NHS
Blood and Transplant

ANNUAL REPORT ON MECHANICAL CIRCULATORY SUPPORT RELATED TO HEART TRANSPLANTATION

REPORT FOR 2020/2021
(1 APRIL 2011 – 31 MARCH 2021)

PUBLISHED FEBRUARY 2022

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, from 1 April 2011 to 31 March 2021, however paediatric data are only available since 1 April 2013. Data were extracted from the UK VAD Database held by NHS Blood and Transplant on 8 February 2022. 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 2020/2021 there were 55 long-term device implants, all long-term VADs. The number of implants was lower than every other year during the decade.
- The most common INTERMACS profile for this patient group was 3 (stable but inotrope dependent) representing 45% of all patients.
- The median duration on long-term VAD support was 1051 days (3 years).
- At 1-year post-implant, 74% of patients remained on support, 5% had received a heart transplant, 3% were explanted without transplant and 18% 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 79.7%. The 3-year survival rate was 63.2%, which has improved over the last 3 years (60.1% in 2019/2020; 58.4% in 2018/2019).

Short-term bridging devices in adults:

- During 2020/2021 there were 108 short-term device implants into 84 patients, comprising 71 VADs and 37 ECMO implants; a 7% decrease from the previous year.
- The majority (59%) of implantations last year were into INTERMACS profile 1 patients (critical cardiogenic shock).
- The median duration on short-term support was 12 days.
- At 30 days post-implant, 24% of patients remained on short term support, 15% had been transplanted, 16% transferred to a long-term device, 19% were explanted without transplant and 27% 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 46.8% (not censored for transplant/explant).

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

- During 2020/2021 there were 43 short-term device implants for PGD into 32 patients, comprising 33 ECMO implants and 10 short-term VADs. This was a 19% increase from the previous year.
- The 1-year patient survival rate for patients requiring MCS for PGD was 56.1%.
- On average, patients spent 5 days on support

Devices used in paediatric patients:

- **Note that ECMO has been underreported for paediatric patients during this period, so the data in this section of the report is incomplete.**
- During 2020/2021, 12 bridging device implants and 2 post-transplant implants were reported; 12 of which were VADs and 2 were ECMO.
- For 78 patients reported as having bridging support between 1 April 2016 and 31 March 2020, the median duration of support was 68 days, 36% of patients received a transplant within 90 days of implant and the 1-year patient survival rate from the point of implant was 77.5%.

Use of the contents of this report should be acknowledged as follows:
Annual Report on Mechanical Circulatory Support Related to Heart Transplantation 2020/2021, 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 2011 to 31 March 2021, however paediatric data are only presented for the period 1 April 2013 to 31 March 2021 since before 2013 there was no national data capture for paediatric MCS therapy. Data were extracted for this report on 8 February 2022 by which date it was expected that most devices used during the audit period had been reported to the database, however there was a known issue with underreporting of ECMO for paediatric patients.

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 2016 – 31 March 2020 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 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 55 in 2020/2021. Short-term device usage has generally increased over the decade, with 108 devices in 2020/2021. **Figure 2.2** shows a breakdown of paediatric bridging implants in the last eight years. The number of VAD implants was comparatively low in 2020/2021, with just 11. ECMO usage in paediatric patients has remained rare in the period.

In total there were 1,929 bridging implants reported across the decade in 1,531 patients; 1,200 (78%) patients had a single device implant, 274 (18%) had two implants, 48 (3%) had three, 8 (1%) 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 2011 to 31 March 2021

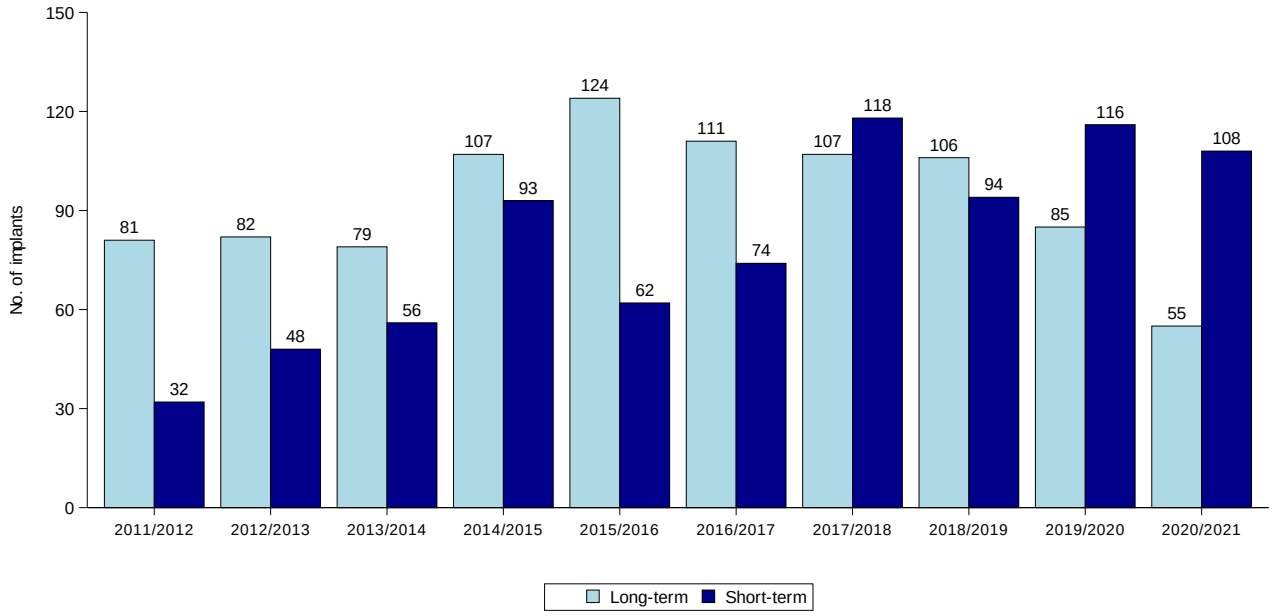
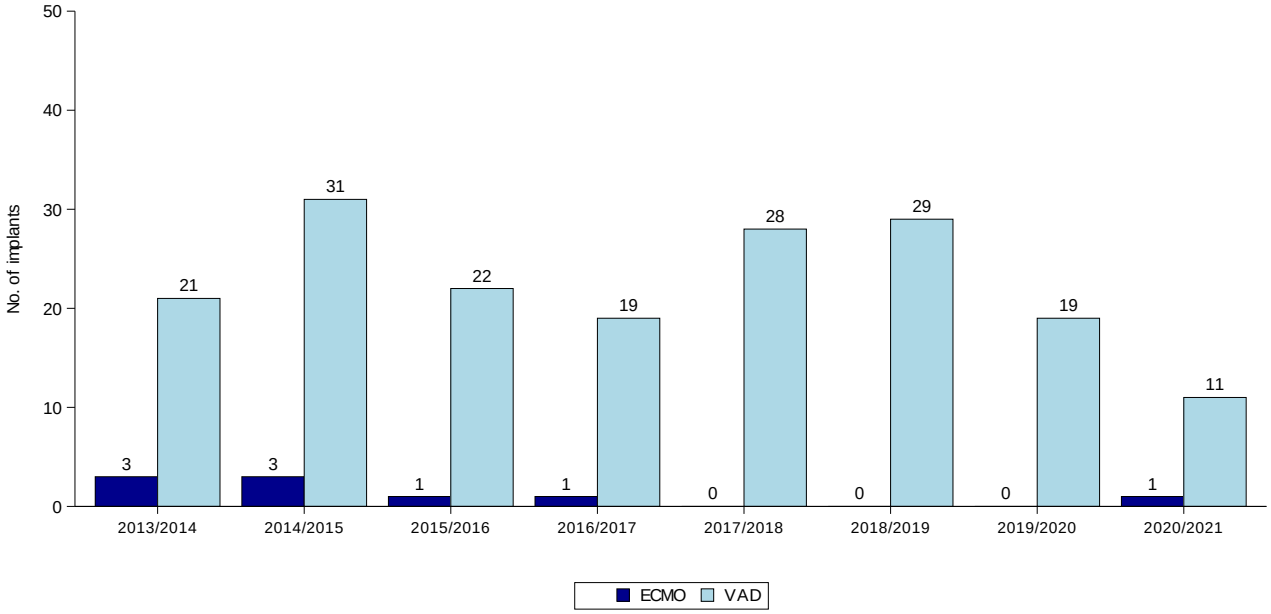


Figure 2.2 Total number of paediatric bridging device implants in the UK, by device type and financial year, 1 April 2013 to 31 March 2021



Note: ECMO reporting for paediatric patients is incomplete for this period

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 49 in 2018/2019 but dropping slightly to 43 in the latest year. Devices used for rejection remain relatively rare, with one performed in 2020/2021. In total there were 373 post-transplant implants across the decade in 308 patients; 252 (82%) patients had a single device implant, 48 (16%) had two implants, 7 (2%) had three and 1 (0.3%) 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 2011 to 31 March 2021

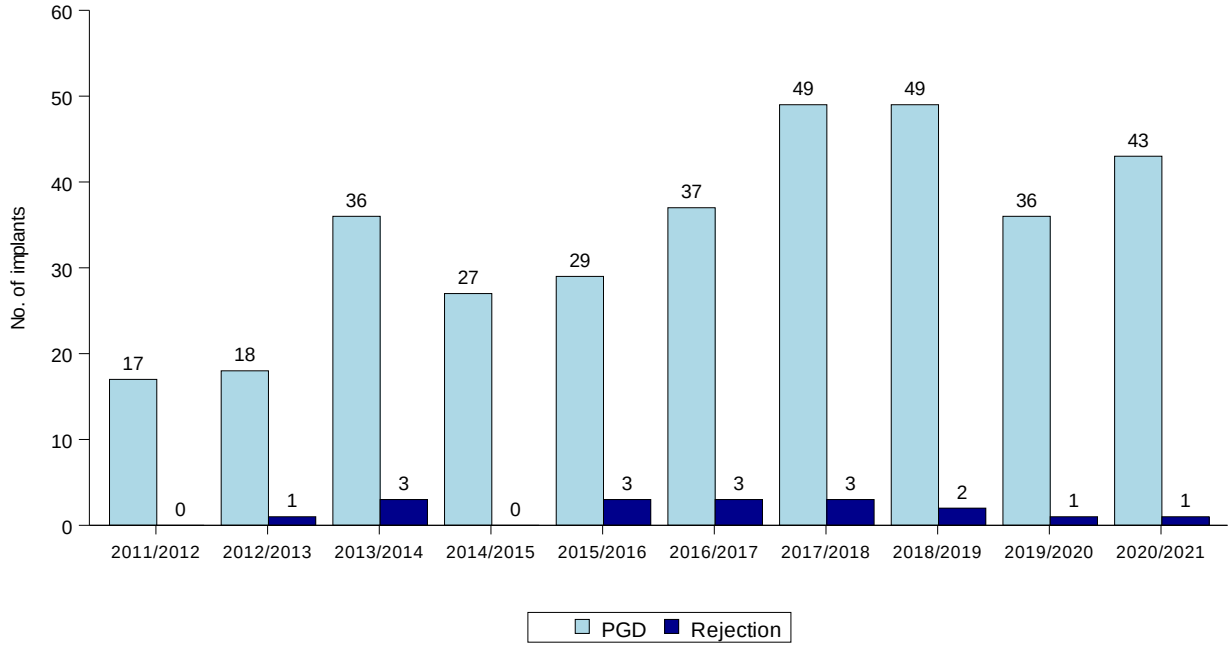


Figure 2.4 shows the number of adult patients reported as alive on bridging support as at 31 March 2021 by centre and device type. In total, there were 303 patients alive on a long-term device and 8 alive on short-term support, with Harefield and Birmingham having the highest number of patients on support. **Figure 2.5** shows the same information but for paediatric patients. There were 9 paediatric patients alive on support on 31 March 2021, all on VAD support.

Figure 2.4 Number of adult patients alive on bridging support on 31 March 2021, by device type and centre

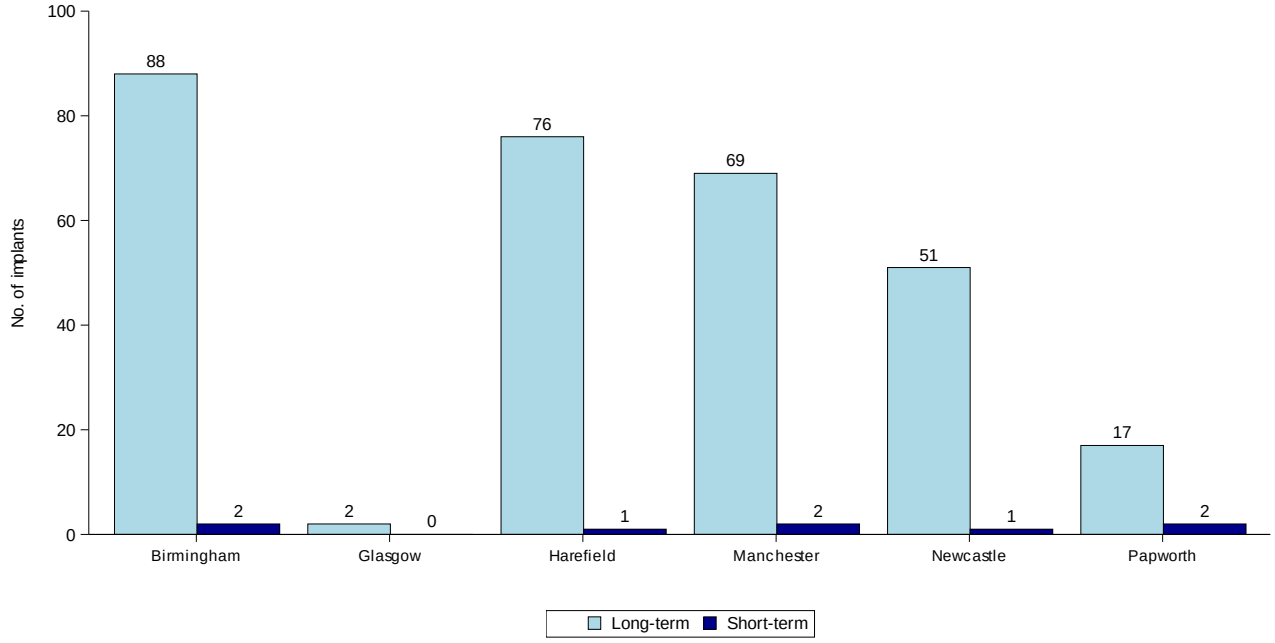
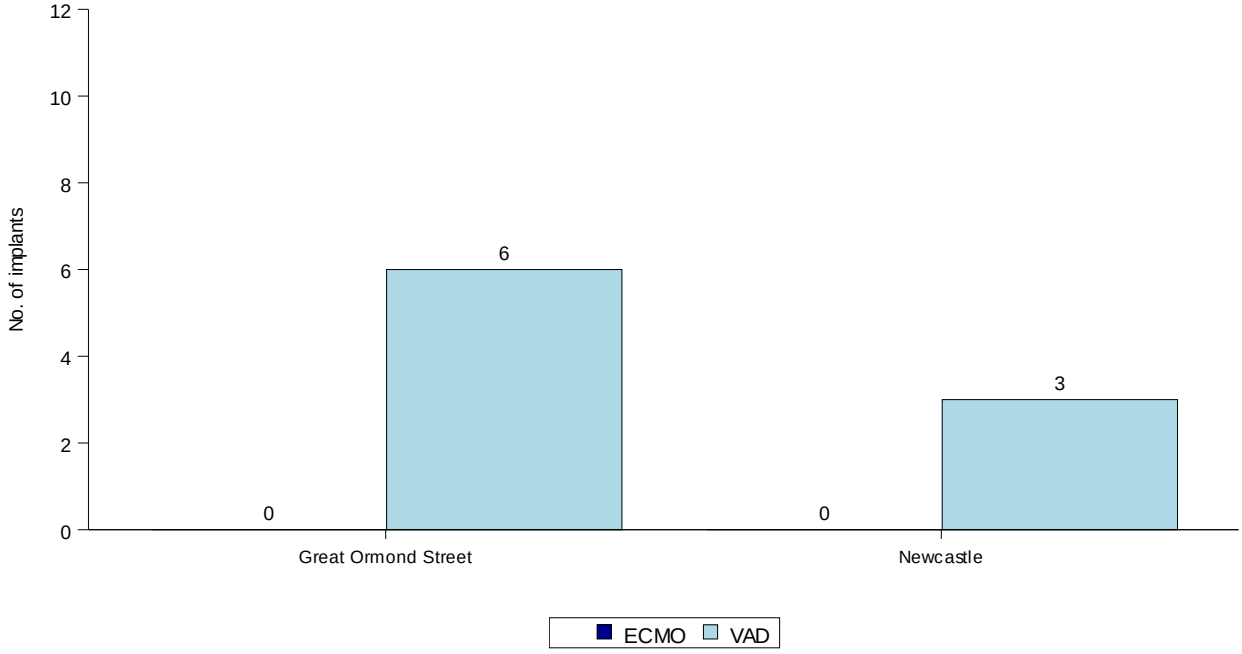


Figure 2.5 Number of paediatric patients alive on bridging support on 31 March 2021, by device type and centre



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 2011 to 31 March 2021 and separately for the most recent year, 1 April 2020 to 31 March 2021. **Table 2.1** reflects the adult data while **Table 2.2** reflects the paediatric data.

Table 2.1 Number of adult patients receiving devices and number of implants, by strategy and centre, 1 April 2011 to 31 March 2021

Strategy	Centre	1 April 2011 - 31 March 2021						1 April 2020 - 31 March 2021					
		No. of implants	Type of device				No. patients	No. of implants	Type of device				No. patients
			LT VAD	TAH	ST VAD*	ECMO			LT VAD	TAH	ST VAD*	ECMO	
Bridging	Birmingham	**334**	159	0	124	51	261	**28**	9	0	18	1	23
	Glasgow	**109**	20	0	44	45	92	**13**	0	0	3	10	10
	Harefield	**494**	270	23	106	95	339	**43**	16	0	17	10	26
	Manchester	**268**	127	0	94	47	225	**30**	13	0	13	4	28
	Newcastle	**320**	234	1	15	70	277	**26**	14	0	6	6	23
	Papworth	**213**	101	2	78	32	175	**23**	3	0	14	6	19
	Total	**1738**	**911**	**26**	**461**	**340**	**1369**	**163**	**55**	**0**	**71**	**37**	**129**
Post-transplant	Birmingham	**87**	0	0	29	58	65	**20**	0	0	6	14	15
	Glasgow	**46**	0	0	13	33	35	**4**	0	0	0	4	4
	Harefield	**58**	0	0	2	56	51	**4**	0	0	0	4	3
	Manchester	**69**	0	0	11	58	59	**7**	0	0	3	4	3
	Newcastle	**57**	0	0	2	55	50	**4**	0	0	0	4	3
	Papworth	**41**	0	0	14	27	33	**5**	0	0	1	4	5
	Total	**358**	**0**	**0**	**71[1]**	**287[1]**	**293**	**44**	**0**	**0**	**10**	**34[2]**	**33**

* Includes Berlin Heart devices
[1] Includes 6 ST VAD and 11 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, 1 April 2013 to 31 March 2021

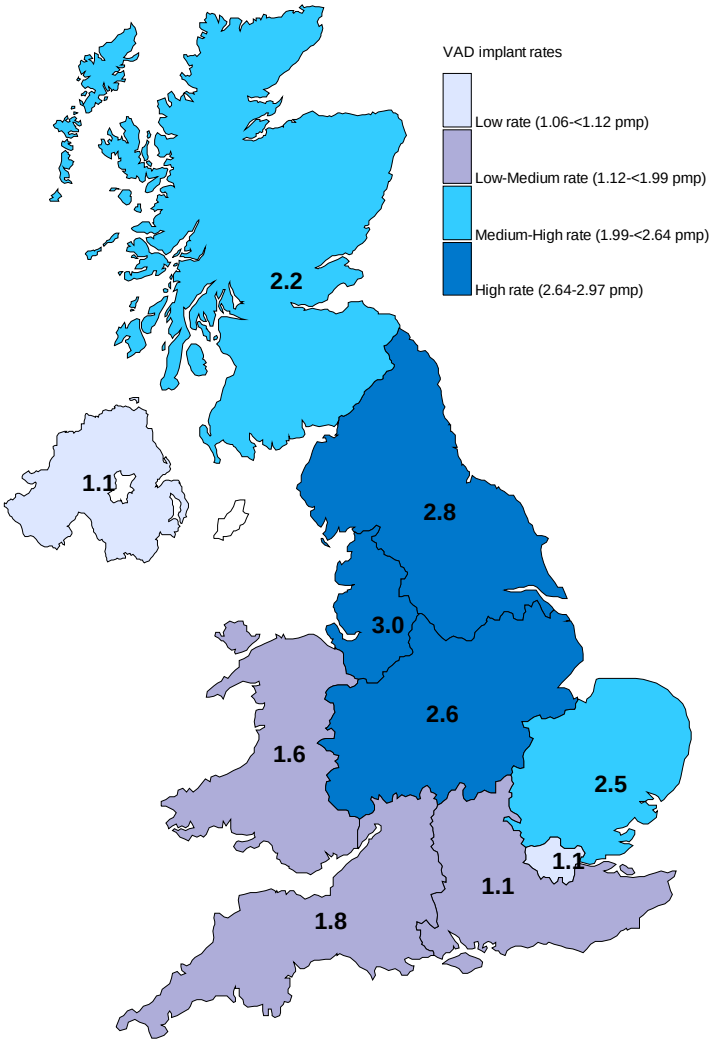
Strategy	Centre	1 April 2013 - 31 March 2021				1 April 2020 - 31 March 2021			
		No. of implants	Type of device VAD	Type of device ECMO	No. patients	No. of implants	Type of device VAD	Type of device ECMO	No. patients
Bridging	Great Ormond Street	**89**	81	8	80	**6**	5	1	6
	Newcastle	**100**	99	1	81	**6**	6	0	6
	Total	**189**	**180**	**9**	**161**	**12**	**11**	**1**	**12**
Post-transplant	Great Ormond Street	**14**	1	13	14	**2**	1	1	2
	Newcastle	**0**	0	0	0	**0**	0	0	0
	Total	**14**	**1**	**13**	**14**	**2**	**1**	**1**	**2**

ECMO reporting for paediatric patients is incomplete for this period

Figure 2.6 shows the number of patients receiving MCS as a bridge to heart transplant per million population (pmp) between 1 April 2020 and 31 March 2021, 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 2.1 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. Implant rates yielded an SCV of 0.06 (p-value = 0.04). 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, there is moderate 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 2020 – 31 March 2021, by country/NHS region of patient residence



Country/ NHS region	Patients	(pmp)
North East and Yorkshire	24	(2.8)
North West	21	(3.0)
Midlands	28	(2.6)
East of England	16	(2.5)
London	10	(1.1)
South East	10	(1.1)
South West	10	(1.8)
England	**119**	**(2.1)**
Isle of Man	**1**	**(12.5)**
Channel Islands	**0**	
Wales	**5**	**(1.6)**
Scotland	**12**	**(2.2)**
Northern Ireland	**2**	**(1.1)**
TOTAL[1]	**141**	**(2.1)**

[1] Implants include 2 recipients whose postcode was unknown

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 2020/2021 there were 55 implants reported: 35% fewer than 2019/2020. In total there were 26 TAH implants. **Figure 3.2** shows the trend per centre, with Birmingham and Manchester having the most marked increases in implantations during the start of the decade, but numbers have fallen in recent years. Harefield have also had a general decrease in long-term device implants since 2014/2015. 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 Harefield, followed by Newcastle.

Figure 3.1 Number of adult long-term bridging device implants in the UK, by financial year and device type, 1 April 2011 to 31 March 2021

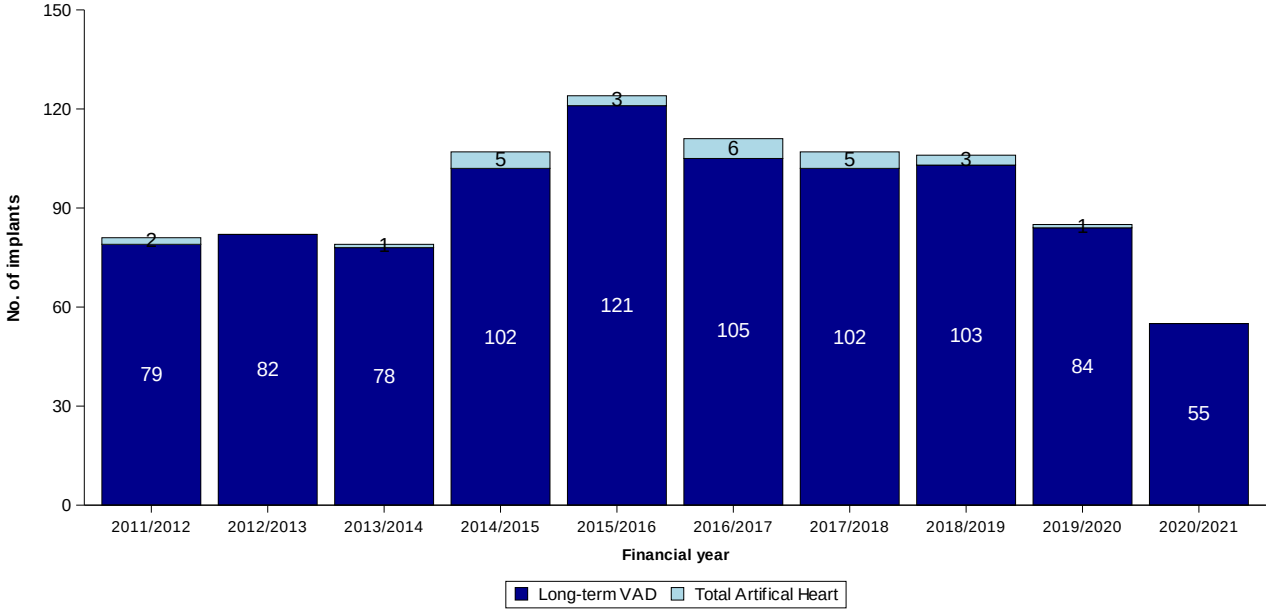


Figure 3.2 Number of adult long-term bridging device implants in the UK, by financial year, centre and device type, 1 April 2011 to 31 March 2021

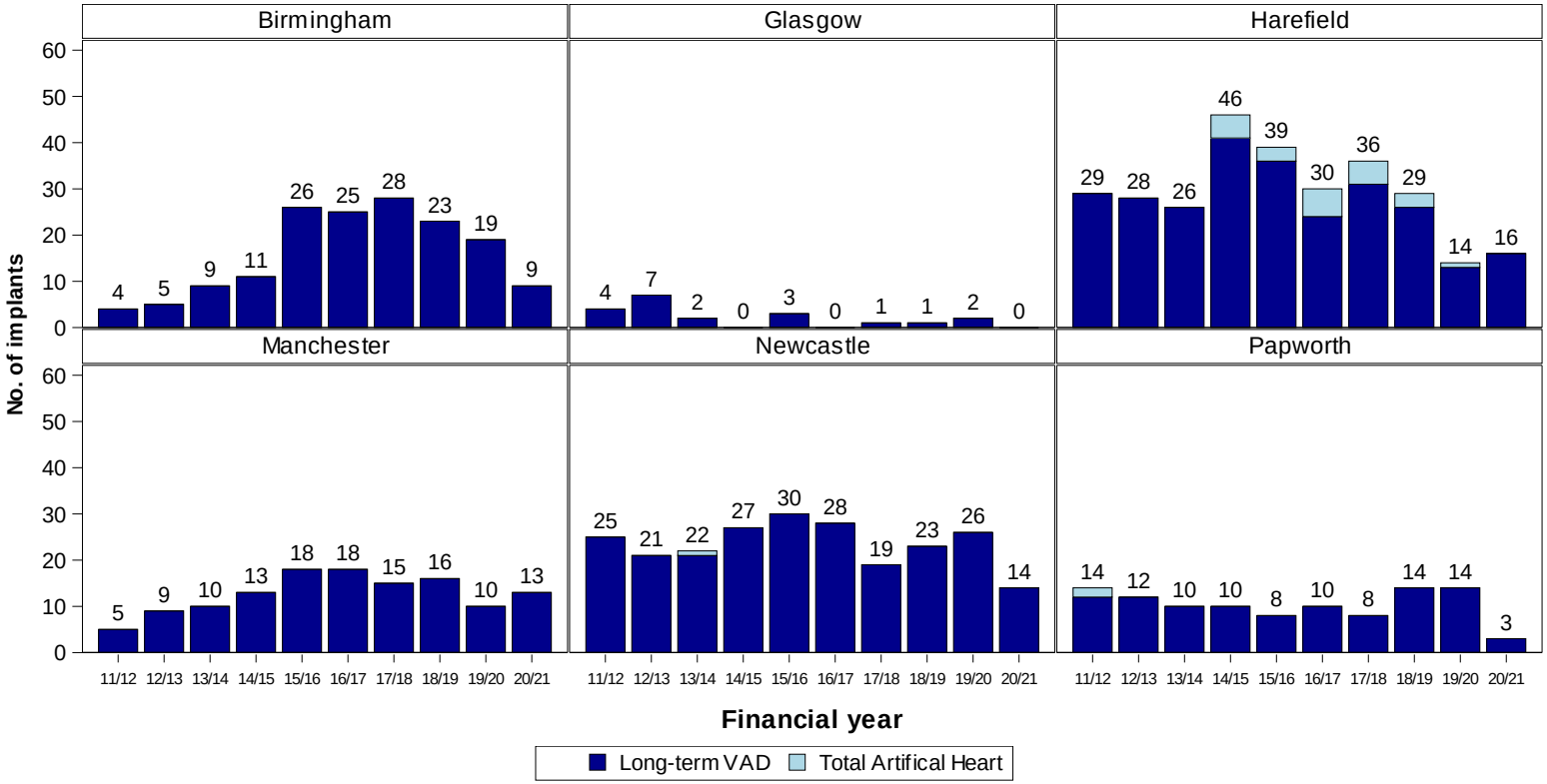


Figure 3.3 Number of adult long-term bridging device implants in the UK, by centre and device type, 1 April 2020 to 31 March 2021

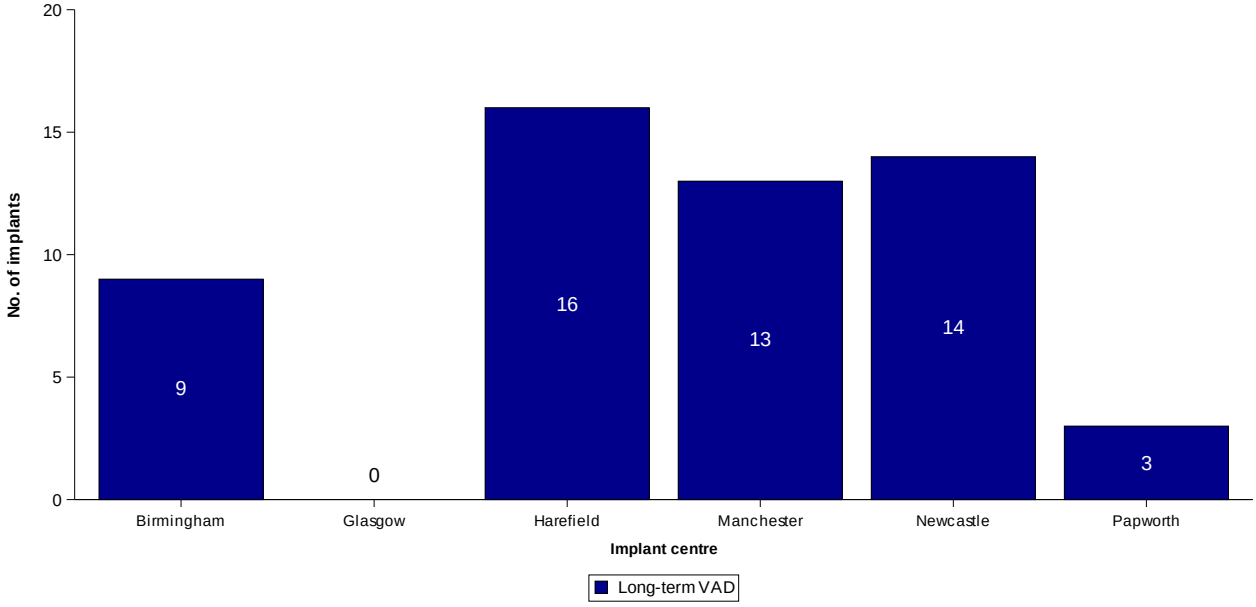
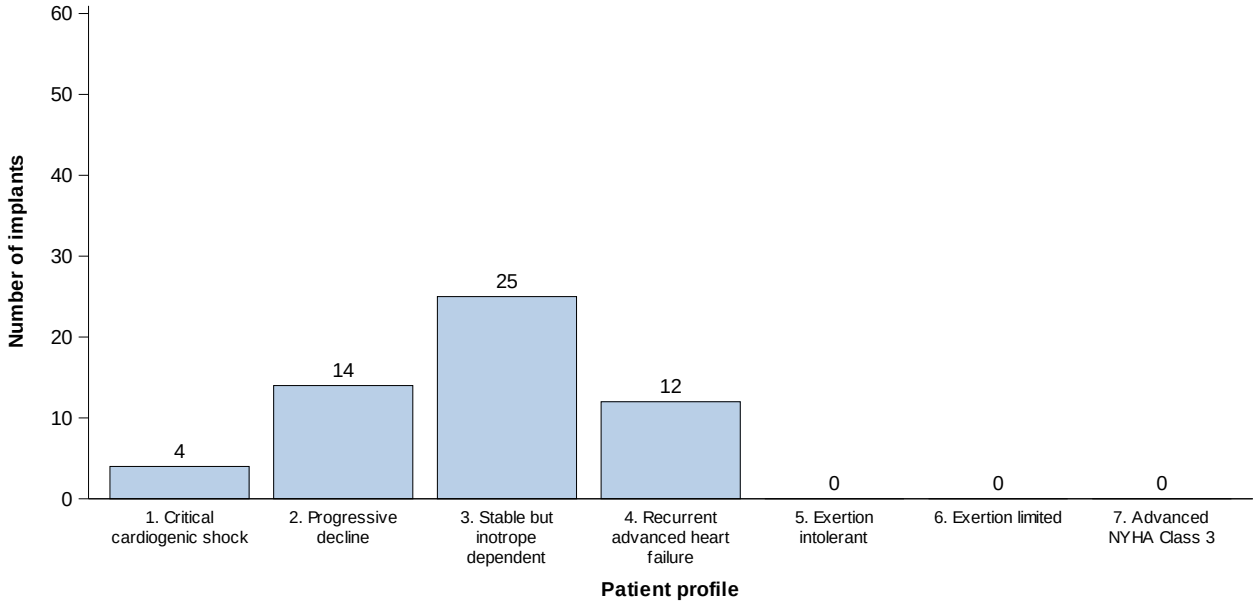


Figure 3.4 shows the INTERMACS patient profile at time of long-term VAD implantation for patients implanted during 2020/2021. Level 3 (stable but inotrope dependent) was the most common, followed by level 2 (progressive decline) and level 4 (recurrent advanced heart failure).

Figure 3.4 INTERMACS patient profile of adult patients receiving long-term bridging device implants during 1 April 2020 – 31 March 2021



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. All patients have follow-up information available, so no patients were excluded due to missing follow-up (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 376 patients analysed in this section are shown below in **Table 4.1**, by centre and overall. Nationally, 80% of patients were male, the median age was 55 years and 51% of patients received a Heartware HVAD device. Note that for some characteristics, such as BMI, there is a high proportion of missing data. Also, due to rounding, percentages may not add up to 100.

Table 4.1 Characteristics of adult patients who received a first long-term VAD between 1 April 2016 and 31 March 2020, by centre

		Birmingham N (%)	Glasgow N (%)	Harefield N (%)	Manchester N (%)	Newcastle N (%)	Papworth N (%)	**Total N (%)**
Number of patients		91	4	89	58	89	45	**376**
Age at implant (years)	Median (IQR)[1]	56 (51-62)	-	52 (42-58)	53 (44-59)	55 (42-60)	55 (46-59)	**55 (45-60)**
Sex	Male	74 (81)	4 (100)	69 (78)	46 (79)	75 (84)	33 (73)	**301 (80)**
	Female	17 (19)	0 (0)	20 (22)	12 (21)	14 (16)	12 (27)	**75 (20)**
Primary disease	Dilated cardiomyopathy	44 (48)	4 (100)	55 (62)	39 (67)	40 (45)	23 (51)	**205 (55)**
	Ischaemic heart disease	35 (38)	0 (0)	27 (30)	14 (24)	33 (37)	19 (42)	**128 (34)**
	Congenital heart disease	2 (2)	0 (0)	1 (1)	1 (2)	13 (15)	0 (0)	**17 (5)**
	Hypertrophic cardiomyopathy	0 (0)	0 (0)	3 (3)	0 (0)	2 (2)	3 (7)	**8 (2)**
	Restrictive cardiomyopathy	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	**1 (0)**
	Valvular heart disease	2 (2)	0 (0)	1 (1)	3 (5)	0 (0)	0 (0)	**6 (2)**
	Infiltrative heart muscle disease	2 (2)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	**3 (1)**
	Other	5 (5)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	**6 (2)**
	Unknown	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	**2 (1)**

Table 4.1 Characteristics of adult patients who received a first long-term VAD between 1 April 2016 and 31 March 2020, by centre

		Birmingham N (%)	Glasgow N (%)	Harefield N (%)	Manchester N (%)	Newcastle N (%)	Papworth N (%)	**Total N (%)**
INTERMACS patient profile	1. Critical cardiogenic shock	17 (19)	0 (0)	21 (24)	5 (9)	10 (11)	0 (0)	**53 (14)**
	2. Progressive decline	21 (23)	4 (100)	48 (54)	14 (24)	12 (13)	10 (22)	**109 (29)**
	3. Stable but inotrope dependent	47 (52)	0 (0)	18 (20)	23 (40)	32 (36)	22 (49)	**142 (38)**
	4. Recurrent advanced heart failure	6 (7)	0 (0)	2 (2)	11 (19)	35 (39)	10 (22)	**64 (17)**
	5. Exertion intolerant	0 (0)	0 (0)	0 (0)	5 (9)	0 (0)	0 (0)	**5 (1)**
	6. Exertion limited	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	3 (7)	**3 (1)**
	7. Advanced NYHA Class 3	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**0 (0)**
Pre-implant BMI (kg/m^2)	Median (IQR)[1]	27 (24-29)	-	26 (23-30)	26 (23-29)	27 (24-30)	26 (23-29)	**27 (23-29)**
	Missing	11	0	23	12	28	15	**89**
Pre-implant serum creatinine (umol/l)	Median (IQR)[1]	110 (89-150)	-	94 (75-121)	85 (72-113)	119 (104-149)	121 (90-153)	**108 (80-134)**
	Missing	5	1	0	0	16	5	**27**
Pre-implant bilirubin (umol/l)	Median (IQR)[1]	16 (10-27)	-	19 (13-29)	20 (11-29)	17 (12-37)	15 (8-21)	**17 (11-29)**
	Missing	8	1	3	4	23	14	**53**
First LT VAD device name	Heartmate II	0 (0)	1 (25)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (0)**
	Heartware	0 (0)	1 (25)	86 (97)	0 (0)	89 (100)	16 (36)	**192 (51)**
	HeartMate III	91 (100)	2 (50)	0 (0)	58 (100)	0 (0)	29 (64)	**180 (48)**
	Reliant Heart aVAD	0 (0)	0 (0)	3 (3)	0 (0)	0 (0)	0 (0)	**3 (1)**
Long-term device configuration	LVAD	90 (99)	4 (100)	89 (100)	58 (100)	84 (94)	45 (100)	**370 (98)**
	RVAD	1 (1)	0 (0)	0 (0)	0 (0)	5 (6)	0 (0)	**6 (2)**
	BiVAD	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**0 (0)**
Conjunction ST RVAD support	No	77 (85)	3 (75)	83 (93)	47 (81)	72 (81)	42 (93)	**324 (86)**
	Yes	14 (15)	1 (25)	6 (7)	11 (19)	17 (19)	3 (7)	**52 (14)**
Previous transplant	No	91 (100)	4 (100)	89 (100)	58 (100)	89 (100)	45 (100)	**376 (100)**
Previous ST support	No	75 (82)	4 (100)	67 (75)	54 (93)	81 (91)	41 (91)	**322 (86)**
	Yes	16 (18)	0 (0)	22 (25)	4 (7)	8 (9)	4 (9)	**54 (14)**

[1] Medians not presented for centres with less than 10 patients

4.2 Duration on support

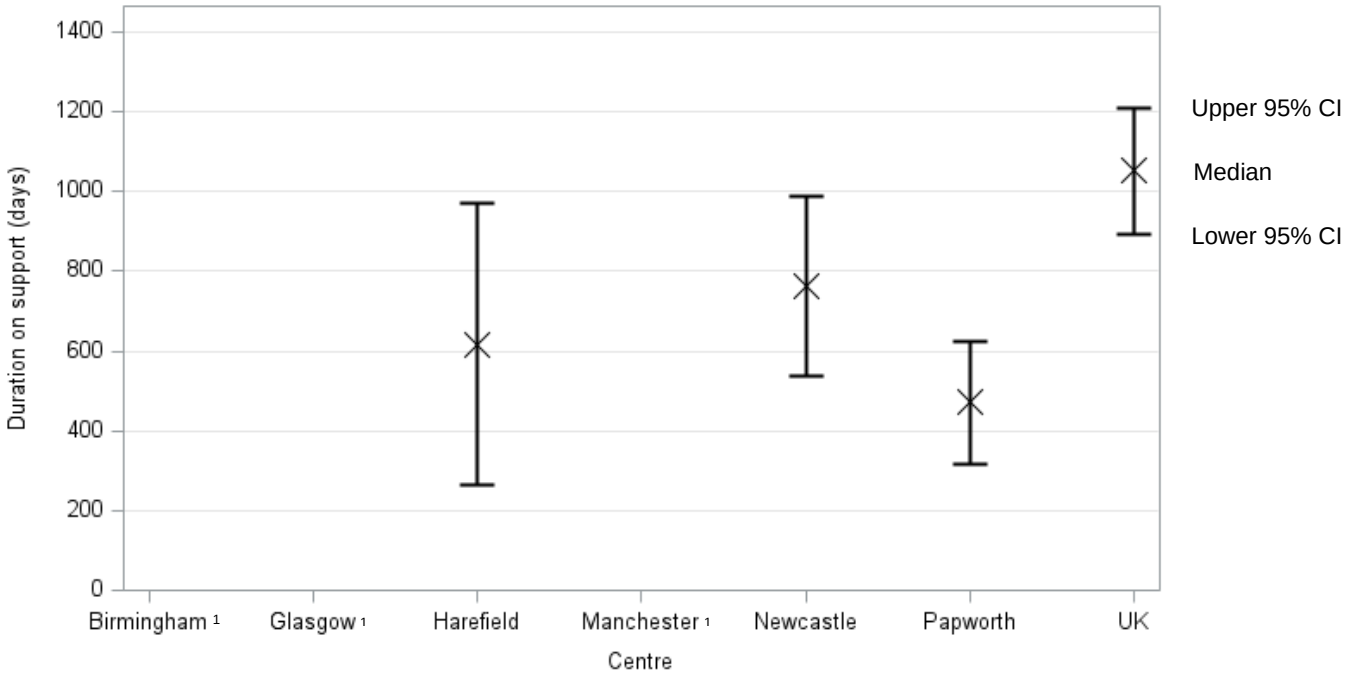
Table 4.2 and **Figure 4.1** show the median duration on long-term VAD support for patients implanted in the analysis period, both nationally and by centre. The medians and confidence intervals are estimated using the Kaplan-Meier method, since not all patients have come to the end of their support, 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 1051 days (3 years). The duration varies significantly across centres (log-rank p<0.0001) with medians not estimable for Birmingham and Manchester as insufficient numbers of patients had come to the end of support at time of analysis, or for Glasgow due to small numbers of patients.

Table 4.2 Median duration on long-term VAD support for adult patients implanted between 1 April 2016 and 31 March 2020, by centre

Centre	Number of patients	Time on support (days) Median	(95% confidence interval)
Birmingham[1]	91	-	-
Glasgow[2]	4	-	-
Harefield	89	616	245 - 987
Manchester[1]	58	-	-
Newcastle	89	762	537 - 987
Papworth	45	472	318 - 626
Overall	**376**	**1051**	**892 - 1210**

[1] Median duration on support cannot be estimated as insufficient numbers of patients have come to the end of support
[2] Median duration on support not presented due to a small number of patients

Figure 4.1 Median duration on long-term VAD support for adult patients implanted between 1 April 2016 and 31 March 2020



[1] Median duration on support cannot be estimated

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 2016 and 31 March 2020, by centre. This includes listing on the super-urgent, urgent or non-urgent heart transplant lists (whichever occurred first). Overall, 28% of patients were on the list at implant, but this proportion ranged significantly across centres (chi-squared p<0.0001). The proportion still on a VAD at one year and not listed was 24% overall and was highest at Birmingham (52%). Note that Glasgow's figures are based on a small number of patients.

Figure 4.2 Heart transplant listing status with respect to long-term VAD implantation for adult patients receiving a first device 1 April 2016 – 31 March 2020, by centre and overall

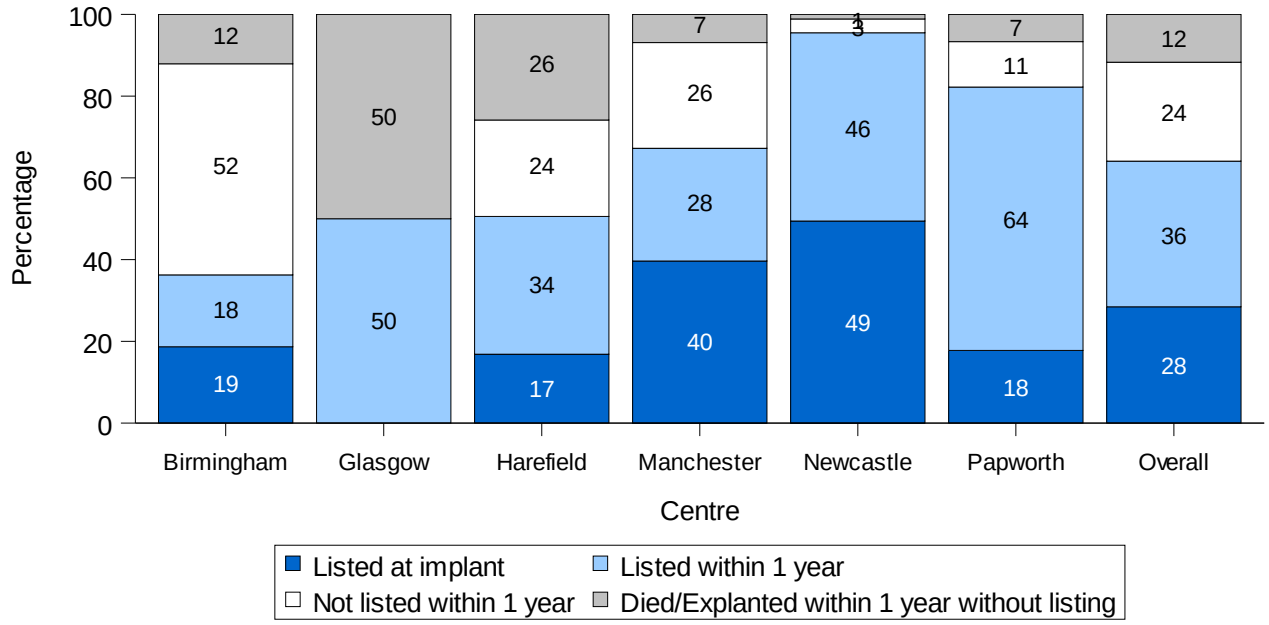


Table 4.3 Heart transplant listing status with respect to long-term VAD implantation for adult patients receiving a first device 1 April 2016 – 31 March 2020, by centre and overall

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	91	17 (19)	16 (18)	47 (52)	11 (12)
Glasgow	4	0 (0)	2 (50)	0 (0)	2 (50)
Harefield	89	15 (17)	30 (34)	21 (24)	23 (26)
Manchester	58	23 (40)	16 (28)	15 (26)	4 (7)
Newcastle	89	44 (49)	41 (46)	3 (3)	1 (1)
Papworth	45	8 (18)	29 (64)	5 (11)	3 (7)
Overall	**376**	**107 (28)**	**134 (36)**	**91 (24)**	**44 (12)**

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 implant, for the cohort of patients receiving a first long-term device between 1 April 2016 and 31 March 2020. 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, nationally, at one year post- long-term implant, 74% of patients remained alive on support, 18% died on support, 5% received a heart transplant and 3% had their device explanted. At two years, the incidence of transplantation rose to 11%, however so did the incidence of death, to 25%, with the remaining 58% of patients still alive on support and 5% explanted. At three years, the incidence of death on support rose to 32%, the incidence of transplant rose to 14%, 6% had been explanted and 48% 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 2016 to 31 March 2020

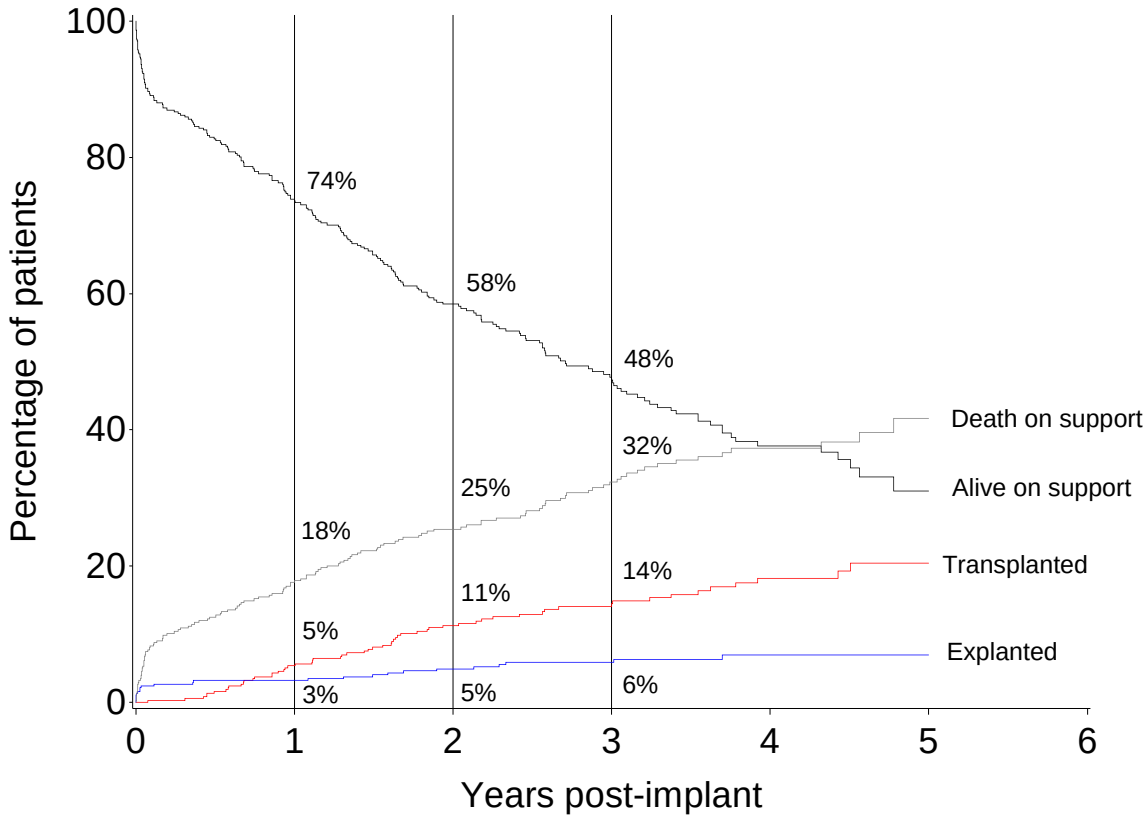


Table 4.4a and **Table 4.4b** shows the centre-specific one-year and three-year estimates for each competing outcome, respectively. The incidence of each outcome varies across centres.

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 2016 to 31 March 2020

Centre	Number of patients	Transplanted %	Explanted %	Alive on support %	Death on support %
Birmingham	91	1	3	82	13
Glasgow	4	0	0	50	50
Harefield	89	2	7	63	28
Manchester	58	0	2	91	7
Newcastle	89	8	2	70	20
Papworth	45	22	2	62	13
Overall	**376**	**5**	**3**	**74**	**18**

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 2016 to 31 March 2020

Centre	Number of patients	Transplanted %	Explanted %	Alive on support %	Death (before transplant) %
Birmingham	91	2	4	70	24
Glasgow	4	50	0	0	50
Harefield	89	7	9	38	46
Manchester	58	11	7	70	12
Newcastle	89	17	6	32	45
Papworth	45	50	2	15	32
Overall	**376**	**14**	**6**	**48**	**32**

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 (, or 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 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 92.2%, 81.6%, and 64.1% at 30 days, 1 year, and 3 years respectively. There was a significant difference between unadjusted survival on support at each time period between centres (log-rank p<0.001).

Figure 4.4 Patient survival during long-term VAD support for adult patients implanted 1 April 2016 – 31 March 2020

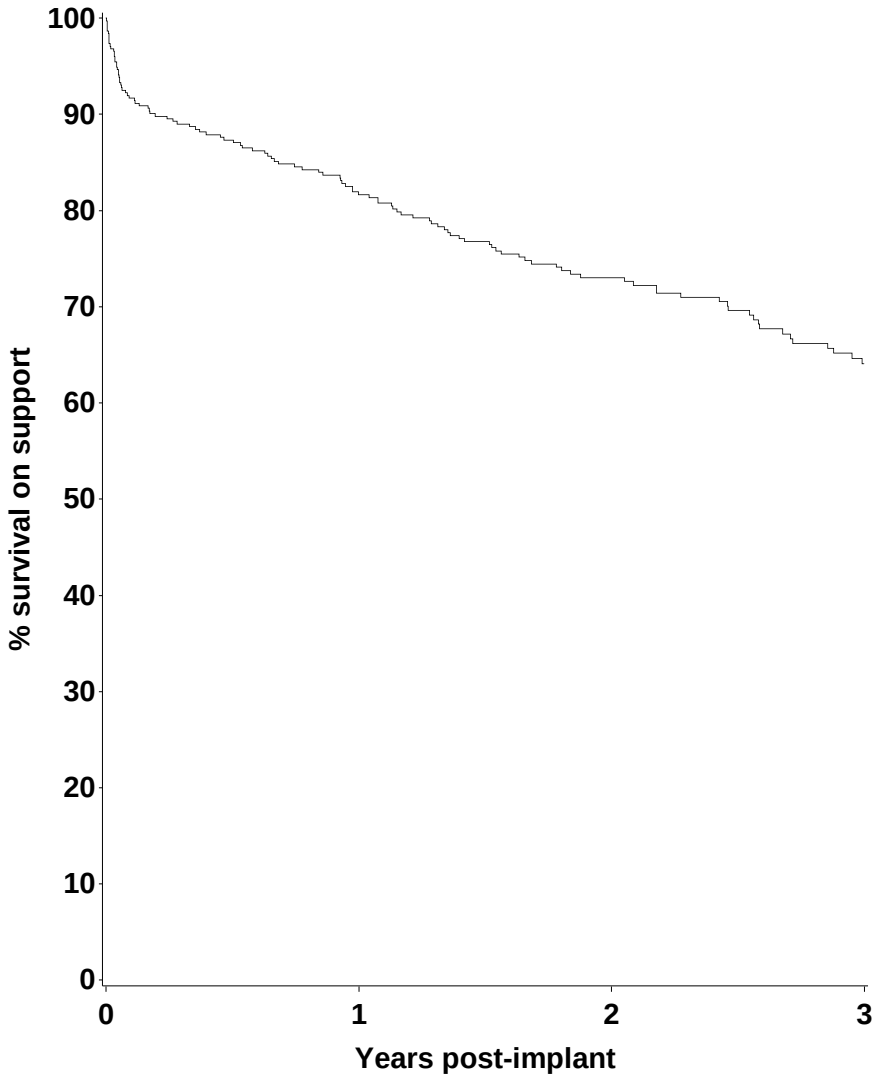


Table 4.5 Unadjusted survival during long-term VAD support, by centre, 1 April 2016 to 31 March 2020

Centre	No. of patients	% 30 day survival (95% CI)		% 1 year survival (95% CI)		% 3 year survival (95% CI)	
Birmingham	91	91.1	(83.0 - 95.4)	86.6	(77.6 - 92.1)	75.6	(64.5 - 83.6)
Glasgow[1]	4	-	-	-	-	-	-
Harefield	89	85.3	(76.1 - 91.2)	71.1	(60.3 - 79.5)	50.3	(38.6 - 60.9)
Manchester	58	96.6	(86.9 - 99.1)	93.1	(82.6 - 97.3)	86.2	(70.4 - 93.9)
Newcastle	89	95.5	(88.4 - 98.3)	78.4	(67.9 - 85.8)	47.5	(34.2 - 59.8)
Papworth	45	97.8	(85.3 - 99.7)	85.5	(70.4 - 93.3)	74.6	(55.7 - 86.3)
Number at risk		342		276		117	
Log-rank p-value		**0.02**		**0.01**		**<0.001**	
UK	**376**	**92.2**	**(89.0 - 94.5)**	**81.6**	**(77.3 - 85.3)**	**64.1**	**(58.2 – 69.4)**

[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 2016 and 31 March 2020. 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 91.8%, 79.7%, and 63.2% 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 376 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 rates for Papworth and Manchester were 97.8% and 96.6% respectively and both exceeded the upper 95% confidence limit, providing some evidence of higher survival at these centres.

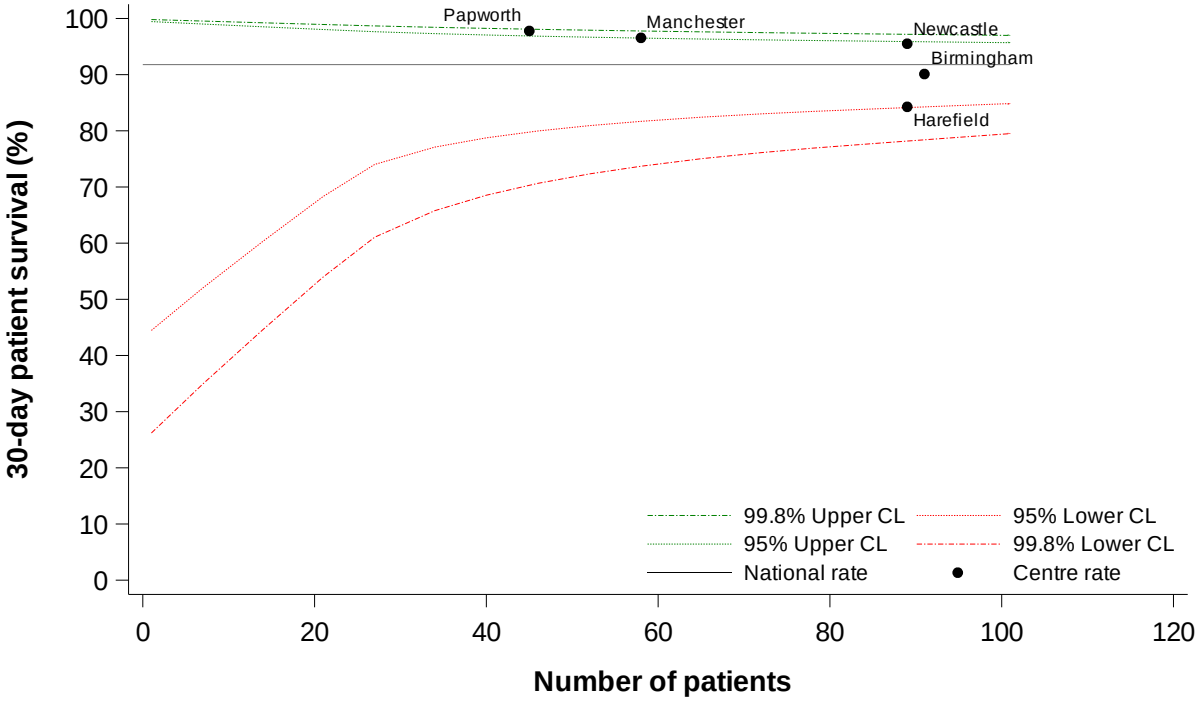
Table 4.6 30-day patient survival rates after long-term VAD implant for adult patients implanted 1 April 2016 – 31 March 2020, by centre

Centre	Number of patients	% 30-day survival (95% CI) Unadjusted	
Birmingham	91	90.1	(81.9 - 94.7)
Glasgow[1]	4	-	-
Harefield	89	84.3	(74.9 - 90.4)
Manchester	58	96.6	(86.9 - 99.1)
Newcastle	89	95.5	(88.5 - 98.3)
Papworth	45	97.8	(85.3 - 99.7)
UK	**376**	**91.8**	**(88.5 - 94.1)**

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 2016 – 31 March 2020, by centre



The unadjusted centre-specific 1-year survival rates are shown in **Table 4.7** and **Figure 4.6**. The centre-specific rates ranged between 67.3% and 93.1% with Manchester having a higher unadjusted rate than the national rate, and there being some evidence of a lower rate at Harefield.

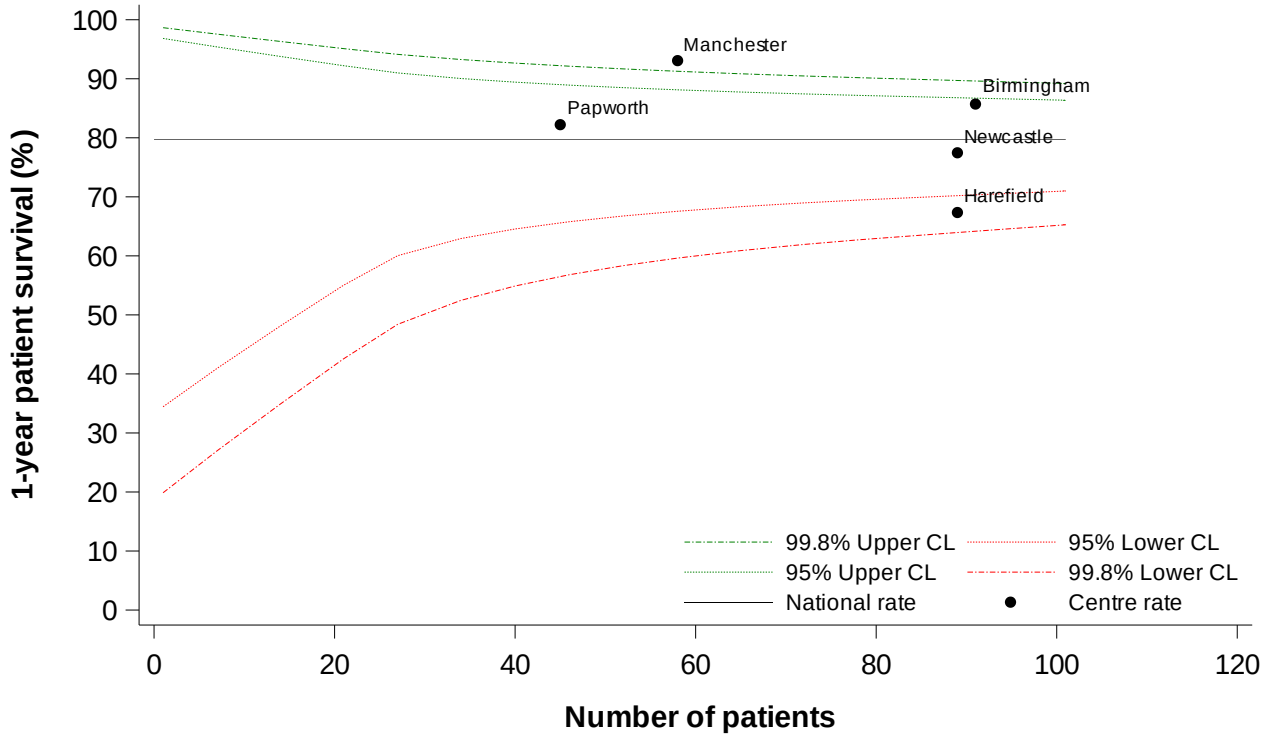
Table 4.7 1-year patient survival rates after long-term VAD implant for adult patients implanted 1 April 2016 – 31 March 2020, by centre

Centre	Number of patients	% 1-year survival (95% CI) Unadjusted	
Birmingham	91	85.7	(76.7 - 91.4)
Glasgow[1]	4	-	-
Harefield	89	67.3	(56.5 - 76.0)
Manchester	58	93.1	(82.6 - 97.3)
Newcastle	89	77.5	(67.4 - 84.9)
Papworth	45	82.2	(67.6 - 90.7)
UK	**376**	**79.7**	**(75.3 - 83.5)**

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 .0survival rates after long-term VAD implant for adult patients implanted 1 April 2016 – 31 March 2020, by centre



The unadjusted centre-specific 3-year survival rates are shown in **Table 4.8** and **Figure 4.7**. The rate for Manchester exceeded the upper 99.8% confidence limit, indicating a higher unadjusted rate than the national rate, and for Birmingham there was also some evidence of higher survival. For Harefield and Newcastle there was some evidence of lower survival, as their rates fell below the lower 95% confidence limit.

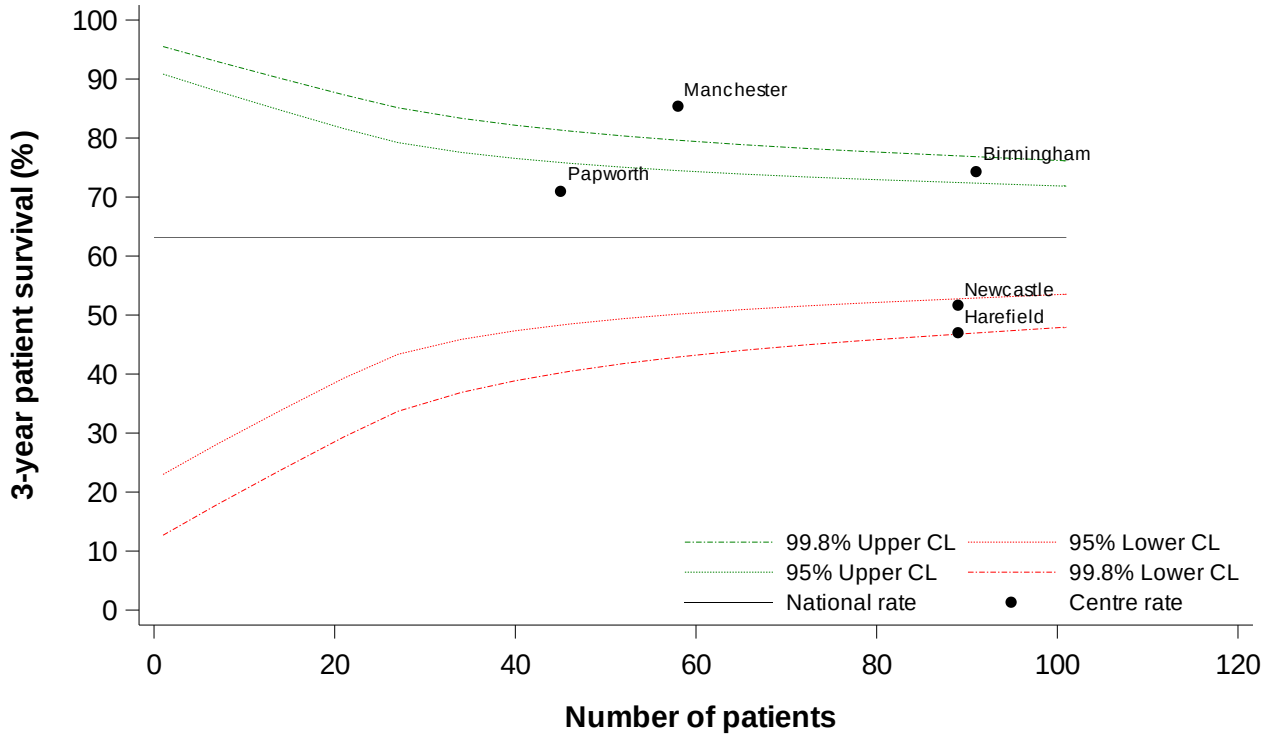
Table 4.8 3-year patient survival rates after long-term VAD implant for adult patients implanted 1 April 2016 – 31 March 2020, by centre

Centre	Number of patients	% 3-year survival (95% CI) Unadjusted	
Birmingham	91	74.3	(63.5 - 82.4)
Glasgow[1]	4	-	-
Harefield	89	47.0	(36.1 - 57.1)
Manchester	58	85.4	(71.1 - 92.9)
Newcastle	89	51.7	(39.8 - 62.3)
Papworth	45	71.0	(55.3 - 82)
UK	**376**	**63.2**	**(57.7 - 68.1)**

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 2016 – 31 March 2020, 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 2011 to 31 March 2021

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 2011 to 31 March 2021

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 2020/2021 there were 108 implants: 7% less than 2019/2020. 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 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 2011 to 31 March 2021

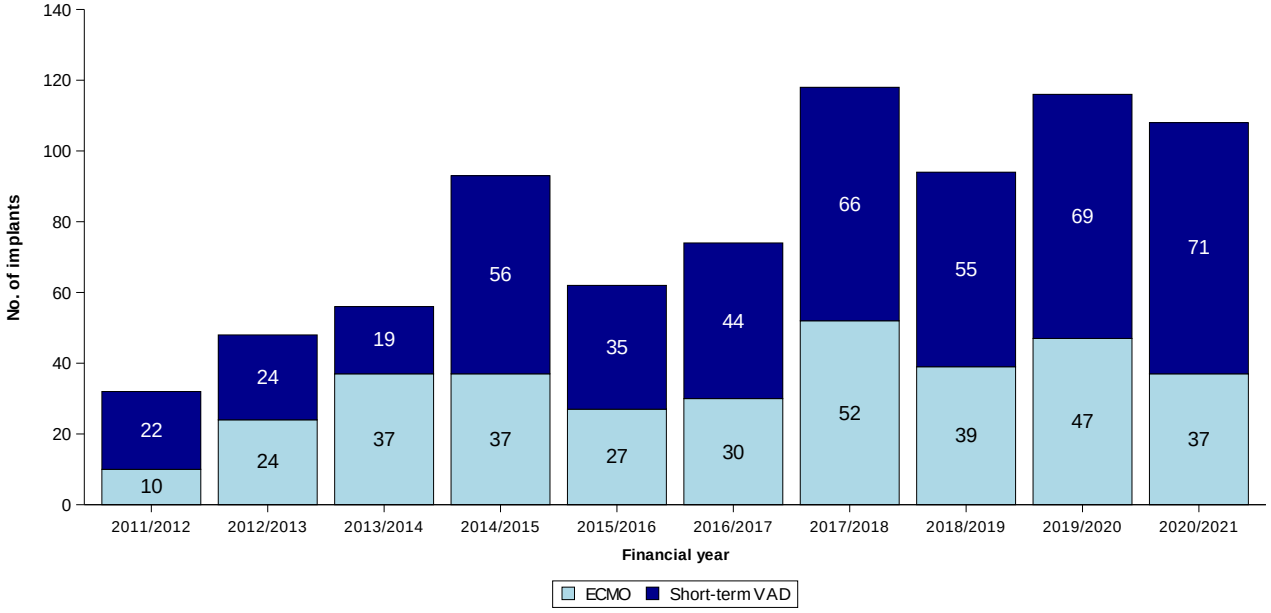


Figure 5.2 Number of adult short-term bridging device implants in the UK, by financial year, centre and device type, 1 April 2011 to 31 March 2021

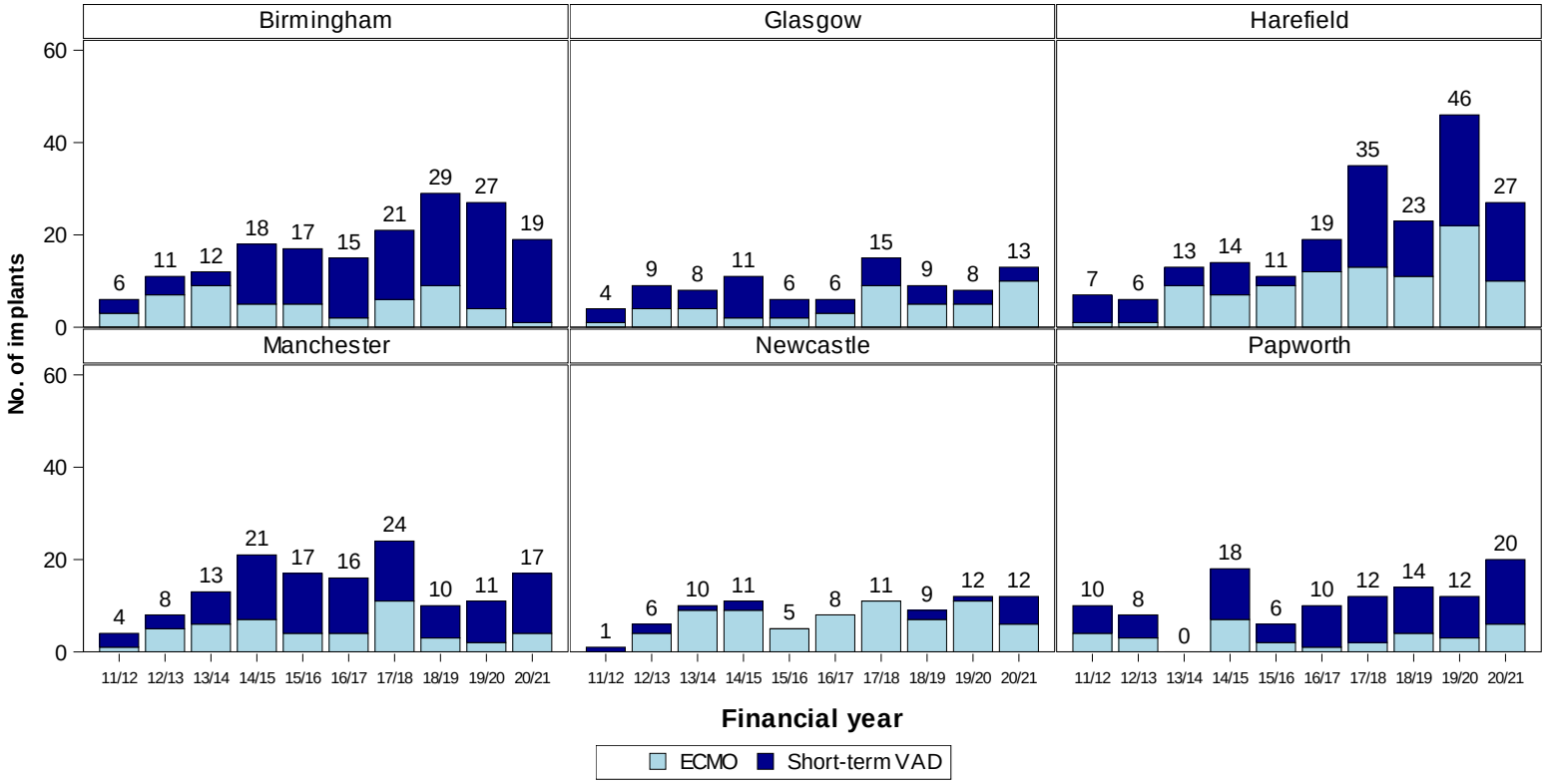


Figure 5.3 Number of adult short-term bridging device implants in the UK, by centre and device type, 1 April 2020 to 31 March 2021

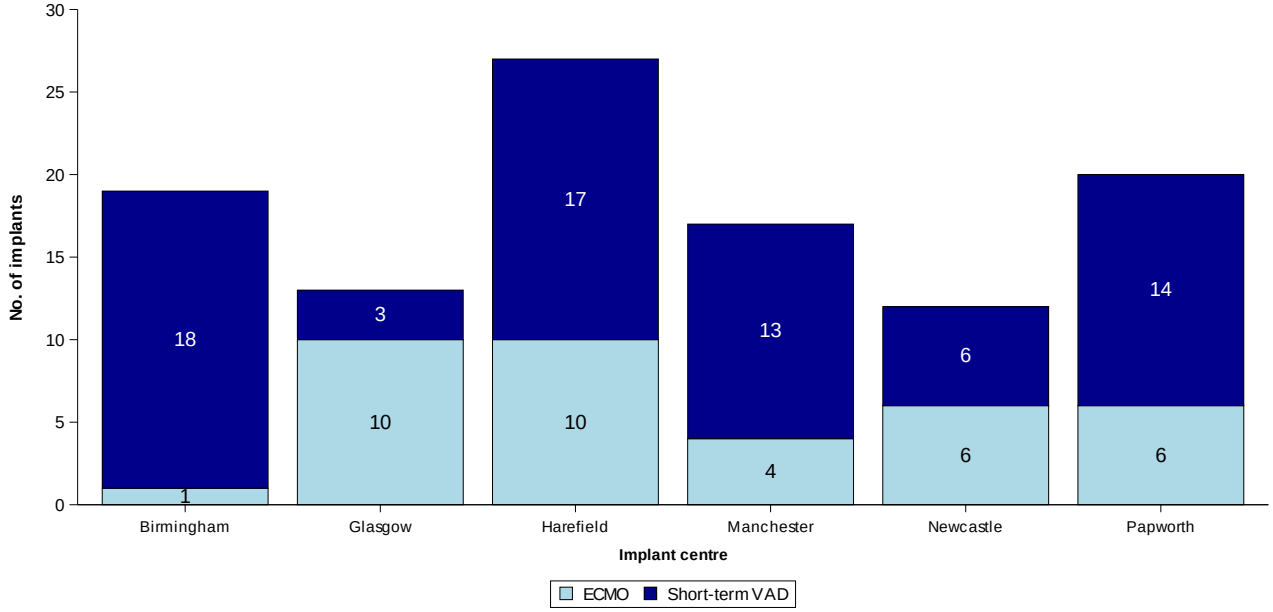
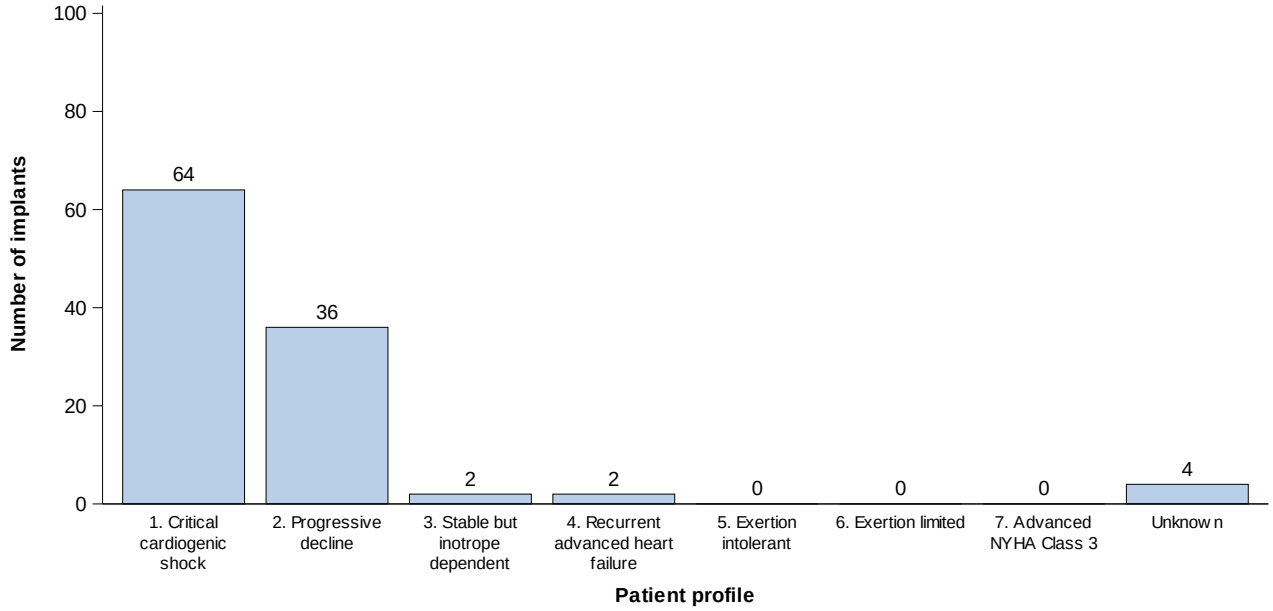


Figure 5.4 shows the INTERMACS patient profile at receipt of short-term support for patients implanted during 2020/2021. Most patients were profile 1 (critical cardiogenic shock).

Figure 5.4 INTERMACS patient profile for all short-term bridging device implants in adult patients in the UK, 1 April 2020 to 31 March 2021



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 6.5 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 323 patients analysed in **Sections 6.2**-**6.4** are shown below in **Table 6.1**, by centre and overall. Nationally, 73% of patients were male, the median age was 47 years, 34% of patients received ventricular assist (Centrimag) devices and 20% were bridged to a long-term device. Note that for some characteristics, particularly pre-implant lactate, there is a high proportion of missing data. Also, due to rounding, percentages may not add up to 100.

Table 6.1 Characteristics of adult patients who received short-term bridging support between 1 April 2016 and 31 March 2020, by centre

		Birmingham N (%)	Glasgow N (%)	Harefield N (%)	Manchester N (%)	Newcastle N (%)	Papworth N (%)	**Total N (%)**
Number of patients		73	33	88	54	38	37	**323**
Age at implant (years)	Median (IQR)	48 (32-57)	49 (40-57)	47 (34-57)	44 (32-51)	47 (30-58)	42 (30-52)	**47 (32-56)**
	Missing	0	0	1	0	0	0	**1**
Sex	Male	54 (74)	26 (79)	67 (76)	36 (67)	26 (68)	28 (76)	**237 (73)**
	Female	19 (26)	7 (21)	21 (24)	18 (33)	12 (32)	9 (24)	**86 (27)**
Primary disease	Dilated cardiomyopathy	39 (53)	11 (33)	55 (63)	29 (54)	23 (61)	19 (51)	**176 (54)**
	Ischaemic heart disease	17 (23)	13 (39)	22 (25)	16 (30)	7 (18)	11 (30)	**86 (27)**
	Congenital heart disease	4 (5)	0 (0)	1 (1)	0 (0)	1 (3)	0 (0)	**6 (2)**
	Hypertrophic cardiomyopathy	0 (0)	0 (0)	2 (2)	1 (2)	1 (3)	2 (5)	**6 (2)**
	Restrictive cardiomyopathy	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	**1 (0)**
	Valvular heart disease	1 (1)	1 (3)	2 (2)	2 (4)	0 (0)	1 (3)	**7 (2)**
	Infiltrative heart muscle disease	1 (1)	0 (0)	0 (0)	1 (2)	1 (3)	0 (0)	**3 (1)**
	Other	8 (11)	6 (18)	4 (5)	5 (9)	5 (13)	3 (8)	**31 (10)**
	Unknown	3 (4)	2 (6)	1 (1)	0 (0)	0 (0)	1 (3)	**7 (2)**

Table 6.1 Characteristics of adult patients who received short-term bridging support between 1 April 2016 and 31 March 2020, by centre

		Birmingham N (%)	Glasgow N (%)	Harefield N (%)	Manchester N (%)	Newcastle N (%)	Papworth N (%)	**Total N (%)**
INTERMACS patient profile	1. Critical cardiogenic shock	52 (71)	26 (79)	72 (82)	46 (85)	22 (58)	24 (65)	**242 (75)**
	2. Progressive decline	21 (29)	6 (18)	15 (17)	7 (13)	15 (39)	11 (30)	**75 (23)**
	3. Stable but inotrope dependent	0 (0)	1 (3)	0 (0)	1 (2)	0 (0)	2 (5)	**4 (1)**
	4. Recurrent advanced heart failure	0 (0)	0 (0)	1 (1)	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	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**0 (0)**
Type of support	Percutaneous VAD	23 (32)	0 (0)	37 (42)	0 (0)	2 (5)	1 (3)	**63 (20)**
	Ventricular assist (Centrimag)	30 (41)	11 (33)	5 (6)	36 (67)	0 (0)	27 (73)	**109 (34)**
	Peripheral ECMO	14 (19)	20 (61)	39 (44)	10 (19)	31 (82)	6 (16)	**120 (37)**
	Central ECMO	6 (8)	2 (6)	7 (8)	8 (15)	5 (13)	3 (8)	**31 (10)**
Previous long-term support	No	69 (95)	33 (100)	79 (90)	54 (100)	35 (92)	36 (97)	**306 (95)**
	Yes	4 (5)	0 (0)	9 (10)	0 (0)	3 (8)	1 (3)	**17 (5)**
Bridged to long-term support	No	57 (78)	33 (100)	57 (65)	49 (91)	30 (79)	33 (89)	**259 (80)**
	Yes	16 (22)	0 (0)	31 (35)	5 (9)	8 (21)	4 (11)	**64 (20)**
Pre-implant serum creatinine (umol/l)	Median (IQR)	131 (98-192)	142 (94-200)	122 (85-162)	120 (108-138)	95 (73-179)	121 (95-162)	**125 (95-172)**
	Missing	5	9	1	17	33	5	**70**
Pre-implant serum bilirubin (umol/l)	Median (IQR)[1]	33 (16-48)	14 (8-26)	26 (14-45)	24 (14-44)	-	31 (15-37)	**25 (14-44)**
	Missing	6	10	3	24	38	11	**92**
Pre-implant lactate (mmol/l)	Median (IQR)[1]	4 (3-7)	-	3 (2-6)	-	-	-	**3 (2-7)**
	Missing	47	28	62	52	38	37	**264**
Pre-implant cardiac arrest	No	58 (79)	18 (55)	76 (86)	41 (76)	28 (74)	32 (86)	**253 (78)**
	Yes	15 (21)	15 (45)	12 (14)	13 (24)	10 (26)	5 (14)	**70 (22)**
Pre-implant intubation and ventilation	No	51 (70)	25 (76)	53 (60)	33 (61)	15 (39)	29 (78)	**206 (64)**
	Yes	22 (30)	8 (24)	35 (40)	21 (39)	23 (61)	8 (22)	**117 (36)**
Pre-implant renal replacement therapy	No	68 (93)	32 (97)	76 (86)	45 (83)	24 (63)	25 (68)	**270 (84)**
	Yes	5 (7)	1 (3)	12 (14)	9 (17)	14 (37)	12 (32)	**53 (16)**

[1] Medians not presented for centres with less than 10 observations reported

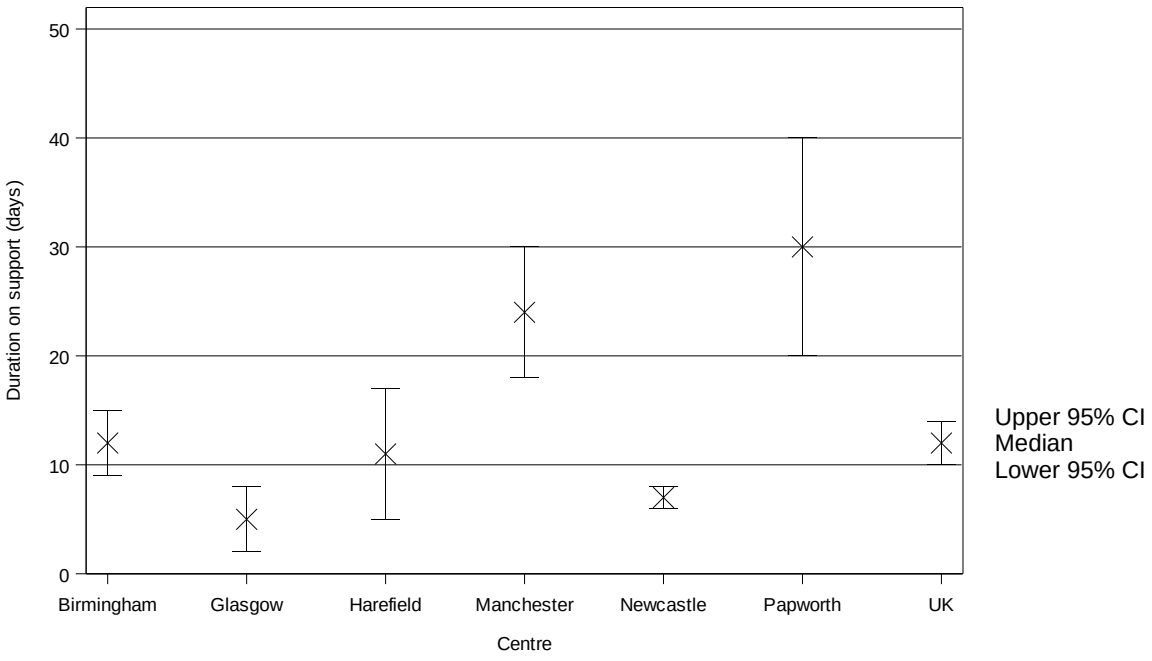
6.2 Duration on support

Table 6.2 and **Figure 6.1** show the median duration on short-term support for patients implanted in the analysis 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 12 days and ranged from 5 days at Glasgow to 30 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 2016 and 31 March 2020, by centre

Centre	Number of patients	Time on support (days) Median	(95% confidence interval)
Birmingham	73	12	9 - 15
Glasgow	33	5	2 - 8
Harefield	88	11	5 - 17
Manchester	54	24	18 - 30
Newcastle	38	7	6 - 8
Papworth	37	30	20 - 40
Overall	**323**	**12**	**10 - 14**

Figure 6.1 Median duration on short-term bridging device support for adult patients implanted between 1 April 2016 and 31 March 2020



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 2016 and 31 March 2020, 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, 18% of patients were on the list at short-term implant, which was a smaller proportion than that observed for long-term implants (28%). This proportion ranged between 7% at Manchester to 27% at Papworth (chi-squared p=0.26). The proportion that died or were explanted within 1 month without listing was 40% overall and ranged significantly across centres (chi-squared p<0.001).

Figure 6.2 Heart transplant listing status with respect to short-term device implantation for adult patients receiving a first bridging device 1 April 2016 – 31 March 2020, by centre and overall

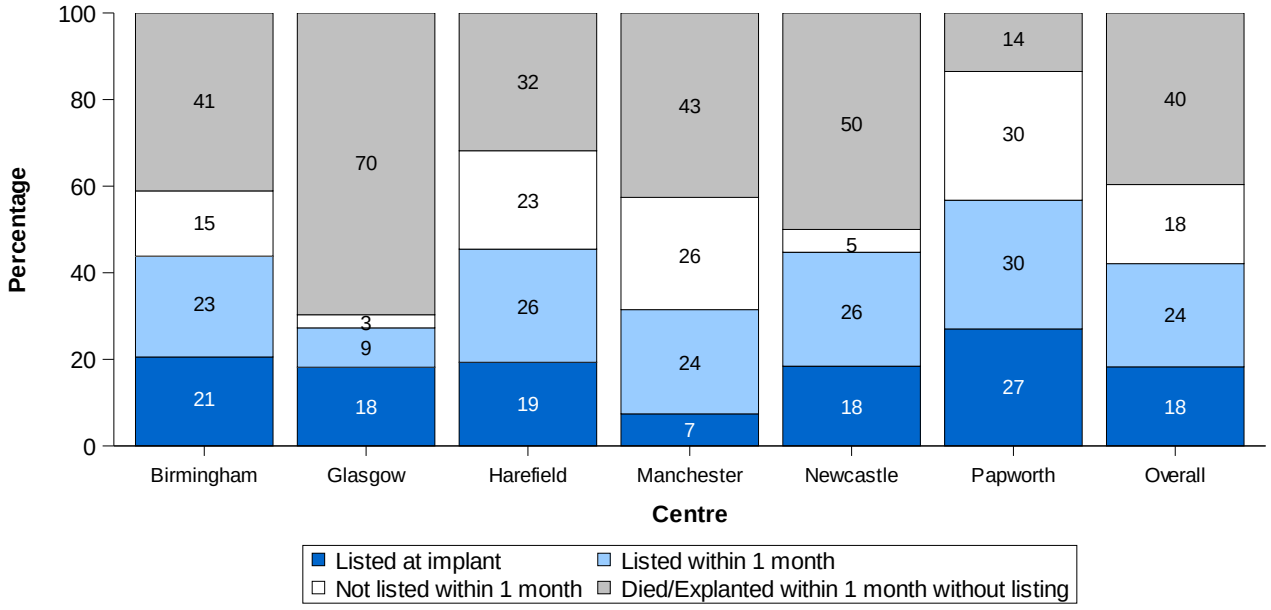


Table 6.3 Heart transplant listing status with respect to short-term device implantation for adult patients receiving a first bridging device 1 April 2016 – 31 March 2020, by centre and overall

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	73	15 (21)	17 (23)	11 (15)	30 (41)
Glasgow	33	6 (18)	3 (9)	1 (3)	23 (70)
Harefield	88	17 (19)	23 (26)	20 (23)	28 (32)
Manchester	54	4 (7)	13 (24)	14 (26)	23 (43)
Newcastle	38	7 (18)	10 (26)	2 (5)	19 (50)
Papworth	37	10 (27)	11 (30)	11 (30)	5 (14)
Overall	**323**	**59 (18)**	**77 (24)**	**59 (18)**	**128 (40)**

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 2016 and 31 March 2020. 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, nationally, one month after receipt of a short-term device, 19% of patients were explanted, 27% died on short-term support, 24% remained alive on support, 15% received a transplant, and 16% 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 6%.

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 2016 to 31 March 2020

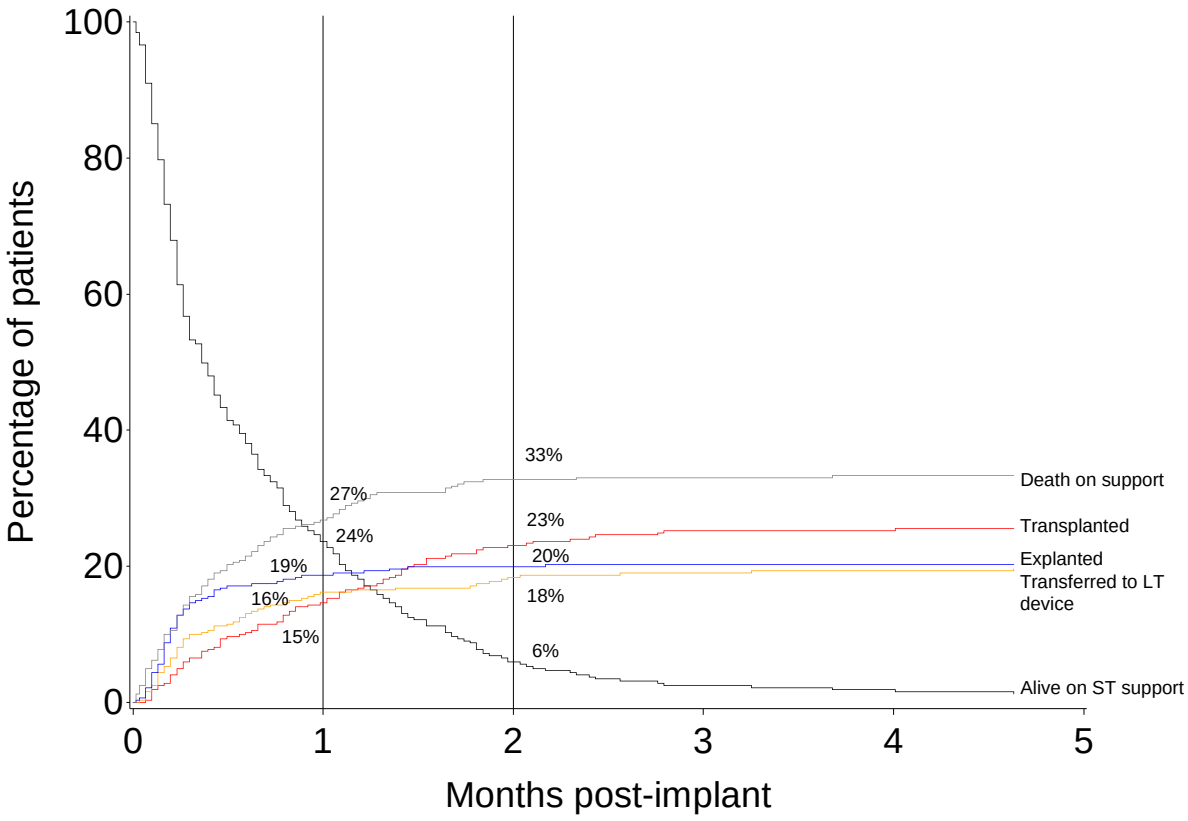


Table 6.4 shows the centre-specific 30-day estimates for each competing outcome. The incidence of each outcome varies across centres.

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 2016 to 31 March 2020

Centre	Number of patients	Transplanted %	Transferred to LT device %	Explanted %	Alive on support %	Death on support %
Birmingham	73	18	21	13	15	33
Glasgow	33	3	0	42	21	33
Harefield	88	14	30	13	22	23
Manchester	54	15	4	15	39	28
Newcastle	38	8	22	46	0	24
Papworth	37	27	3	3	49	19
Overall	**323**	**15**	**16**	**19**	**24**	**27**

6.5 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 2016 and 31 March 2020. In **Tables 6.6**-**6.8** and **Figures 6.4**-**6.6** 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 6.5** which displays the baseline characteristics of the 242 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 242 patients in this analysis are shown below in **Table 6.5**, by centre and overall. Nationally, 73% of patients were male, the median age was 46 years and 38% of patients received ventricular assist (Centrimag) devices. Note that for some characteristics, particularly pre-implant lactate, there is a high proportion of missing data. Also, due to rounding, percentages may not add up to 100.

Table 6.5 Characteristics of patients who received short-term bridging support only between 1 April 2016 and 31 March 2020, by centre

		Birmingham N (%)	Glasgow N (%)	Harefield N (%)	Manchester N (%)	Newcastle N (%)	Papworth N (%)	**Total N (%)**
Number of patients		53	33	48	49	27	32	**242**
Age at implant (years)	Median (IQR)	43 (28-55)	49 (40-57)	49 (36-58)	43 (32-51)	48 (30-60)	47 (31-53)	**46 (32-55)**
	Missing	0	0	1	0	0	0	**1**
Sex	Male	38 (72)	26 (79)	38 (79)	32 (65)	18 (67)	25 (78)	**177 (73)**
	Female	15 (28)	7 (21)	10 (21)	17 (35)	9 (33)	7 (22)	**65 (27)**
Primary disease	Dilated cardiomyopathy	32 (60)	11 (33)	31 (65)	27 (55)	14 (52)	18 (56)	**133 (55)**
	Ischaemic heart disease	7 (13)	13 (39)	10 (21)	13 (27)	6 (22)	9 (28)	**58 (24)**
	Congenital heart disease	3 (6)	0 (0)	0 (0)	0 (0)	1 (4)	0 (0)	**4 (2)**
	Hypertrophic cardiomyopathy	0 (0)	0 (0)	1 (2)	1 (2)	1 (4)	1 (3)	**4 (2)**
	Valvular heart disease	1 (2)	1 (3)	1 (2)	2 (4)	0 (0)	1 (3)	**6 (2)**
	Infiltrative heart muscle disease	1 (2)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	**2 (1)**
	Other	7 (13)	6 (18)	4 (8)	5 (10)	5 (19)	2 (6)	**29 (12)**
	Unknown	2 (4)	2 (6)	1 (2)	0 (0)	0 (0)	1 (3)	**6 (2)**
INTERMACS patient profile	1. Critical cardiogenic shock	37 (70)	26 (79)	35 (73)	42 (86)	17 (63)	21 (66)	**178 (74)**
	2. Progressive decline	15 (28)	6 (18)	12 (25)	6 (12)	10 (37)	10 (31)	**59 (24)**
	3. Stable but inotrope dependent	0 (0)	1 (3)	0 (0)	1 (2)	0 (0)	1 (3)	**3 (1)**
	4. Recurrent advanced heart failure	0 (0)	0 (0)	1 (2)	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	16 (30)	0 (0)	30 (63)	0 (0)	2 (7)	0 (0)	**48 (20)**
	Ventricular assist (Centrimag)	24 (45)	11 (33)	1 (2)	33 (67)	0 (0)	24 (75)	**93 (38)**
	Peripheral ECMO	9 (17)	20 (61)	15 (31)	8 (16)	22 (81)	5 (16)	**79 (33)**
	Central ECMO	4 (8)	2 (6)	2 (4)	8 (16)	3 (11)	3 (9)	**22 (9)**

Table 6.5 Characteristics of patients who received short-term bridging support only between 1 April 2016 and 31 March 2020, by centre

		Birmingham N (%)	Glasgow N (%)	Harefield N (%)	Manchester N (%)	Newcastle N (%)	Papworth N (%)	**Total N (%)**
Pre-implant serum creatinine (umol/l)	Median (IQR)[1]	123 (93-164)	142 (94-200)	135 (93-164)	119 (107-133)	-	113 (95-149)	**124 (95-162)**
	Missing	3	9	0	17	25	4	**58**
Pre-implant serum bilirubin (umol/l)	Median (IQR)[1]	29 (16-47)	14 (8-26)	27 (14-49)	28 (14-54)	-	28 (13-36)	**25 (12-43)**
	Missing	4	10	1	23	27	10	**75**
Pre-implant lactate (mmol/l)	Median (IQR)[1]	4 (3-8)	-	3 (2-5)	-	-	-	**3 (2-7)**
	Missing	34	28	37	47	27	32	**205**
Pre-implant cardiac arrest	No	43 (81)	18 (55)	40 (83)	36 (73)	20 (74)	27 (84)	**184 (76)**
	Yes	10 (19)	15 (45)	8 (17)	13 (27)	7 (26)	5 (16)	**58 (24)**
Pre-implant intubation and ventilation	No	38 (72)	25 (76)	31 (65)	29 (59)	9 (33)	27 (84)	**159 (66)**
	Yes	15 (28)	8 (24)	17 (35)	20 (41)	18 (67)	5 (16)	**83 (34)**
Pre-implant renal replacement therapy	No	51 (96)	32 (97)	41 (85)	40 (82)	17 (63)	21 (66)	**202 (83)**
	Yes	2 (4)	1 (3)	7 (15)	9 (18)	10 (37)	11 (34)	**40 (17)**

[1] Medians not presented for centres with less than 10 observations reported

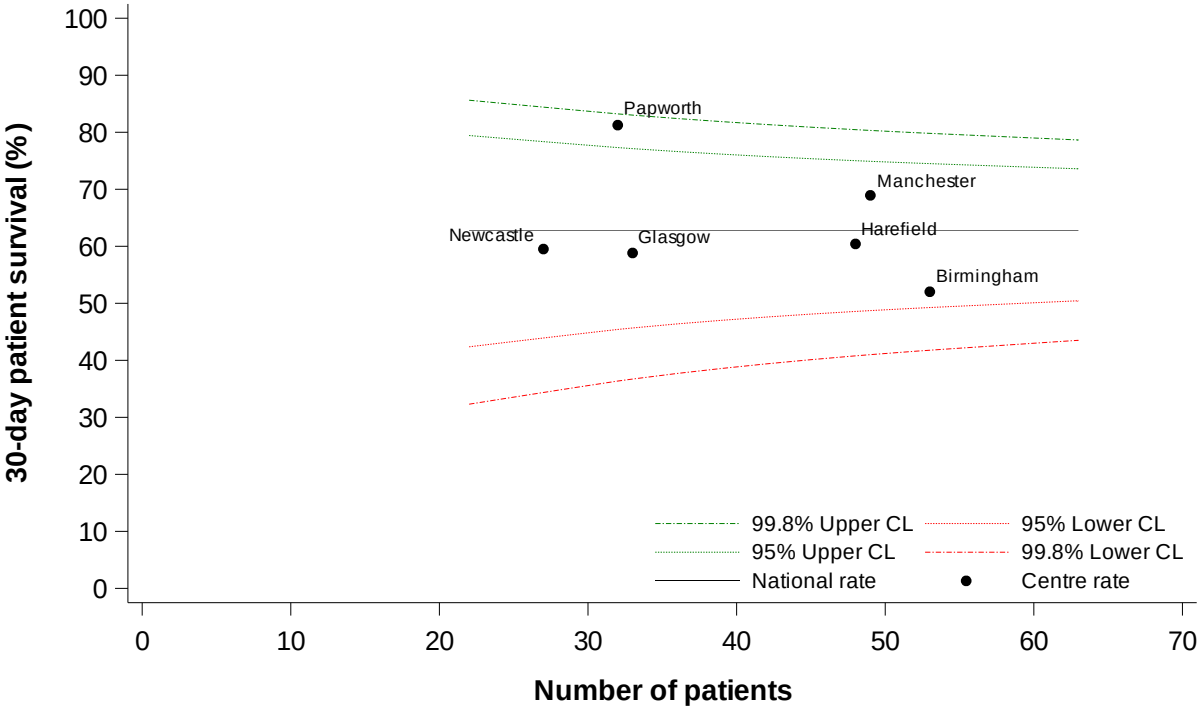
The unadjusted centre-specific 30-day survival rates for patients receiving short-term support are shown in **Table 6.6** and **Figure 6.4**. The rate for Papworth exceeded the upper 95% confidence limit, indicating some evidence of a significantly higher unadjusted rate.

Table 6.6 30-day patient survival rates after short-term bridging device implant for adult patients implanted 1 April 2016 – 31 March 2020, by centre

Centre	Number of patients	% 30-day survival (95% CI) Unadjusted	
Birmingham	53	52.0	(37.8 - 64.5)
Glasgow	33	58.8	(37.1 - 75.3)
Harefield	48	60.4	(45.2 - 72.6)
Manchester	49	68.9	(53.8 - 80.0)
Newcastle	27	59.5	(37.7 - 75.9)
Papworth	32	81.3	(62.9 - 91.1)
UK	**242**	**62.7**	**(56.1 - 68.6)**

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 6.4 Unadjusted 30-day patient survival rates after short-term bridging device implant for adult patients implanted 1 April 2016 – 31 March 2020, by centre



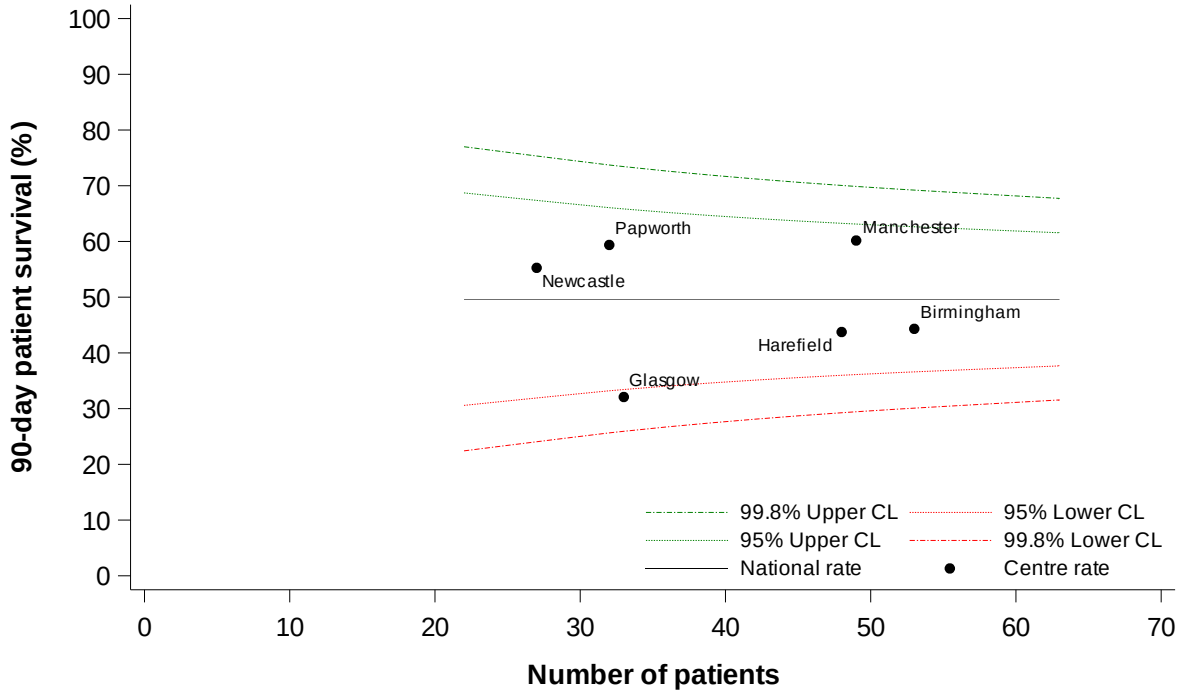
The unadjusted centre-specific 90-day survival rates are shown in **Table 6.7** and **Figure 6.5**. The national rate of survival was 49.6%, and there was some evidence of a lower rate at Glasgow.

Table 6.7 90-day patient survival rates after short-term bridging device implant for adult patients implanted 1 April 2016 – 31 March 2020, by centre

Centre	Number of patients	% 90-day survival (95% CI) Unadjusted	
Birmingham	53	44.3	(30.6 - 57.1)
Glasgow	33	32.1	(13.8 - 52.1)
Harefield	48	43.8	(29.6 - 57.1)
Manchester	49	60.2	(44.8 - 72.5)
Newcastle	27	55.3	(33.8 - 72.3)
Papworth	32	59.4	(40.5 - 74.0)
UK	**242**	**49.6**	**(42.9 - 55.9)**

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

Figure 6.5 Unadjusted 90-day patient survival rates after short-term bridging device implant for adult patients implanted 1 April 2016 – 31 March 2020, by centre



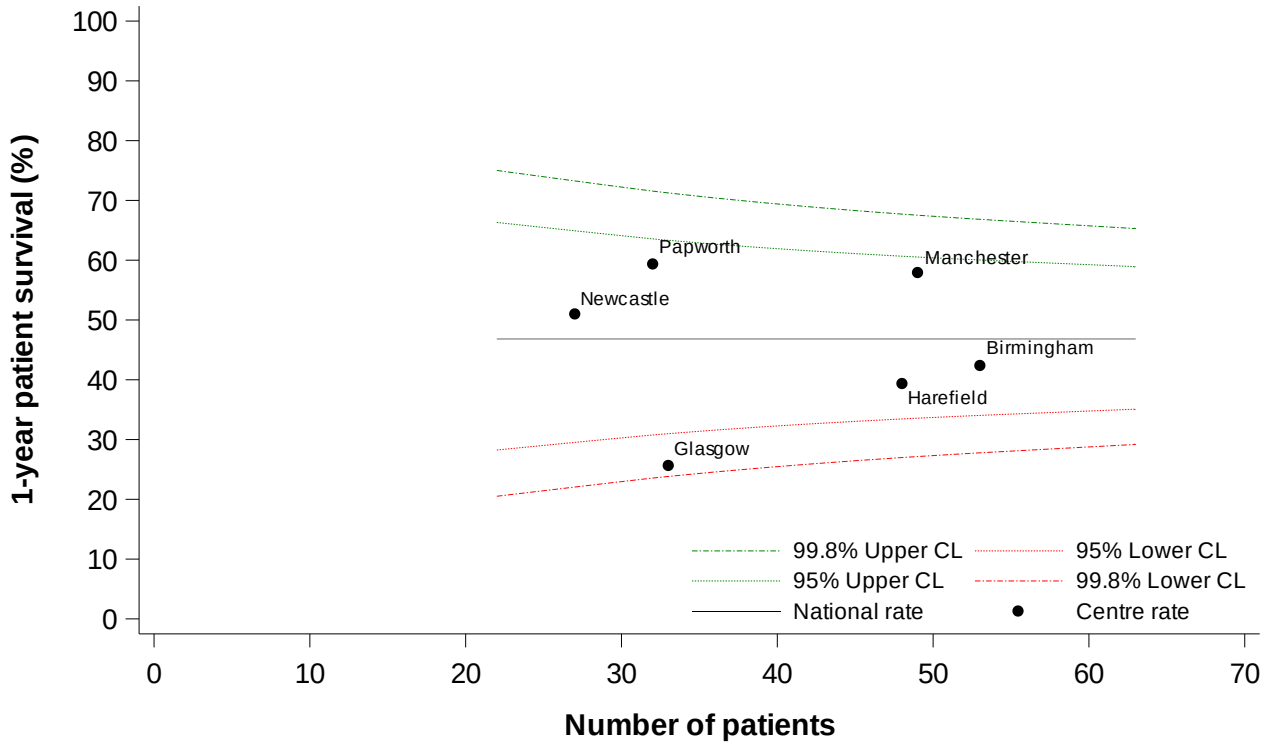
The unadjusted centre-specific 1-year survival rates are shown in **Table 6.8** and **Figure 6.6**. The national rate of survival was 46.8%, and there was some evidence of a lower rate at Glasgow.

Table 6.8 1-year patient survival rates after short-term bridging device implant for adult patients implanted 1 April 2016 – 31 March 2020, by centre

Centre	Number of patients	% 1-year survival (95% CI) Unadjusted	
Birmingham	53	42.4	(28.9 - 55.3)
Glasgow	33	25.7	(9.1 - 46.2)
Harefield	48	39.6	(25.9 – 53.0)
Manchester	49	57.9	(42.6 - 70.5)
Newcastle	27	51.0	(30.0 - 68.7)
Papworth	32	59.4	(40.5 - 74.0)
UK	**242**	**46.8**	**(40.2 - 53.2)**

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

Figure 6.6 Unadjusted 1-year patient survival rates after short-term bridging device implant for adult patients implanted 1 April 2016 – 31 March 2020, 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 (17 recorded in the time period) as are long-term devices used post-transplant (counted as bridging devices). Two 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 2020/2021 there were 43 implants: 19% higher than 2019/2020 and 2.5 times higher than in 2011/2012. 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 implanted the most devices for PGD in 2020/2021.

Figure 7.1 Number of adult short-term device implants for PGD in the UK, by financial year and device type, 1 April 2011 to 31 March 2021

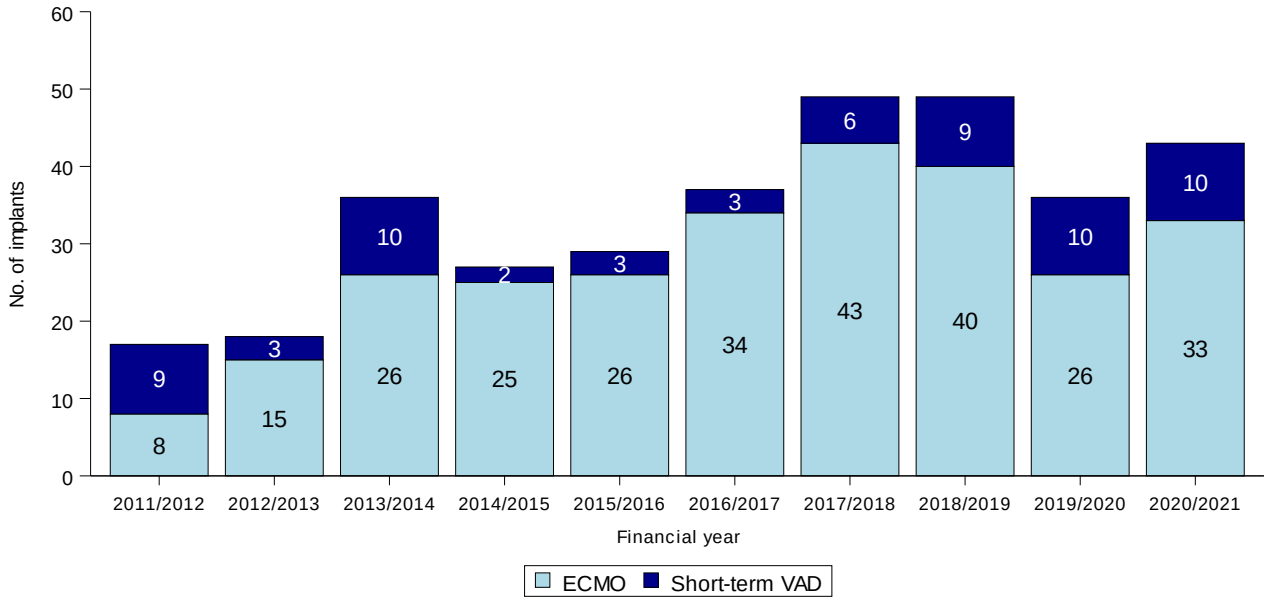


Figure 7.2 Number of adult short-term device implants for PGD in the UK, by financial year, centre and device type, 1 April 2011 to 31 March 2021

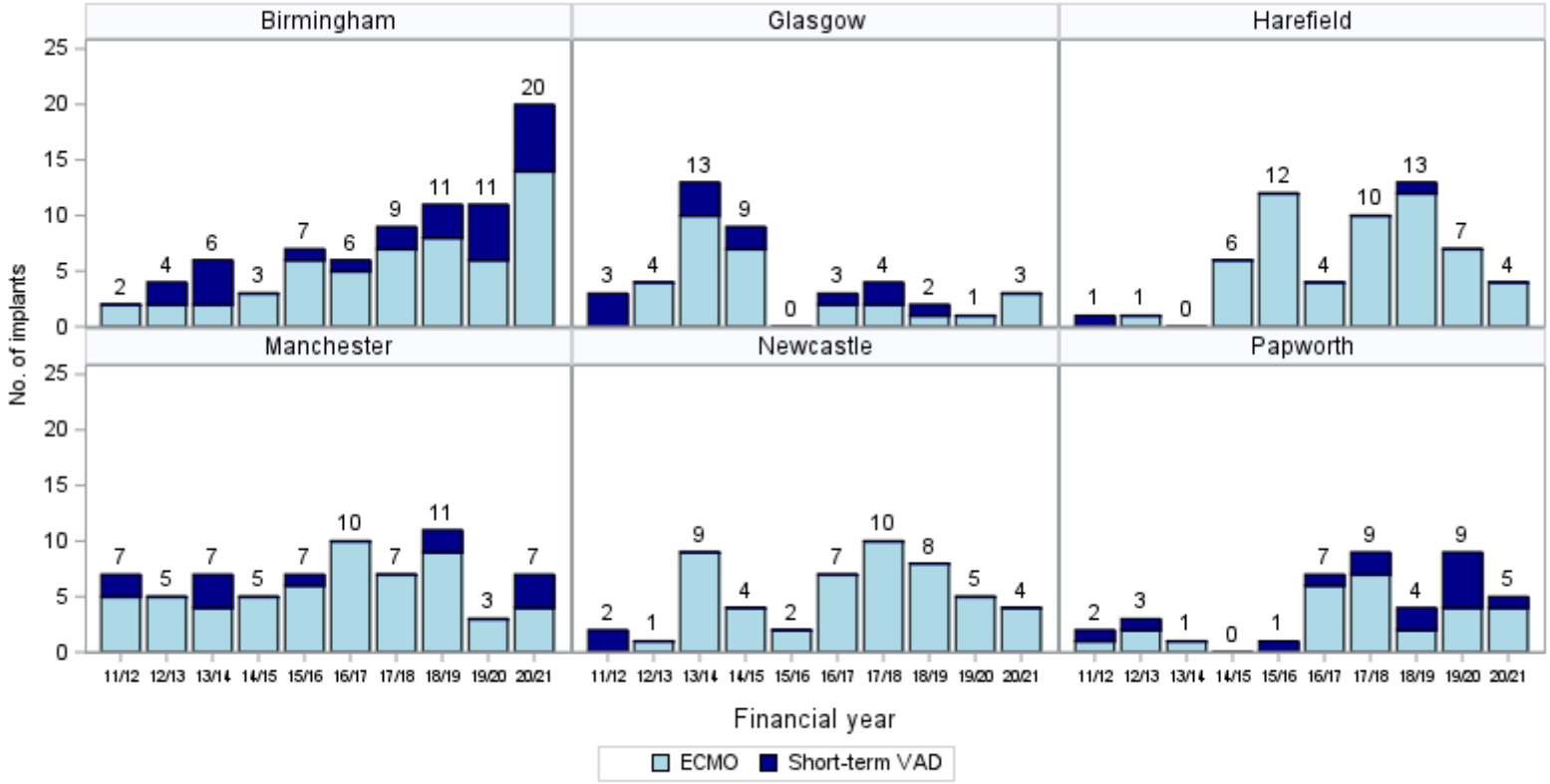
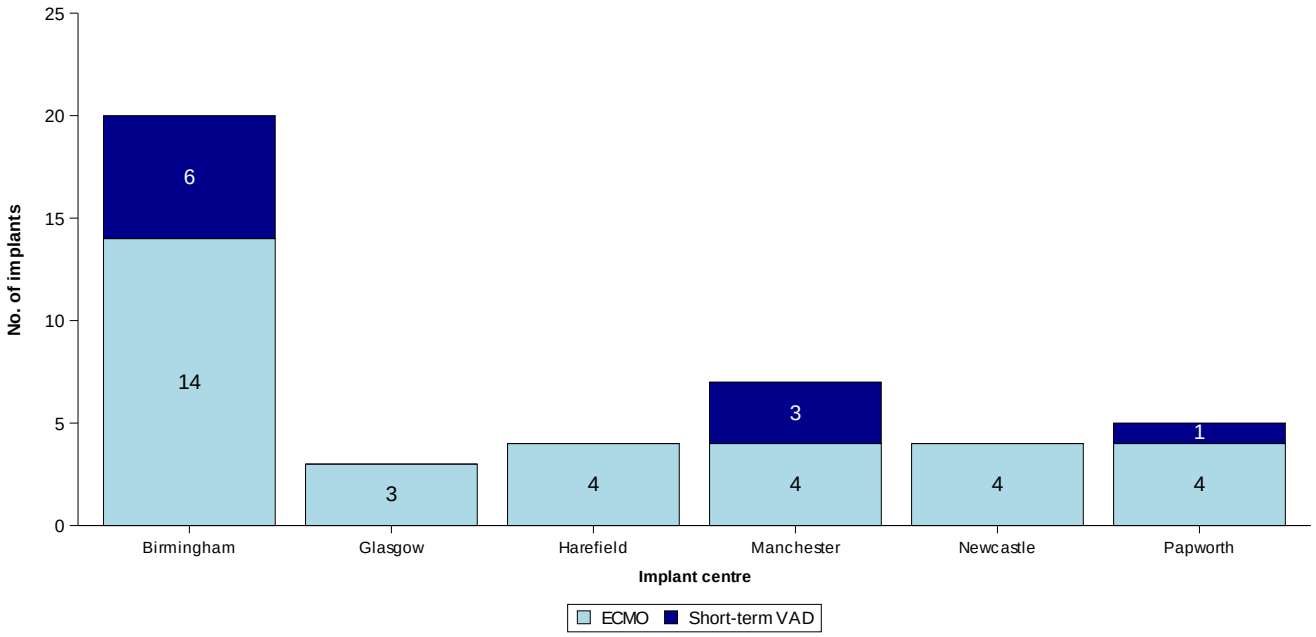


Figure 7.3 Number of adult short-term device implants for PGD in the UK, by centre and device type, 1 April 2020 to 31 March 2021



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 142 patients analysed in this section are shown in **Table 8.1**, by centre and overall. Nationally, 76% of patients were in hospital pre-transplant, the median age was 48 years and 62% 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 adult patients receiving short-term support for PGD between 1 April 2016 and 31 March 2020, by centre

		Birmingham N (%)	Glasgow N (%)	Harefield N (%)	Manchester N (%)	Newcastle N (%)	Papworth N (%)	**Total N (%)**
Number of patients		27	8	30	30	26	21	**142**
Urgency at transplant	Non-urgent	2 (7)	2 (25)	3 (10)	4 (13)	5 (19)	8 (38)	**24 (17)**
	Urgent	21 (78)	3 (38)	22 (73)	17 (57)	16 (62)	7 (33)	**86 (61)**
	Super-urgent	4 (15)	3 (38)	5 (17)	9 (30)	5 (19)	6 (29)	**32 (23)**
Recipient age at transplant (years)	Median (IQR)[1]	50 (36-59)	-	44 (26-56)	46 (37-56)	41 (32-52)	50 (35-57)	**48 (34-56)**
	Missing	0	0	0	0	0	0	**0**
Diabetes at registration	No	23 (85)	5 (63)	30 (100)	28 (93)	25 (96)	15 (71)	**126 (89)**
	Yes	4 (15)	0 (0)	0 (0)	2 (7)	1 (4)	5 (24)	**12 (8)**
	Missing	0 (0)	3 (38)	0 (0)	0 (0)	0 (0)	1 (5)	**4 (3)**
Recipient primary disease at registration	Coronary heart disease	1 (4)	2 (25)	3 (10)	7 (23)	0 (0)	7 (33)	**20 (14)**
	Cardiomyopathy	22 (81)	6 (75)	19 (63)	19 (63)	17 (65)	11 (52)	**94 (66)**
	Congenital heart disease	3 (11)	0 (0)	2 (7)	0 (0)	9 (35)	1 (5)	**15 (11)**
	Graft failure/Rejection	0 (0)	0 (0)	2 (7)	0 (0)	0 (0)	0 (0)	**2 (1)**
	Other	1 (4)	0 (0)	4 (13)	4 (13)	0 (0)	2 (10)	**11 (8)**

Table 8.1 Characteristics of adult patients receiving short-term support for PGD between 1 April 2016 and 31 March 2020, by centre

		Birmingham N (%)	Glasgow N (%)	Harefield N (%)	Manchester N (%)	Newcastle N (%)	Papworth N (%)	**Total N (%)**
Recipient BMI (kg/m^2)	Median (IQR)[1]	26 (24-29)	-	27 (22-29)	25 (23-27)	25 (22-28)	27 (23-30)	**26 (23-29)**
	Missing	0	0	0	1	0	0	**1**
In hospital at transplant	No	4 (15)	2 (25)	7 (23)	4 (13)	9 (35)	8 (38)	**34 (24)**
	Yes	23 (85)	6 (75)	23 (77)	26 (87)	17 (65)	13 (62)	**108 (76)**
If in hospital, recipient on inotropes	No	6 (26)	3 (50)	4 (17)	15 (58)	2 (12)	7 (54)	**37 (34)**
	Yes	17 (74)	3 (50)	19 (83)	11 (42)	14 (82)	6 (46)	**70 (65)**
	Unknown	0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	**1 (1)**
If in hospital, recipient on VAD	None	14 (61)	2 (33)	19 (83)	13 (50)	10 (59)	7 (54)	**65 (60)**
	LVAD	3 (13)	2 (33)	4 (17)	3 (12)	5 (29)	1 (8)	**18 (17)**
	RVAD	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	**1 (1)**
	BiVAD	6 (26)	2 (33)	0 (0)	10 (38)	1 (6)	4 (31)	**23 (21)**
	Missing	0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	**1 (1)**
If in hospital, recipient on TAH	No	23 (100)	5 (83)	20 (87)	26 (100)	16 (94)	13 (100)	**103 (95)**
	Yes	0 (0)	0 (0)	3 (13)	0 (0)	0 (0)	0 (0)	**3 (3)**
	Unknown	0 (0)	1 (17)	0 (0)	0 (0)	1 (6)	0 (0)	**2 (2)**
If in hospital, recipient on ECMO	No	21 (91)	5 (83)	20 (87)	26 (100)	14 (82)	11 (85)	**97 (90)**
	Yes	2 (9)	1 (17)	3 (13)	0 (0)	2 (12)	2 (15)	**10 (9)**
	Unknown	0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	**1 (1)**
If in hospital, recipient on IABP	No	22 (96)	4 (67)	23 (100)	24 (92)	16 (94)	13 (100)	**102 (94)**
	Yes	1 (4)	2 (33)	0 (0)	2 (8)	0 (0)	0 (0)	**5 (5)**
	Unknown	0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)	**1 (1)**
Recipient serum creatinine (umol/l)	Median (IQR)[1]	118 (75-163)	-	83 (69-110)	89 (72-108)	131 (94-142)	96 (76-119)	**101 (75-130)**
	Missing	0	0	0	0	1	0	**1**
Donor cause of death	CVA	20 (74)	8 (100)	27 (90)	23 (77)	19 (73)	16 (76)	**113 (80)**
	Trauma	1 (4)	0 (0)	1 (3)	5 (17)	2 (8)	2 (10)	**11 (8)**
	Other	6 (22)	0 (0)	2 (7)	2 (7)	5 (19)	3 (14)	**18 (13)**
Donor age (years)	Median (IQR)	38 (27-53)	-	36 (24-47)	32 (24-47)	39 (26-46)	35 (31-44)	**36 (26-47)**
	Missing	0	0	0	0	0	0	**0**

Table 8.1 Characteristics of adult patients receiving short-term support for PGD between 1 April 2016 and 31 March 2020, by centre

		Birmingham N (%)	Glasgow N (%)	Harefield N (%)	Manchester N (%)	Newcastle N (%)	Papworth N (%)	**Total N (%)**
Donor BMI (kg/m^2)	Median (IQR)[1]	26 (23-29)	-	25 (22-27)	24 (22-27)	26 (24-29)	24 (23-29)	**25 (23-29)**
	Missing	0	0	0	0	0	0	**0**
Donor past smoker	No	13 (48)	5 (63)	13 (43)	16 (53)	8 (31)	5 (24)	**60 (42)**
	Yes	14 (52)	3 (38)	15 (50)	14 (47)	16 (62)	16 (76)	**78 (55)**
	Unknown	0 (0)	0 (0)	2 (7)	0 (0)	2 (8)	0 (0)	**4 (3)**
Donor:Recipient sex mismatch	RF:DF	7 (26)	1 (13)	10 (33)	6 (20)	5 (19)	4 (19)	**33 (23)**
	RF:DM	2 (7)	0 (0)	3 (10)	2 (7)	4 (15)	2 (10)	**13 (9)**
	RM:DM	18 (67)	7 (88)	14 (47)	17 (57)	16 (62)	15 (71)	**87 (61)**
	RM:DF	0 (0)	0 (0)	3 (10)	5 (17)	1 (4)	0 (0)	**9 (6)**
Total ischaemia time (hours)	Median (IQR)	3.5 (2.7-3.7)	-	5.4 (4.7-6.2)	2.9 (2.5-3.4)	3.5 (3.1-4)	3.7 (3-5)	**3.5 (2.9-5.2)**
	Missing	1	0	0	0	1	0	**2**
Type of support	Ventricular assist (Centrimag)	3 (11)	2 (25)	0 (0)	1 (3)	0 (0)	4 (19)	**10 (7)**
	Peripheral ECMO	6 (22)	2 (25)	9 (30)	14 (47)	11 (42)	2 (10)	**44 (31)**
	Central ECMO	18 (67)	4 (50)	21 (70)	15 (50)	15 (58)	15 (71)	**88 (62)**

[1] Medians not presented for centres with less than 10 patients

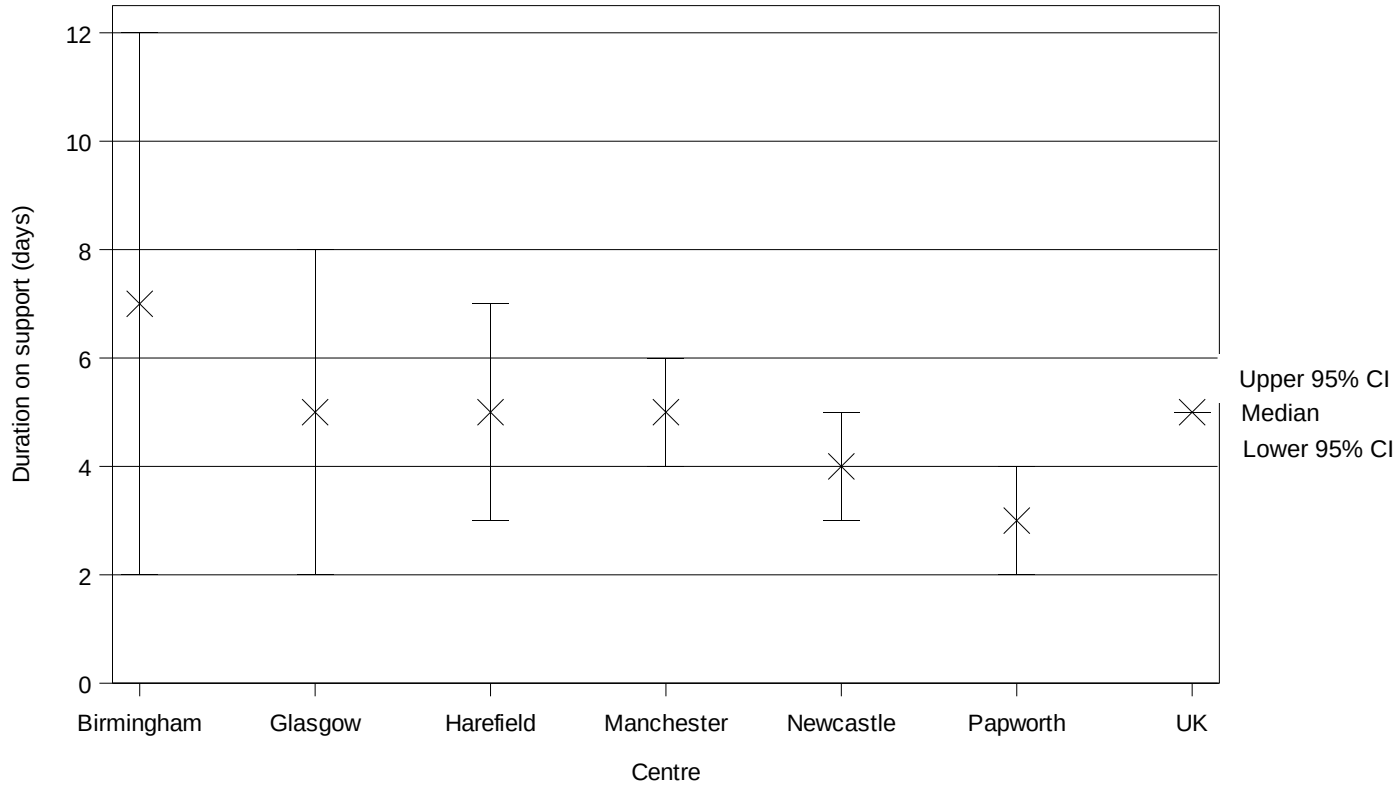
8.2 Duration on support

Table 8.2 and **Figure 8.1** show the median duration on short-term support for patients implanted in the analysis 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 2016 and 31 March 2020, by centre

Centre	Number of patients	Time of support (days) Median	(95% confidence interval)
Birmingham	27	7	2 - 12
Glasgow	8	5	2 - 8
Harefield	30	5	3 - 7
Manchester	30	5	4 - 6
Newcastle	26	4	3 - 5
Papworth	21	3	2 - 4
Overall	**142**	**5**	**5 - 5**

Figure 8.1 Median duration on short-term device support for PGD for adult patients implanted between 1 April 2016 and 31 March 2020



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. If the patient was re-transplanted, any subsequent survival time is included. The rates are estimated at 30 days, 90 days and 1 year and are based on the 143 patients recorded as receiving a short-term device for PGD between 1 April 2016 and 31 March 2020. 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 72.4%, 62.4% and 56.1%, respectively.

Table 8.3 30-day patient survival rates after short-term device implant for PGD for adult patients implanted 1 April 2016 – 31 March 2020, by centre

Centre	Number of patients	Number of deaths	% 30-day survival (95% CI) Unadjusted	
Birmingham	27	7	74.1	(53.2 - 86.7)
Glasgow[1]	8	3	-	-
Harefield	30	9	65.7	(45.6 - 79.9)
Manchester	30	4	86.7	(68.3 - 94.8)
Newcastle	26	5	80.8	(59.8 - 91.5)
Papworth	21	8	57.1	(33.8 - 74.9)
UK	**142**	**36**	**72.4**	**(64.2 - 79.0)**

[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 2016 – 31 March 2020, by centre

Centre	Number of patients	Number of deaths	% 90-day survival (95% CI) Unadjusted	
Birmingham	27	9	66.7	(45.7 - 81.1)
Glasgow[1]	8	4	-	-
Harefield	30	13	51.9	(32.6 - 68)
Manchester	30	8	73.3	(53.7 - 85.7)
Newcastle	26	8	69.2	(47.8 - 83.3)
Papworth	21	10	52.4	(29.7 - 70.9)
UK	**142**	**52**	**62.4**	**(53.9 - 69.8)**

[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 2016 – 31 March 2020, by centre

Centre	Number of patients	Number of deaths	% 1-year survival (95% CI) Unadjusted	
Birmingham	27	10	63	(42.1 - 78.1)
Glasgow[1]	8	4	-	-
Harefield	30	17	41.5	(23.7 - 58.4)
Manchester	30	10	66.7	(46.9 - 80.5)
Newcastle	26	10	61.5	(40.3 - 77.1)
Papworth	21	11	47.6	(25.7 - 66.7)
UK	**142**	**62**	**56.1**	**(47.5 - 63.8)**

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

PAEDIATRIC DEVICES USED FOR BRIDGING

Activity

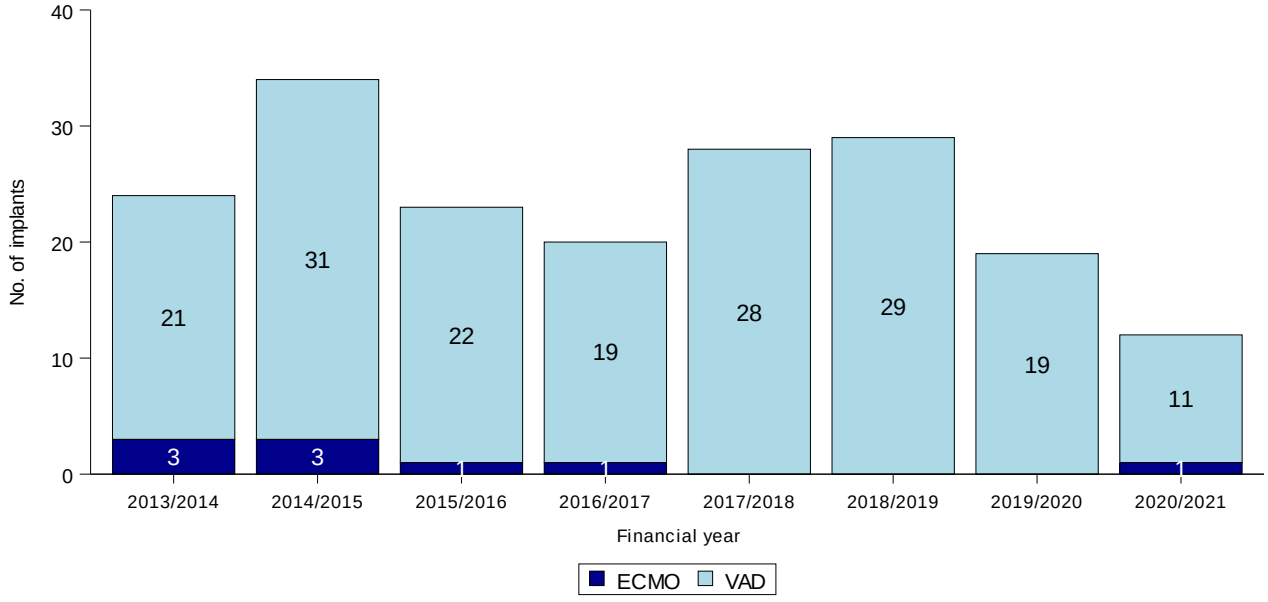
Note that the data in this section are incomplete. ECMO has been underreported for paediatric patients during this period. Efforts are underway to improve the data collection for future reports.

9 Mechanical circulatory support in paediatrics

This section considers all paediatric (aged less than 16 years) patients who received mechanical circulatory support as a bridge to heart transplantation between 1 April 2013 and 31 March 2021, as reported to the VAD Database by 8 February 2022. 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).

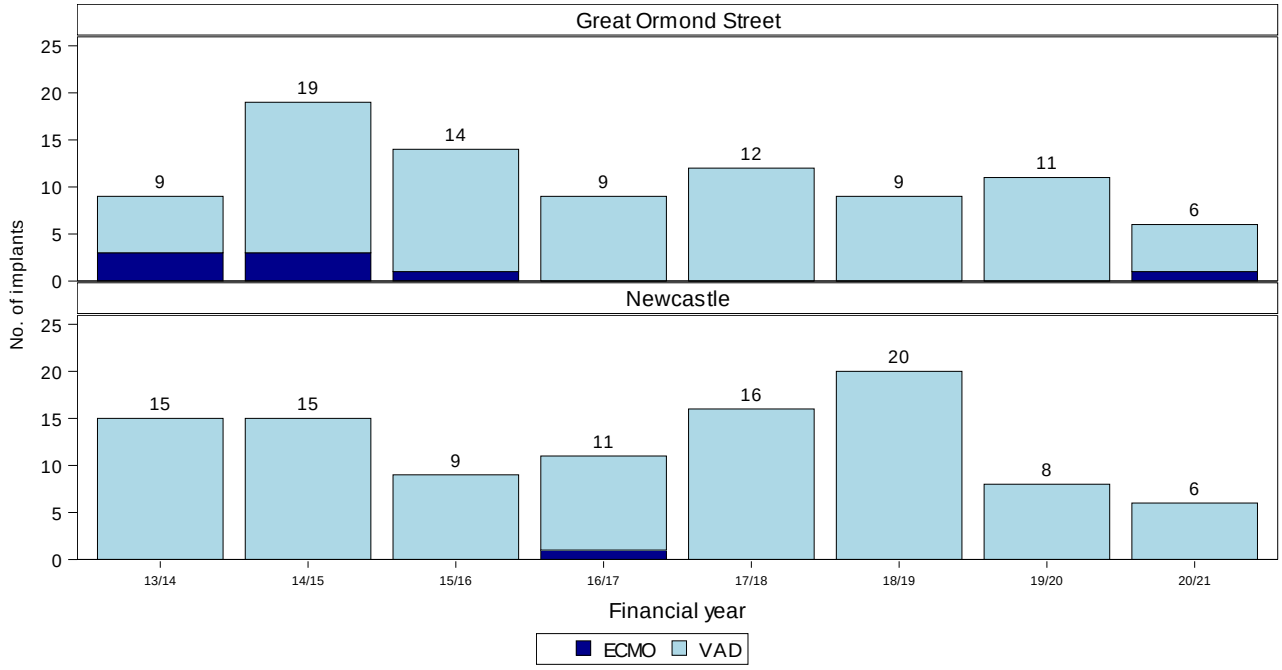
Figure 9.1 shows the total number of bridging device implants each year nationally by device type (VAD and ECMO). During 2020/2021 there were 12 implants: 7 fewer than 2019/2020. The highest activity was recorded in 2014/2015. Overall, there were 189 implants, with VAD implants making up 95%. **Figure 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 2021



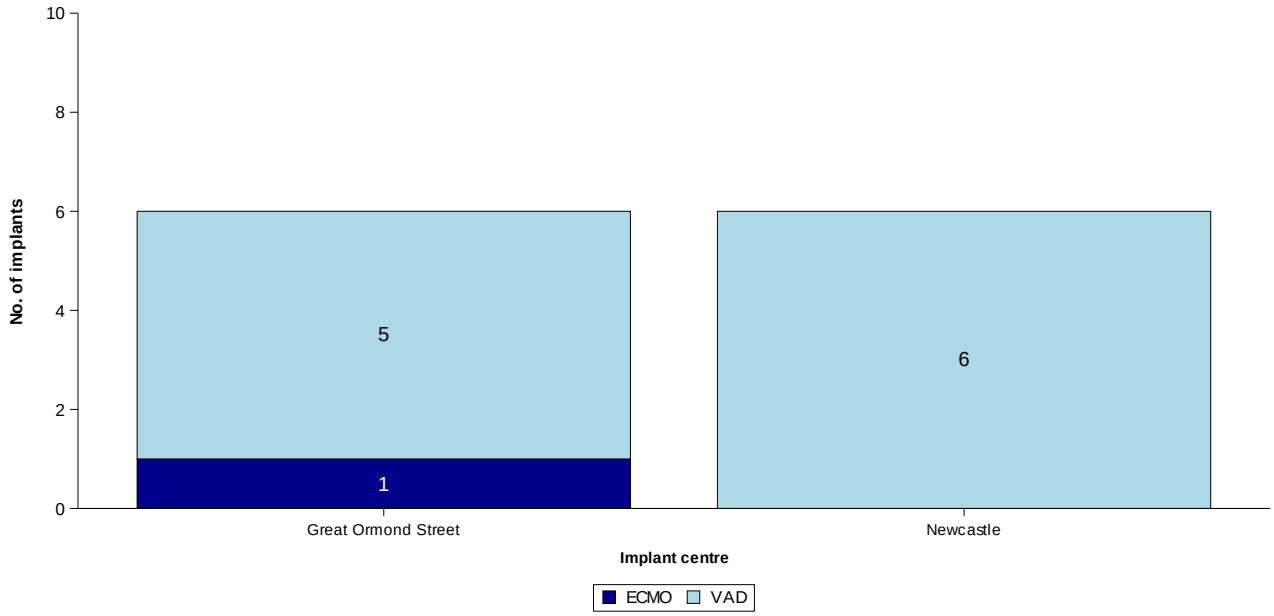
Note: ECMO reporting for paediatric patients is incomplete for this period

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 2021



Note: ECMO reporting for paediatric patients is incomplete for this period

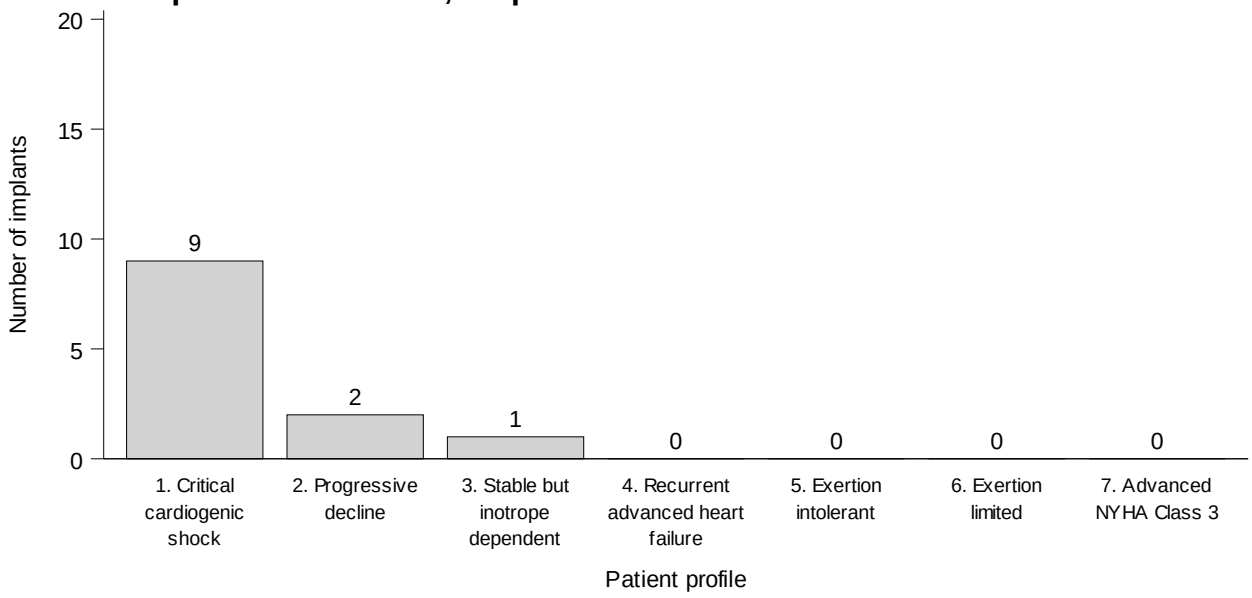
Figure 9.3 Number of paediatric bridging device implants in the UK, by centre and device type, 1 April 2020 to 31 March 2021



Note: ECMO reporting for paediatric patients is incomplete for this period

Figure 9.4 shows the INTERMACS patient profile at implant for paediatric patients implanted during 2020/2021. 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 2020 to 31 March 2021



Note: Number of bridging devices for paediatric patients is incomplete for this period

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 bridging support between 1 April 2016 and 31 March 2020, **however due to underreporting of ECMO in this period the results should be interpreted with caution**. 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 78 patients who received bridging support in the analysis period are shown below in **Table 10.1**, by centre and overall. Nationally, 53% of patients were female, the median age was 3 years and the most common device was Heartware followed by Centrimag. Note that for some characteristics, particularly for Newcastle, there is a high proportion of missing data. Also, due to rounding, percentages may not add up to 100.

Table 10.1 Characteristics of paediatric patients who received a bridging device between 1 April 2016 and 31 March 2020, by centre

		GOSH N (%)	Newcastle N (%)	**Total N (%)**
Number of patients		41	37	**78**
Age at implant (years)	Median (IQR)	4 (2-10)	3 (1-10)	**3 (1-10)**
Sex	Male	19 (46)	18 (49)	**37 (47)**
	Female	22 (54)	19 (51)	**41 (53)**
Primary disease	Dilated cardiomyopathy	28 (68)	27 (73)	**55 (71)**
	Congenital heart disease	2 (5)	6 (16)	**8 (10)**
	Hypertrophic cardiomyopathy	2 (5)	0 (0)	**2 (3)**
	Restrictive cardiomyopathy	5 (12)	0 (0)	**5 (6)**
	Valvular heart disease	1 (2)	0 (0)	**1 (1)**
	Other	2 (5)	4 (11)	**6 (8)**
	Unknown	1 (2)	0 (0)	**1 (1)**
INTERMACS patient profile	1. Critical cardiogenic shock	10 (24)	21 (57)	**31 (40)**
	2. Progressive decline	18 (44)	16 (43)	**34 (44)**
	3. Stable but inotrope dependent	9 (22)	0 (0)	**9 (12)**
	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) [1]	102 (80-143)	-	**102 (80-136)**
	Missing	6	35	**41**
Weight (kg)	Median (IQR) [1]	14 (10-29)	-	**14 (10-28)**
	Missing	4	30	**34**
Body surface area (m^2)	Median (IQR)[1]	0.62 (0.46-1.08)	-	**0.62 (0.46-1.06)**
	Missing	6	35	**41**
First VAD device name	Berlin Heart Excor	17 (41)	0 (0)	**17 (22)**
	Heartware	16 (39)	8 (22)	**24 (31)**
	Centrimag	8 (20)	13 (35)	**21 (27)**
	Centrimag with BH cannulae	0 (0)	15 (41)	**15 (19)**
	ECMO only	0 (0)	1 (3)	**1 (1)**

[1] Medians not presented for centres with less than 10 observations reported

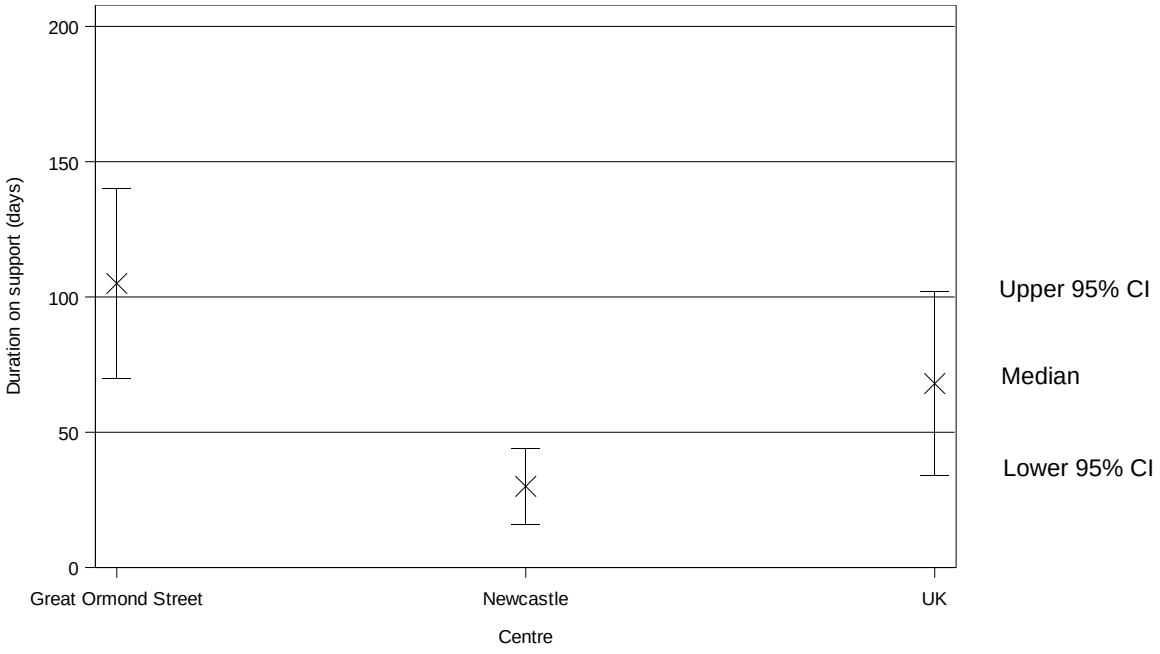
10.2 Duration on support

Table 10.2 and **Figure 10.1** show the median duration on support for patients implanted between 1 April 2016 and 31 March 2020, 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 Hospital (log-rank p=0.004).

Table 10.2 Median duration on support for paediatric patients implanted with a bridging device between 1 April 2016 and 31 March 2020, by centre

Centre	Number of patients	Time on support (days) Median	(95% confidence interval)
Great Ormond Street Hospital	41	105	70 - 140
Newcastle	37	30	16 - 44
Overall	**78**	**68**	**34 - 102**

Figure 10.1 Median duration on support for paediatric patients implanted with a bridging device between 1 April 2016 and 31 March 2020



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 2016 and 31 March 2020 by centre. This includes listing on the super-urgent, urgent or non-urgent heart transplant lists (whichever occurred first). Overall, 59% of patients were on the list at implant, with a further 35% 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 2016 – 31 March 2020, by centre and overall

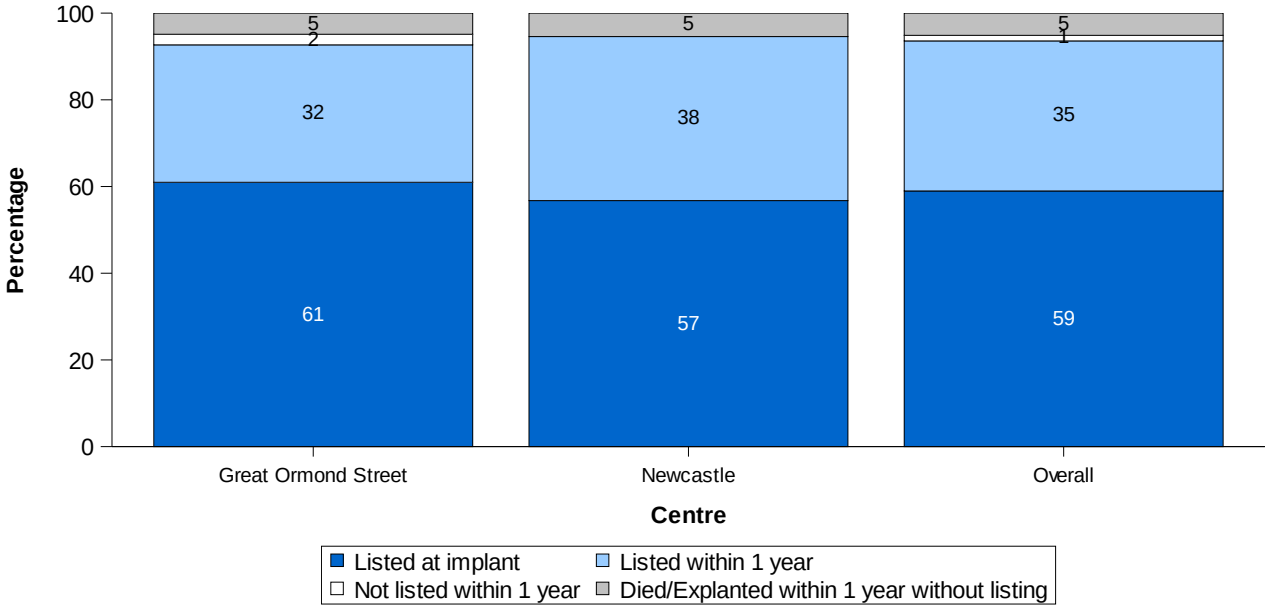


Table 10.3 Heart transplant listing status with respect to bridging device implantation for paediatric patients implanted 1 April 2016 – 31 March 2020, by centre and overall

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	25 (61)	13 (32)	1 (2)	2 (5)
Newcastle	37	21 (57)	14 (38)	0 (0)	2 (5)
Overall	**78**	**46 (59)**	**27 (35)**	**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 implant, for the cohort of paediatric patients receiving a first device between 1 April 2016 and 31 March 2020. 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 device 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 receiving a device, 63% of patients remained alive on support, 21% received a heart transplant, 6% died on support and 10% had their device explanted. At three months, the incidence of transplantation rose to 36%, the incidence of death rose slightly, to 13%, and the proportion explanted remained at 10%, leaving 41% left on support. By six months, 51% had received a heart transplant, 12% were explanted, 15% had died on support, leaving 22% alive on support.

Figure 10.3 Cumulative incidence functions for transplant, death and explant for paediatric patients receiving a bridging device, 1 April 2016 to 31 March 2020

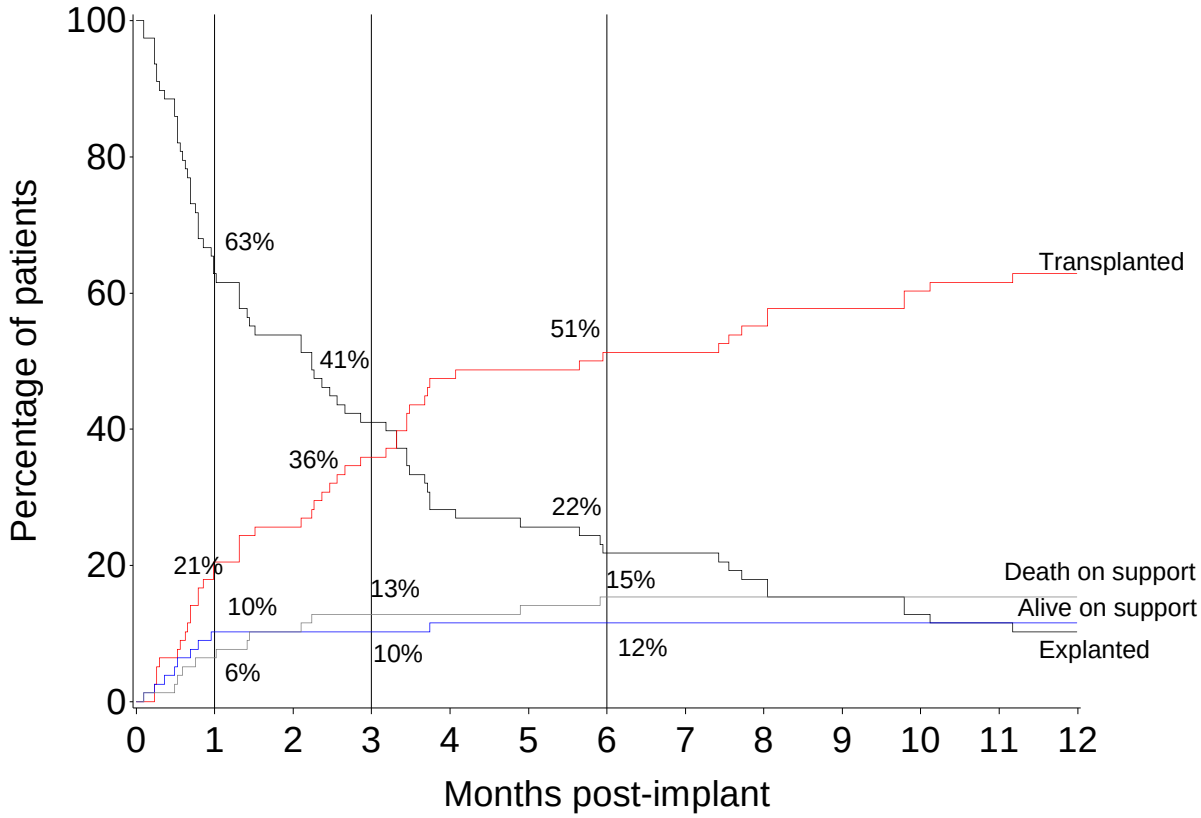


Table 10.4 shows the centre-specific estimates for each competing outcome. A higher proportion of patients had received a transplant by 6 months at Newcastle (59%) compared with Great Ormond Street (44%).

Table 10.4 Cumulative incidence of each outcome, by centre, for paediatric patient implanted with a first patients implanted with a first bridging device, 1 April 2016 to 31 March 2020

Period	Centre	Number of patients	Transplanted %	Explanted %	Alive on support %	Death on support %
30 day	GOSH	41	10	5	80	5
	Newcastle	37	32	16	43	8
	Overall	**78**	**21**	**10**	**63**	**6**
90 day	GOSH	41	29	5	56	10
	Newcastle	37	43	16	27	14
	Overall	**78**	**36**	**10**	**41**	**13**
6 months	GOSH	41	44	7	37	12
	Newcastle	37	59	16	5	19
	Overall	**78**	**51**	**12**	**22**	**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 94.8%, 87.0% and 77.5%, respectively.

Table 10.5	30-day patient survival rates after bridging device implant for paediatric patients implanted 1 April 2016 – 31 March 2020, by centre			
Centre	Number of patients	Number of deaths	% 30-day survival (95% CI) Unadjusted	
Great Ormond Street	41	2	95.1	(81.7 - 98.7)
Newcastle	37	2	94.6	(80.1 - 98.6)
UK	**78**	**4**	**94.8**	**(86.8 - 98.0)**

Table 10.6	90-day patient survival rates after bridging device implant for paediatric patients implanted 1 April 2016 – 31 March 2020, by centre			
Centre	Number of patients	Number of deaths	% 90-day survival (95% CI) Unadjusted	
Great Ormond Street	41	4	90.1	(75.6 - 96.1)
Newcastle	37	6	83.8	(67.4 - 92.4)
UK	**78**	**10**	**87.0**	**(77.3 - 92.8)**

Table 10.7	1-year patient survival rates after bridging device implant for paediatric patients implanted 1 April 2016 – 31 March 2020, by centre			
Centre	Number of patients	Number of deaths	% 1-year survival (95% CI) Unadjusted	
Great Ormond Street	41	5	87.4	(72.3 - 94.6)
Newcastle	37	12	66.7	(48.8 - 79.6)
UK	**78**	**17**	77.5	(66.2 - 85.3)

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 2011 – 31 March 2021	• Introduction/Activity	None	937 implants
1 April 2016 – 31 March 2020	• 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	376 patients
1 April 2011 – 31 March 2021	• TAH outcomes	None	26 patients
Adult – Short-term bridging			
1 April 2011 – 31 March 2021	• Introduction/Activity	None	801 implants
1 April 2016 – 31 March 2020	• Duration on support • Rate of transplant listing • Competing outcomes • Survival on support	• Patients with no follow-up information	323 patients
1 April 2016 – 31 March 2020	• Patient survival from implant	• Patients who had a long-term device before or after the short-term device • Patients with no follow-up information	242 patients
Adult – Short-term post-transplant			
1 April 2011 – 31 March 2021	• Introduction/Activity	• Implants for rejection • Long-term devices used post-transplant	341 implants
1 April 2016 – 31 March 2020	• Duration on support • Patient survival from implant	• Implants for rejection • Long-term devices used post-transplant • Patients with no follow-up information	142 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 2021	• Introduction/Activity	None	189 implants
1 April 2016 – 31 March 2020	• Duration on support • Rate of transplant listing • Competing outcomes • Patient survival from implant	• Patients with no follow-up information	78 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	91	0	91	0 (0)
	Glasgow	4	0	4	0 (0)
	Harefield	89	0	89	1 (1)
	Manchester	58	0	58	4 (7)
	Newcastle	89	0	89	0 (0)
	Papworth	45	0	45	0 (0)
	Overall	**376**	**0**	**376**	**5 (1)**
Adult short-term bridging	Birmingham	73	0	73	1 (1)
	Glasgow	33	0	33	13 (39)
	Harefield	88	0	88	1 (1)
	Manchester	54	0	54	9 (17)
	Newcastle	38	0	38	11 (29)
	Papworth	37	0	37	0 (0)
	Overall	**323**	**0**	**323**	**35 (11)**
Adult post-transplant	Birmingham	27	0	27	0 (0)
	Glasgow	8	0	8	0 (0)
	Harefield	30	0	30	1 (3)
	Manchester	30	0	30	0 (0)
	Newcastle	26	0	26	0 (0)
	Papworth	21	0	21	0 (0)
	Overall	**142**	**0**	**142**	**1 (1)**
Paediatric bridging	Great Ormond Street	41	0	41	5 (12)
	Newcastle	37	0	37	7 (19)
	Overall	**78**	**0**	**78**	**12 (15)**

[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 October 2020

Table A1.4 details the device history of adult patients receiving a device between 1 April 2011 and 31 March 2021 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 explanation 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 2011 – 31 March 2021, by strategy

Device history	No. bridging patients	No. post-transplant patients
LT	666	
LT-ECMO	13	
LT-ECMO-LT	1	
LT-ECMO-ST	2	
LT-ECMO-ST-ST	1	
LT-LT	40	
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	2	
LT/LT-ECMO	1	
LT/LT-LT	1	
LT/LT-LT/ST	1	
LT/ST	2	
TAH	12	
ST	235	27
ST-ECMO	10	1
ST-ECMO-ST	2	
ST-ECMO-ST-LT	1	
ST-LT	40	
ST-LT-LT	2	
ST-LT-LT-ECMO	1	
ST-ST	20	1
ST-ST-ECMO	1	1
ST-ST-ECMO-LT	1	
ST-ST-LT	5	
ST-TAH	2	
ST/ECMO	2	1
ST/ST-ECMO	1	
ECMO	139	213
ECMO-ECMO	4	
ECMO-ECMO-ST		1
ECMO-LT	47	
ECMO-LT-ECMO	1	
ECMO-LT-LT	1	
ECMO-LT-LT-ST	1	
ECMO-ST	59	29
ECMO-ST-ECMO		2
ECMO-ST-LT	14	
ECMO-ST-ST	3	1
ECMO-ST-ST-ST	1	
ECMO-ST-ST-ST-ST	1	
ECMO-ST-TAH	1	
ECMO-ST/LT	1	
ECMO-ST/ST		1
ECMO-ST/TAH	1	
ECMO-TAH	8	
ECMO/ECMO	3	12
ECMO/ECMO-ST	1	
ECMO/ECMO/ECMO/ECMO		1
ECMO/LT	4	
ECMO/ST	1	2
Overall	**1369**	**293**

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 2021

Device history	No. of patients
BH	52
BH/BH	1
BH/ECMO-BH	1
HVAD	42
HVAD-CM-CM	1
HVAD-HVAD	1
CM	42
CM-BH	7
CM-BH-CM	1
CM-BH-CM-BH	1
CM-BH/CM	1
CM-CM	1
CM/CM	2
ECMO	3
ECMO-BH	4
ECMO-CM	1
ECMO-HVAD	1
Overall	**162**

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-2019 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 Research, NHS Blood and Transplant

Lewis Downward
Rachel Hogg
Sally Rushton

Cardiothoracic Advisory Group (CTAG) Clinical Audit Group