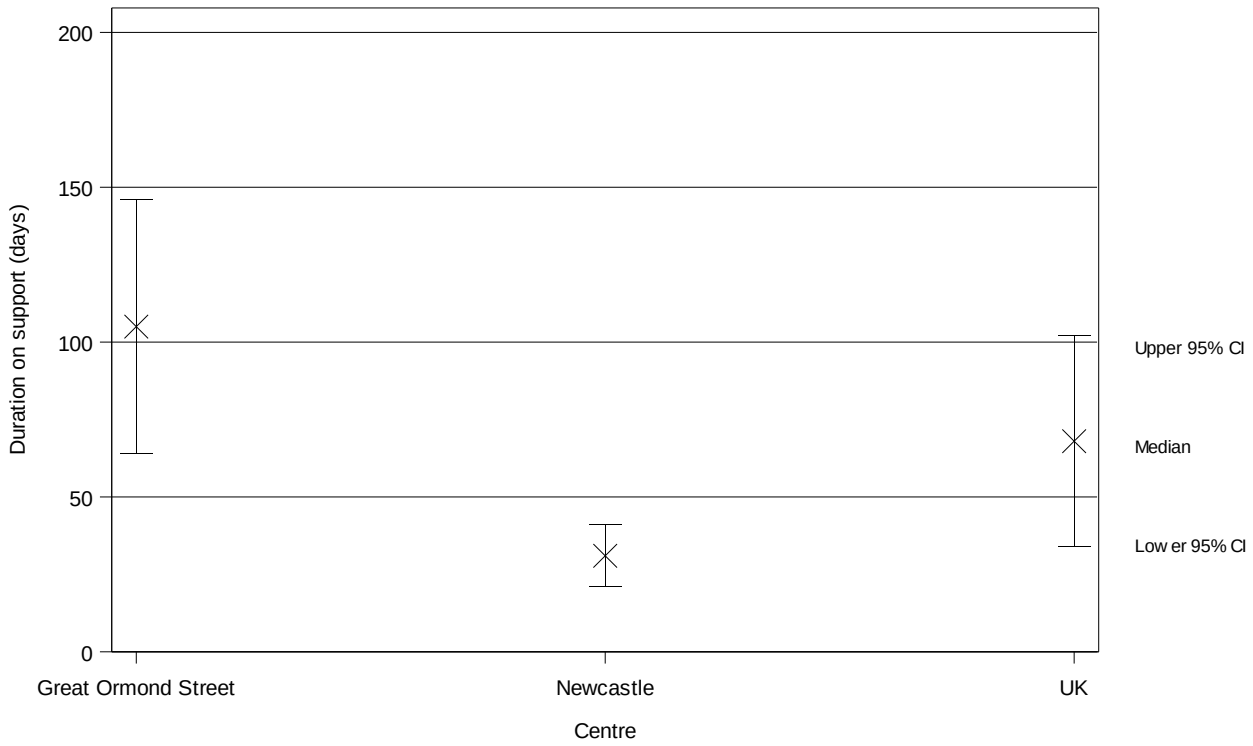
10.2 Duration on support

Table 10.2 shows the median duration on support for patients implanted in a recent four year period, both nationally and by centre. The medians and confidence intervals are estimated using the Kaplan-Meier method since not all patients may have come to the end of support and this method allows these (censored) patients to be included in the analysis. Transplant, explant or death signify end of support. Nationally, the median time on support was 68 days, but it was significantly longer at Great Ormond Street (log-rank p=0.003).

Table 10.2 Median duration on support for paediatric patients implanted with a bridging device between 1 April 2015 and 31 March 2019, by centre

Centre	Number of patients	Time on support (days) Median	(95% confidence interval)
Great Ormond Street	41	105	64 - 146
Newcastle	38	31	21 - 41
Overall	**79**	**68**	**34 - 102**

Figure 10.1 Median duration on support for paediatric patients implanted with a bridging device between 1 April 2015 and 31 March 2019



10.3 Rate of transplant listing

Figure 10.2 and **Table 10.3** show the rate of transplant listing for patients implanted between 1 April 2015 and 31 March 2019 by centre. This includes listing on the urgent or non-urgent heart transplant lists (whichever occurred first). Overall, 63% of patients were on the list at implant, with a further 30% listed after implant and 5% who had died or been explanted within one-year post-implant without being listed.

Figure 10.2 Heart transplant listing status with respect to bridging device implantation for paediatric patients implanted 1 April 2015 – 31 March 2019, by centre and overall

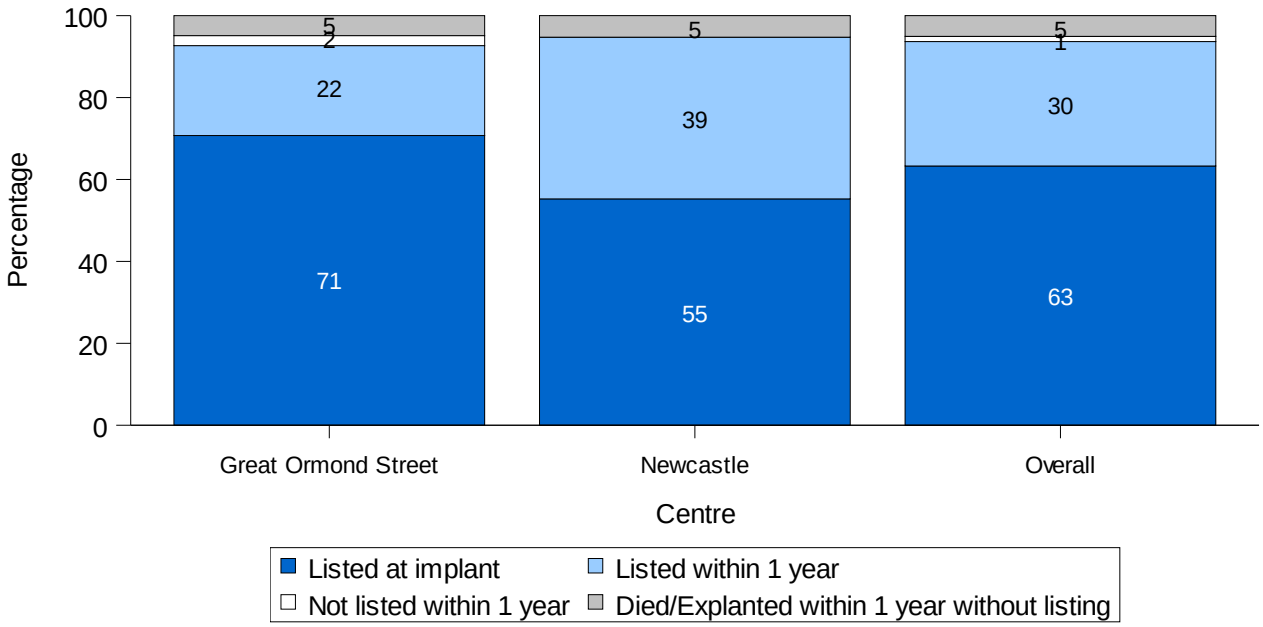


Table 10.3 Heart transplant listing status with respect to bridging device implantation for paediatric patients implanted 1 April 2015 – 31 March 2019, by centre and overall

Centre	Number of patients N	Listed before VAD implant N (%)	Listed within 1 year N (%)	Not listed within 1 year N (%)	Died/explanted within 1 year without listing N (%)
Great Ormond Street	41	29 (71)	9 (22)	1 (2)	2 (5)
Newcastle	38	21 (55)	15 (39)	0 (0)	2 (5)
Overall	**79**	**50 (63)**	**24 (30)**	**1 (1)**	**4 (5)**

10.4 Competing outcomes

Whilst on short-term support, patients are susceptible to different outcomes. Death on support, transplant and explant without transplant (with or without recovery) are all possible outcomes. **Figure 10.3** shows the cumulative incidence of each of these outcomes occurring from time of implantation, for the cohort of paediatric patients receiving a first device between 1 April 2015 and 31 March 2019. This is calculated using the Aalen-Johansen method to account for competing outcomes. At time zero, 100% of patients are on support and as time passes, patients either experience death on support, transplant or explant without transplant. At any time point, the proportion alive on support plus the proportions experiencing each outcome will add up to 100%. Deaths after transplant are not counted and these patients are classed simply as transplanted. Patients who were explanted and died within 30 days of explant are counted as deaths at time of explant. Any subsequent VAD support post-explant is not counted and any such patients are classed simply as explanted. If a patient is moved from one device to another (of any type) without a period free of support, they are counted as still on support.

For this cohort, one month after receipt of a device, 66% of patients remained alive on support, 18% received a heart transplant, 8% died on support and 9% had their device explanted. At three months, the incidence of transplantation rose to 35%, the incidence of death rose slightly, to 13%, and the proportion explanted remained 9%, leaving 43% left on support. By six months, 54% had received a heart transplant, 10% were explanted, 15% had died on support, leaving 21% alive on support.

Figure 10.3 Cumulative incidence functions for transplant, death and explant for paediatric patients receiving a bridging device, 1 April 2015 to 31 March 2019

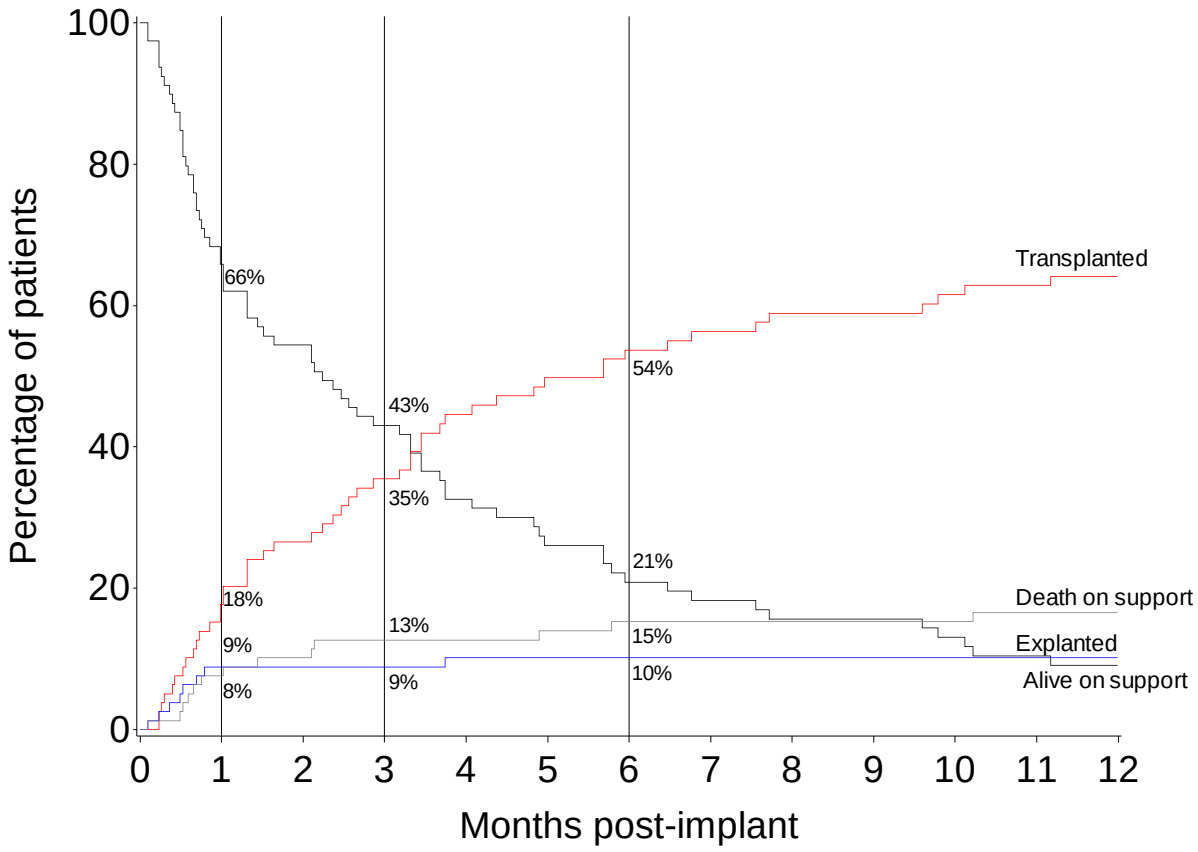


Table 10.4 shows the centre-specific estimates for each competing outcome. A higher proportion of patients had received a transplant by 6 months at Newcastle (61%) compared with Great Ormond Street (47%).

Table 10.4 Cumulative incidence of each outcome, by centre, for paediatric patients implanted with a first bridging device, 1 April 2015 to 31 March 2019

Period	Centre	Number of patients	Transplanted %	Explanted %	Alive on support %	Death on support %
30 day	Great Ormond Street	41	10	2	83	5
	Newcastle	38	26	13	53	8
	Overall	**79**	**18**	**9**	**66**	**8**
90 day	Great Ormond Street	41	27	2	59	12
	Newcastle	38	45	13	32	11
	Overall	**79**	**35**	**9**	**43**	**13**
6 months	Great Ormond Street	41	47	7	31	15
	Newcastle	38	61	13	11	16
	Overall	**79**	**54**	**10**	**21**	**15**

10.5 Patient survival from implant

Overall survival rates from the point of first device implant, not censored for transplant or explant, are presented in this section. Survival data from the UK Transplant Registry were incorporated, as was any additional survival time recorded on the VAD Database for patients who were explanted. Time on additional devices is also counted, so for example if a patient had a period on more than one type of support, all this time is included. Times are censored if the patient was still alive at last known event or follow-up.

Survival rates are calculated using the Kaplan-Meier method. The rates are estimated at 30 days, 90 days and 1 year and are given nationally and for individual centres in **Tables 10.5**, **10.6** and **10.7**. The centre-specific rates are unadjusted for potential differences in risk between patients treated at different centres. The national rate of survival at each time point was 93.6%, 87.2% and 76.2%, respectively.

Table 10.5	30-day patient survival rates after bridging device implant for paediatric patients implanted 1 April 2015 – 31 March 2019, by centre			
Centre	Number of patients	Number of deaths	% 30-day survival (95% CI) Unadjusted	
Great Ormond Street	41	3	92.6	(78.7 - 97.5)
Newcastle	38	2	94.7	(80.6 - 98.7)
UK	**79**	**5**	**93.6**	**(85.4 - 97.3)**

Table 10.6	90-day patient survival rates after bridging device implant for paediatric patients implanted 1 April 2015 – 31 March 2019, by centre			
Centre	Number of patients	Number of deaths	% 90-day survival (95% CI) Unadjusted	
Great Ormond Street	41	5	87.6	(72.6 - 94.6)
Newcastle	38	5	86.8	(71.2 - 94.3)
UK	**79**	**10**	**87.2**	**(77.5 - 92.9)**

Table 10.7	1-year patient survival rates after bridging device implant for paediatric patients implanted 1 April 2015 – 31 March 2019, by centre			
Centre	Number of patients	Number of deaths	% 1-year survival (95% CI) Unadjusted	
Great Ormond Street	41	6	84.8	(69.2 - 92.9)
Newcastle	38	12	67.8	(50.4 - 80.3)
UK	**79**	**18**	**76.2**	**(64.9 - 84.3)**

APPENDIX

A1: Data

The cohort of patients in this report varies by section and type of analysis. **Tables A1.1** and **A1.2** summarise the number of adult and paediatric patients/implants (respectively) in each cohort and the section this applies to.

Table A1.1 Data analysed for adults

Time period	Report Section	Exclusion criteria	No. implants/ patients
Adult – Long-term bridging			
1 April 2010 – 31 March 2020	• Introduction/Activity	None	959 (implants)
1 April 2015 – 31 March 2019	• Duration on support • Rate of transplant listing • Competing outcomes • Survival on support • Patient survival from implant	• TAH and pulsatile devices • Patients with no follow-up information	403 (patients)
1 April 2010 – 31 March 2020	• TAH outcomes	None	26 (patients)
Adult – Short-term bridging			
1 April 2010 – 31 March 2020	• Introduction/Activity	None	704 (implants)
1 April 2015 – 31 March 2019	• Duration on support • Rate of transplant listing • Competing outcomes • Survival on support	• Patients with no follow-up information	284 (patients)
1 April 2015 – 31 March 2019	• Patient survival from implant	• Patients who had a long-term device before or after the short-term device • Patients with no follow-up information	211 (patients)
Adult – Short-term post-transplant			
1 April 2010 – 31 March 2020	• Introduction/Activity	• Implants for rejection • Long-term devices used post-transplant	315 (implants)
1 April 2015 – 31 March 2019	• Duration on support • Patient survival from implant	• Implants for rejection • Long-term devices used post-transplant • Patients with no follow-up information	140 (patients)

Table A1.2 Data analysed for paediatrics

Time period	Report Section	Exclusion criteria	No. implants/ patients
Paediatric – Bridging devices			
1 April 2013 – 31 March 2020	• Introduction/Activity	None	176 (implants)
1 April 2015 – 31 March 2019	• Duration on support • Rate of transplant listing • Competing outcomes • Patient survival from implant	• Patients with no follow-up information	79 (patients)

Limitations and classifications:

- BiVADs are counted as one implant.
- “Bridging” includes devices entered onto the VAD Database under “bridge to decision” as well as “bridge to transplant” along with any long-term devices used post-transplant.
- Patients who received concurrent short-term support with long-term support are classed simply as long-term device recipients.
- Patients who received concurrent ECMO support with a VAD are classed simply as VAD recipients.
- Any paediatric (age<16) activity reported by an adult only centre is presented in the adult sections.
- Berlin Heart implants into adult patients are counted as short-term support.

Table A1.3 details the number of patients meeting the criteria for each of the four patient outcomes sections, along with how many were excluded due to no follow-up post-implant and the number of patients with no follow-up information received in the previous year.

Table A1.3 Follow-up information for patients analysed in the patient outcomes sections of the report

Outcomes section	Centre	Patients meeting section criteria	Patients with no follow-up	Patients analysed	Patients with no follow-up in last year[1] (%)
Adult long-term bridging	Birmingham	93	0	93	0 (0)
	Glasgow	5	0	5	0 (0)
	Harefield	110	0	110	2 (2)
	Manchester	66	0	66	3 (5)
	Newcastle	90	0	90	2 (2)
	Papworth	39	0	39	3 (8)
	Overall	**403**	**0**	**403**	**10 (2)**
Adult short-term bridging	Birmingham	62	0	62	9 (15)
	Glasgow	31	0	31	12 (39)
	Harefield	69	0	69	3 (4)
	Manchester	59	0	59	9 (15)
	Newcastle	32	0	32	10 (31)
	Papworth	32	1	31	7 (23)
	Overall	**285**	**1**	**284**	**50 (18)**
Adult short-term post-transplant	Birmingham	28	0	28	10 (36)
	Glasgow	7	0	7	1 (14)
	Harefield	34	0	34	1 (3)
	Manchester	33	0	33	1 (3)
	Newcastle	23	0	23	2 (9)
	Papworth	15	0	15	1 (7)
	Overall	**140**	**0**	**140**	**16 (11)**
Paediatric bridging	Great Ormond Street	41	0	41	13 (32)
	Newcastle	38	0	38	6 (16)
	Overall	**79**	**0**	**79**	**19 (24)**

[1] Patients analysed who are not reported as died and no information on patient status has been returned via VAD Database or UK Transplant Registry since 1 August 2019

Table A1.4 details the device history of adult patients receiving a device between 1 April 2010 and 31 March 2020 by strategy. **Table A1.5** shows the same information for paediatric recipients. In both these tables, a dash ("-") between devices indicate that the subsequent device was implanted immediately following explantation of the prior device and a slash ("/") indicates the patient had a period of no support between the two devices.

Table A1.4 Device history of adult patients receiving device implants, 1 April 2010 – 31 March 2020, by strategy

Device history	No. bridging patients	No. post-transplant patients
LT	695	
LT-ECMO	10	
LT-ECMO-LT	1	
LT-ECMO-ST	1	
LT-ECMO-ST-ST	1	
LT-LT	41	
LT-LT-ECMO	1	
LT-LT-ECMO-ST	1	
LT-LT-LT	1	
LT-LT-LT-LT	1	
LT-LT-ST	1	
LT-LT-ST-LT	1	
LT-ST	4	
LT-ST-LT	1	
LT-TAH	2	
LT/ECMO	1	
LT/LT-ECMO	1	
LT/LT-LT	1	
LT/LT-LT/ST	1	
LT/ST	1	
TAH	12	
ST	207	30
ST-ECMO	9	1
ST-ECMO-ST	1	
ST-ECMO-ST-LT	1	
ST-LT	35	
ST-LT-LT	2	
ST-LT-LT-ECMO	1	
ST-ST	15	1
ST-ST-ECMO	1	1
ST-ST-LT	2	
ST-TAH	2	
ST/ECMO	2	1
ST/ST-ECMO	1	
ECMO	127	203
ECMO-ECMO	3	
ECMO-ECMO-ST		1
ECMO-LT	46	
ECMO-LT-ECMO	1	
ECMO-LT-LT	1	
ECMO-LT-LT-ST	1	
ECMO-ST	51	23
ECMO-ST-ECMO		1
ECMO-ST-LT	14	
ECMO-ST-ST	2	1
ECMO-ST-ST-ST	1	
ECMO-ST-ST-ST-ST	1	
ECMO-ST-TAH	1	
ECMO-ST/ECMO		1
ECMO-ST/LT	1	
ECMO-ST/TAH	1	
ECMO-TAH	8	
ECMO/ECMO	3	10
ECMO/ECMO-ST	1	
ECMO/ECMO/ECMO/ECMO		1
ECMO/LT	4	
ECMO/ST	1	2
Total	**1326**	**277**

Note: a dash ("-") between devices indicate that the subsequent device was implanted immediately following explantation of the prior device and a slash ("/") indicates the patient had a period of no support between the two devices

Table A1.5 Device history of paediatric patients receiving bridging device implants, 1 April 2013 – 31 March 2020

Device history	No. of patients
BH	47
BH/BH	1
BH/ECMO-BH	1
HVAD	40
HVAD-CM-CM	1
HVAD-HVAD	1
CM	38
CM-BH	7
CM-BH-CM	1
CM-BH-CM-BH	1
CM-BH/CM	1
CM-CM	1
CM/CM	2
ECMO	1
ECMO-BH	3
ECMO-CM	1
ECMO-HVAD	1
Total	**148**

BH = Berlin Heart; HVAD = Heartware HVAD, CM = Centrimag, ECMO = Extracorporeal Membrane Oxygenation
Note: a dash ("-") between devices indicate that the subsequent device was implanted immediately following explantation of the prior device and a slash ("/") indicates the patient had a period of no support between the two devices

A2: Methods

Analysis of geographical variation in MCS rates

Patients were assigned to NHS regions in England or country for Wales, Scotland and Northern Ireland using their postcode of residence, as reported at implant. Patients were only counted once regardless of how many devices they received in the period. The number of patients receiving a device per million population (pmp) of NHS region/country was obtained using mid-2018 population estimates based on the Office for National Statistics (ONS) 2011 Census figures (denominator). No NHS region age- or sex-specific standardisation of rates was performed when calculating the systematic component of variation. The MCS rates pmp were categorised into four groups – low, low-medium, medium-high and high – based on the quartiles of their distribution and visualised in a map using contrasting colours.

Systematic component of variation

For a given individual who is a resident in a given English NHS region, provision of a bridging device is modelled as a Bernoulli trial. At the whole area level, this becomes a Binomial process which can be approximated by a Poisson distribution when rare events are modelled.

To allow for the possibility that, even after allowing for area-specific Poisson rates, area differences remain, introduce an additional multiplicative rate factor which varies from area to area. Postulate a non-parametric distribution for the multiplicative factor, with variance σ^2. If the factor is one for all areas, then area differences are fully explained by the area-specific Poisson rate. If the factor varies with a nonzero variance, σ^2, then we conclude that there are unexplained area differences.

The systematic component of variation (SCV; McPherson et al., N Engl J Med 1982, 307: 1310-4) is the moment estimator of σ^2. Under the null hypothesis of homogeneity across areas, the SCV would be zero. The SCV, therefore, allows us to detect variability across areas beyond that expected by chance; the larger the SCV, the greater the evidence of systematic variation across areas.

A one-sided p-value for the hypothesis that the SCV is greater than zero versus the null hypothesis that the SCV is equal to zero was derived using a parametric bootstrap where data were simulated from the Poisson distribution that would be consistent with the null hypothesis (multiplicative rate factor is equal to one in all areas and σ^2 equal to zero). The observed SCV was then compared against this simulated data to calculate the probability that an SCV of at least this size would be observed due to chance if the null hypothesis were true.

10,000 bootstrap samples of size 7 (number of areas) were simulated, where the bridging implant count in each area was drawn from a Poisson distribution with its expected value being the area-specific expected count (the rate of bridging implants in the total population multiplied by the population of the area) . The SCV was then calculated in each of the 10,000 samples and a bootstrap p-value for the SCV in the observed data was estimated as:

$$P_{boot} = \frac{1 + \#\{SCV_{sim} \geq SCV_{obs}\}}{10000 + 1}$$

where $\#\{SCV_{sim} \geq SCV_{obs}\}$ is the number of SCV values in the simulated datasets which are greater than or equal to the SCV in the observed data. This follows the simulation method given in Ibanez et al., BMC Health Services Research, 2009, 9:60. No adjustment was made for area-specific demographic characteristics that may impact the rates of bridging implantation such as age and sex.

Unadjusted survival rates

The Kaplan-Meier method is used to estimate unadjusted patient survival rates. Patients can be included in this method of analysis irrespective of the length of follow-up recorded. If a patient is alive at the end of the follow-up then information about the survival of the patient is censored, which means they have not yet experienced the outcome of death.

Funnel plots

The funnel plot is a graphical method to show how consistent the survival rates of the different centres are with the national rate. The graph shows for each centre a survival rate plotted against the number of procedures undertaken, with the national rate and confidence limits around this national rate superimposed. In this report, 95% and 99.8% confidence limits were used. Centres that lie within the confidence limits have survival rates that are statistically consistent with the national rate. When a centre is close to or outside the limits, this is an indication that the centre may have a rate that is different from the national rate.

A3: Glossary of terms

Aalen-Johansen method
A method for calculating the cause-specific cumulative incidence which allows for patients experiencing one of a set of outcomes where each outcome may preclude or change the probability of a patient experiencing any of the others ("competing risks"). It allows for patients with incomplete follow-up to be included as per the Kaplan-Meier method.

Competing outcomes
A situation when patients or subjects can experience one or more events or outcomes which 'compete' with the outcome of interest. For instance, when the event of interest is death on VAD support, receiving a transplant or having ones' device explanted and recovering are competing outcomes. Generally, the competing outcomes hinder the observation of the event of interest or modify the chance that this event occurs.

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 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.

Continuous-flow device
An electrically driven rotary pump that pumps blood continuously throughout the cardiac cycle.

Cumulative incidence
The probability of an event (death, transplant or explant in this context) occurring before a particular point in time.

ECMO
Extra Corporeal Membrane Oxygenation. The term ECMO is this report is used to describe veno-arterial (VA) ECMO, rather than veno-venous (VV) ECMO.

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 and other time related statistics such as median duration on support. 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 (LT) devices
Long-term devices are implantable and intended to support the patient for years. Patients can be discharged from hospital with a LT device. Most LT devices are continuous-flow devices but some are pulsatile.

MCS
Mechanical Circulatory Support.

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 estimated percentage of patients who are still alive. This is usually specified for a given time period after implant. For example, a 1 year patient survival rate is the estimated percentage of patients who are still alive 1 year after their first device implant.

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

Pulsatile device
A device that mimics the natural pulsing action of the heart.

***p* value**
In the context of comparing listing rates across centres, as an example, 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 after heart transplantation.

Short-term (ST) devices
Short-term devices are intended to support the heart 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 from implant, survival on support is censored at time of device explantation or transplantation. This is usually specified for a given time period after implantation. For example, a three-year survival on support rate is the estimate of patients who are still alive on support three years after their first short-term or long-term VAD implantation.

TAH
Total Artificial Heart.

UK Transplant Registry
A national database held by NHS Blood and Transplant collecting data on all organ transplant procedures. Information is accrued prospectively at recipient registration on the national transplant list, at organ donation, at time of transplantation and at regular intervals thereafter.

Unadjusted survival rate
Unadjusted patient survival rates do not take account of potential confounders and are based only on the number of patients at a given centre and the number and timing of those that die within the post-implant 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 happen to have patients that have increased risks of death. All results presented in this report are unadjusted as the risk factors affecting survival post-MCS in the UK have not yet been examined.

VAD
Ventricular Assist Device. A mechanical pump used to increase the amount of blood that flows through the body, relieving the symptoms of advanced heart failure.

VAD Database
Database used for an ongoing extensive audit to capture in-depth data prior to and at implant of device, explant, transplant and death along with follow-up at various time points post-implant and post-explant. The database captures data on long-term and short-term mechanical circulatory support, including VADs, TAH and ECMO, for the purpose of bridge to transplant, bridge to decision (in this report both analysed together as “bridging”), primary graft dysfunction and “other” (allowing capture of devices for rejection). Devices used post-cardiotomy are not funded via the NHS England bridge to transplant or recovery programme and so are excluded from the VAD Database. Destination Therapy is not explicitly captured on the database but these cases may be captured within “bridge to transplant” or “bridge to decision” where the patient never received a transplant.

Prepared by:

Statistics and Clinical Studies, NHS Blood and Transplant

Rachel Hogg

Cardiothoracic Advisory Group (CTAG) Clinical Audit Group