NHS
Blood and Transplant

ANNUAL REPORT ON MECHANICAL CIRCULATORY SUPPORT RELATED TO HEART TRANSPLANTATION

REPORT FOR 2016/2017
(1 APRIL 2007 – 31 MARCH 2017)

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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 extracorporeal membrane oxygenation (ECMO). The period reported covers 10 years of MCS activity, from 1 April 2007 to 31 March 2017, however paediatric data are only available since 1 April 2013. Data were obtained from the UK VAD Database held by NHS Blood and Transplant as at 5 October 2017. Results are generally presented separately for adult and paediatric patients, for long-term and short-term devices and for bridging or post-transplant strategies.

Key findings

Long-term bridging devices in adults

- During 2016/2017 there were 110 long-term device implantations, including 106 long-term VADs and 4 TAHs. This represents an 11% decline from the previous year.
- The majority (63%) of long-term VAD implantations last year were into INTERMACS patient profile 2 (progressive decline) or 3 (stable but inotrope dependent) patients.
- On average, patients spent 675 days (1.8 years) on long-term VAD support.
- At 1-year post-implant, 59% of patients were alive on support, 30% had died on support, 8% had been transplanted and 2% were explanted without transplant.
- For patients in a recent period, the national survival rate at 1-year post-implant, regardless of subsequent intervention, was 70.2%.

Short-term bridging devices in adults

- During 2016/2017 there were 65 short-term device implantations into 56 patients, including 43 VADs and 22 ECMOs; a 14% increase from the previous year.
- The majority (78%) of implantations last year were into INTERMACS patient profile 1 patients (critical cardiogenic shock).
- The median duration on short-term support was 17 days.
- At 30 days post-implant, 26% of patients were alive on support, 28% had died on support, 19% had been transplanted, 18% transferred to a long-term device and 9% were explanted without transplant.
- For patients in a recent period, the national survival rate at 1-year post-implant, regardless of subsequent intervention, was 44.8%.

Short-term devices used for PGD in adults

- During 2016/2017 there were 33 short-term device implantations for PGD into 29 patients, including 28 ECMOs and 5 VADs; a 14% increase from the previous year.
- On average, patients spent 6 days on support and 44.1% survived to 1-year post-implant regardless of subsequent intervention.

Bridging devices used in paediatrics

- During 2016/2017 there were 19 device implantations into 16 patients, including 13 long-term and 6 short-term devices. Patients spent 59 days on average on support.
- 46% of patients received a transplant within 90 days of implantation and 79.1% survived to 1-year post-implant regardless of subsequent intervention.

Use of the contents of this report should be acknowledged as follows:
Annual Report on Mechanical Circulatory Support Related to Heart Transplantation 2016/2017, 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 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, 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.

The cohort covered in this report is from 1 April 2007 to 31 March 2017, however paediatric data are only presented for the period 1 April 2013 to 31 March 2017 since before 2013 there was no national data capture for paediatric MCS therapy. Data were obtained from the database as at 5 October 2017 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 by Newcastle since 2013). Fourteen patients refused to give consent for their data to be recorded on the VAD Database and they are not included in this report.

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 (short- and long- term VADs 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 3-5 year period. See Appendix A1 for a breakdown of the number of observations analysed in each section and notes on limitations and classifications.

Methods used to produce the report are described in Appendix A2. Patient survival rates are estimated from the point of first device implant, for both the national cohort and for individual centres. The reader should note that the results are unadjusted 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 implants for bridging in the last ten years, split by long-term and short-term devices. Up to 2015/2016, long-term implant activity has increased steadily but has since decreased in 2016/2017. Short-term device usage increased up to a peak of 95 in 2014/2015, but has since decreased. In total there were 1274 bridging implants across the decade into 1053 patients; 864 (82%) patients had a single device implant, 162 (15%) had two implants, 22 (2%) had three and 5 (0.5%) had four (see **Table A1.3** in Appendix A1 for details of device histories).

Figure 2.1 Total number of bridging device implants in the UK (adult and paediatric), by device type and financial year, 1 April 2007 to 31 March 2017

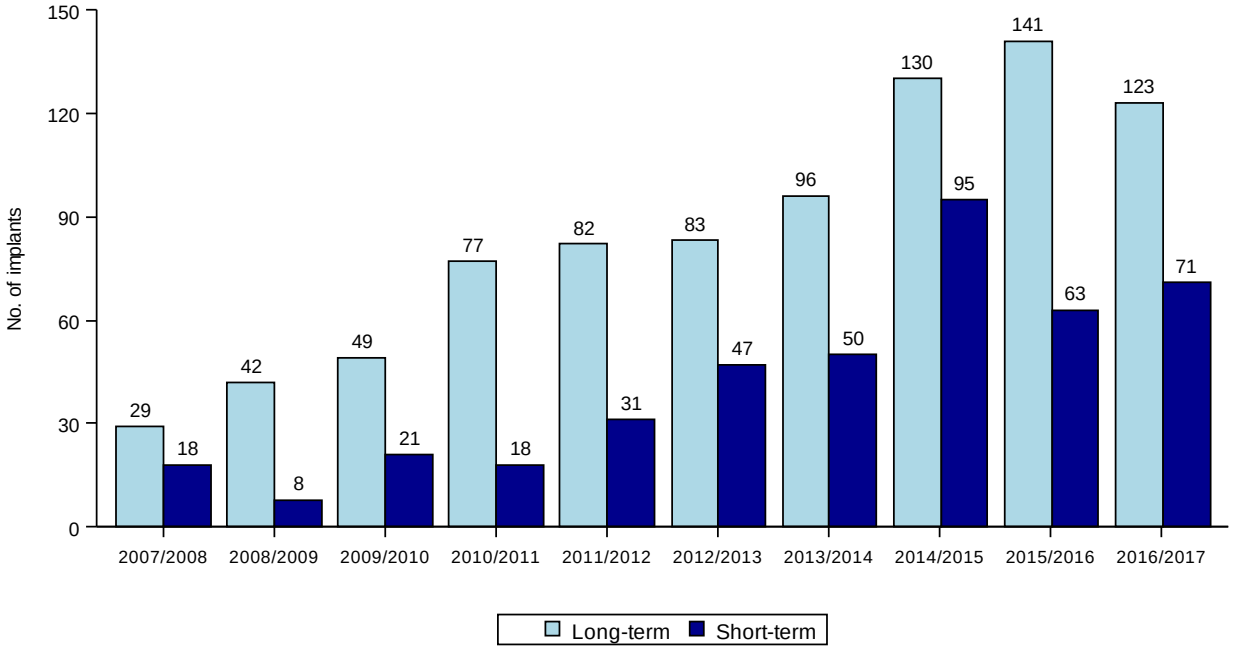


Figure 2.2 shows the number of implants post-heart transplant in the last ten years, split by primary graft dysfunction and rejection strategies. The number of implants for PGD has increased over the period, reaching 34 in 2016/2017. Devices used for rejection remain relatively rare, with none performed in 2016/2017. In total there were 204 post-transplant implants across the decade into 178 patients; 155 (87%) patients had a single device implant, 20 (11%) had two implants and 3 (2%) had three (see **Table A1.4** in Appendix A1 for details of device histories).

Figure 2.2 Total number of post-transplant device implants in the UK (adult and paediatric), by strategy and financial year, 1 April 2007 to 31 March 2017

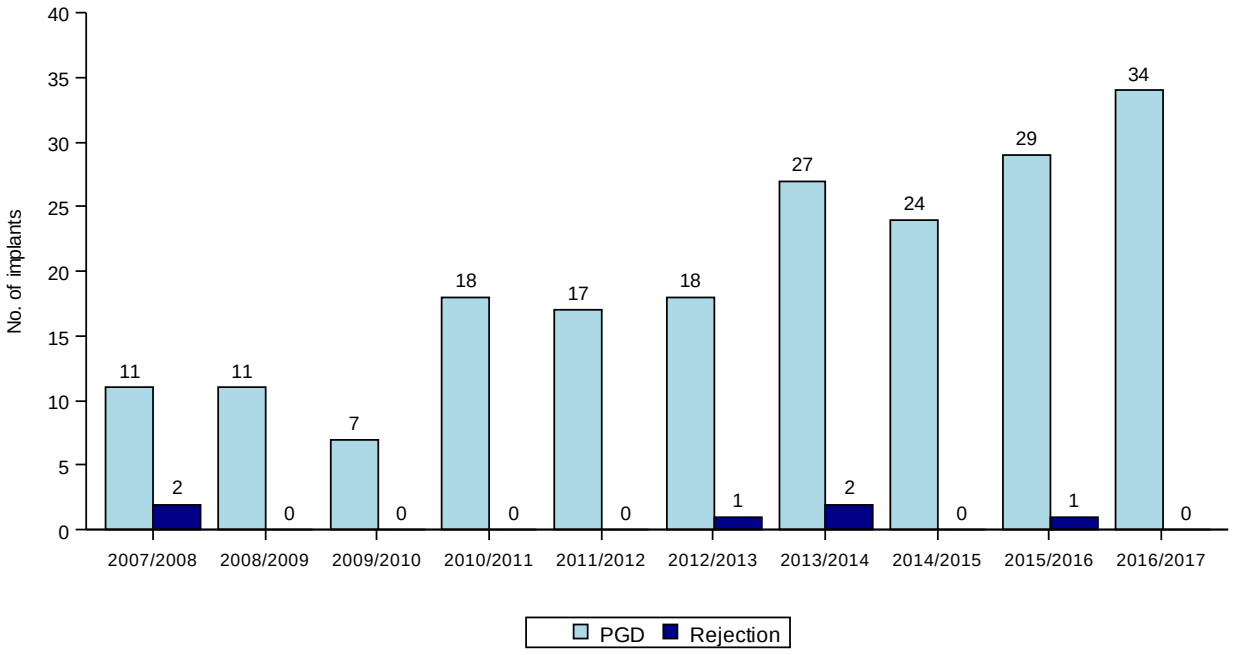


Table 2.1 and **2.2** summarise the number of patients and implants that have been reported to the VAD Database by centres for the period 1 April 2007 to 31 March 2017 and separately for the most recent year, 1 April 2016 to 31 March 2017. **Table 2.1** reflects the bridge to transplant data while **Table 2.2** reflects the post-transplant data.

Table 2.1 Number of patients receiving bridging devices and number of implants, by age group and centre, during the decade and the most recent year

Age group	Centre	1 April 2007 - 31 March 2017						1 April 2016 - 31 March 2017					
		No. implants	Type of device				No. patients	No. implants	Type of device				No. patients
			LT VAD	TAH	ST VAD	ECMO			LT VAD	TAH	ST VAD	ECMO	
Adult	Birmingham	170	81	0	55	34	138	40	25	0	13	2	36
	Glasgow	72	19	0	36	17	59	6	0	0	3	3	3
	Harefield	371	269	12	52	38	281	47	25	4	6	12	35
	Manchester	163	79	0	56	28	131	34	18	0	12	4	30
	Newcastle[1]	239	225	1	7	6	219	28	28	0	0	0	28
	Papworth	162	95	2	38	27	141	20	10	0	9	1	18
	Total	**1177**	**768**	**15**	**244**	**150**	**969**	**175**	**106**	**4**	**43**	**22**	**150**
		1 April 2013 - 31 March 2017						**1 April 2016 - 31 March 2017**					
		No. implants	Type of device				No. patients	No. implants	Type of device				No. patients
			LT VAD	TAH	ST VAD	ECMO			LT VAD	TAH	ST VAD	ECMO	
Paediatric	Great Ormond Street	50	39	0	5	6	41	9	9	0	0	0	9
	Newcastle	47	30	0	17	0	43	10	4	0	6	0	7
	Total	**97**	**69**	**0**	**22**	**6**	**84**	**19**	**13**	**0**	**6**	**0**	**16**
TOTAL		**1274**	**837**	**15**	**266**	**156**	**1053**	**194**	**119**	**4**	**49**	**22**	**166**

LT VAD=Long-Term Ventricular Assist Device, TAH=Total Artificial Heart, ST VAD=Short-Term Ventricular Assist Device, ECMO=Extra Corporeal Membrane Oxygenation

[1] It is known that Newcastle performed 12 ECMO procedures for bridging in adults during 2016/2017 which are currently missing from the UK VAD Database and so are not reflected in this table. Any missing ECMO activity for the other years cannot be quantified.

Table 2.2 Number of patients receiving post-transplant devices and number of implants, by age group and centre, during the decade and the most recent year

Age group	Centre	1 April 2007 - 31 March 2017									1 April 2016 - 31 March 2017					
		No. implants	Primary graft dysfunction				Rejection			No. patients	No. implants	Primary graft dysfunction				No. patients
			LT VAD	TAH	ST VAD	ECMO	LT VAD	ST VAD	ECMO			LT VAD	TAH	ST VAD	ECMO	
Adult	Birmingham	36	0	0	12	23	0	0	1	30	9	0	0	3	6	7
	Glasgow	37	0	0	10	24	0	1	2	28	3	0	0	1	2	2
	Harefield	45	0	1	21	23	0	0	0	42	5	0	1	0	4	4
	Manchester	51	0	0	9	42	0	0	0	44	10	0	0	0	10	10
	Newcastle[1]	10	3	0	3	2	0	2	0	10	0	0	0	0	0	0
	Papworth	23	0	0	6	17	0	0	0	22	7	0	0	1	6	6
	Total	**202**	**3**	**1**	**61**	**131**	**0**	**3**	**3**	**176**	**34**	**0**	**1**	**5**	**28**	**29**
		1 April 2013 - 31 March 2017									**1 April 2016 - 31 March 2017**					
		No. implants	Primary graft dysfunction				Rejection			No. patients	No. implants	Primary graft dysfunction				No. patients
			LT VAD	TAH	ST VAD	ECMO	LT VAD	ST VAD	ECMO			LT VAD	TAH	ST VAD	ECMO	
Paediatric	Great Ormond Street	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Newcastle	2	0	0	0	0	2	0	0	2	0	0	0	0	0	0
	Total	**2**	**0**	**0**	**0**	**0**	**2**	**0**	**0**	**2**	**0**	**0**	**0**	**0**	**0**	**0**
TOTAL		**204**	**3**	**1**	**61**	**131**	**2**	**3**	**3**	**178**	**34**	**0**	**1**	**5**	**28**	**29**

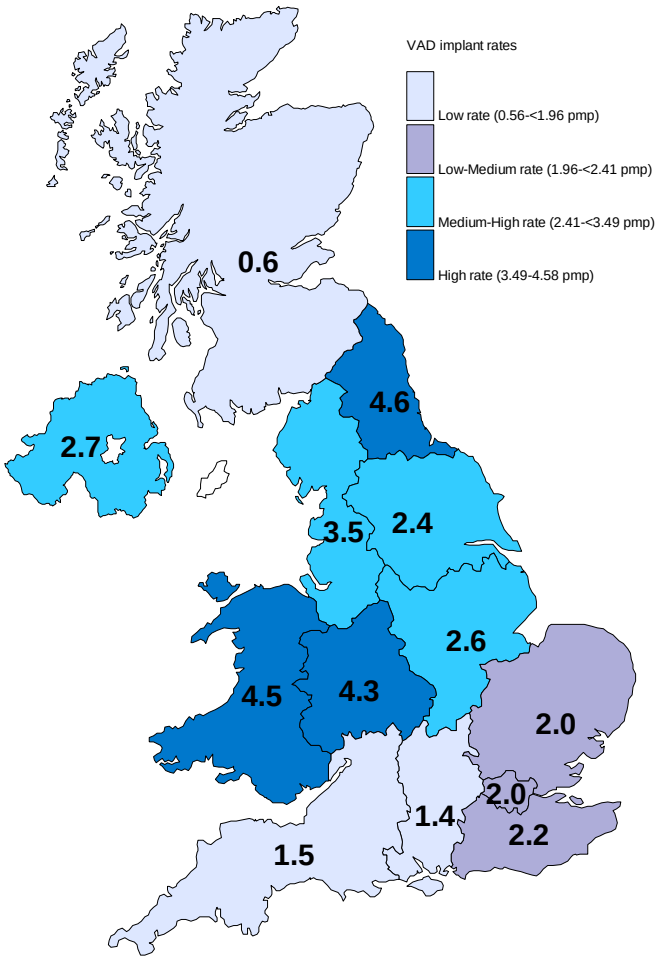
LT VAD=Long-Term Ventricular Assist Device, TAH=Total Artificial Heart, ST VAD=Short-Term Ventricular Assist Device, ECMO=Extra Corporeal Membrane Oxygenation

Note: there were no device used for rejected in the most recent year

[1] It is known that Newcastle performed 6 ECMO procedures for PGD in adults during 2016/2017 which are currently missing from the UK VAD Database and so are not reflected in this table. Any missing ECMO activity for the other years cannot be quantified.

Figure 2.3 shows the number of patients receiving MCS as a bridge to heart transplant per million population (pmp) between 1 April 2016 and 31 March 2017, by country/Strategic Health Authority (SHA) of patient residence. Overall, the number of patients receiving MCS was 2.5 pmp of the UK. No adjustments have been made for potential demographic differences in populations. 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 SHAs in England only. The larger the SCV the greater the evidence of a high level of systematic variation between areas. The device rate yielded a low SCV at 0.1, and therefore, there was no evidence of geographical variation beyond what would be expected at random.

Figure 2.3 Number of patients receiving MCS as a bridge to heart transplantation per million population (pmp) in the UK, 1 April 2016 – 31 March 2017, by country/Strategic Health Authority of patient residence



Country/Strategic Health Authority	Number of patients receiving bridging devices (pmp)	
North East	12	(4.6)
North West	25	(3.5)
Yorkshire and The Humber	13	(2.4)
North of England	**50**	**(3.3)**
East Midlands	12	(2.6)
West Midlands	25	(4.3)
East of England	12	(2.0)
Midlands and East	**49**	**(3.0)**
London	**17**	**(2.0)**
South East Coast	10	(2.2)
South Central	6	(1.4)
South West	8	(1.5)
South of England	**24**	**(1.7)**
England	**140**	**(2.6)**
Isle of Man	**0**	**-**
Channel Islands	**0**	**-**
Wales	**14**	**(4.5)**
Scotland	**3**	**(0.6)**
Northern Ireland	**5**	**(2.7)**
TOTAL	**165**[1]	**(2.5)**

[1] includes 3 patients whose postcode was unknown and excludes 1 patient who resides in the Republic of Ireland

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 2016/2017 there were 110 implantations; 14 fewer than 2015/2016 and 3.8 times higher than in 2007/2008. In total there were 15 TAH implantations. **Figure 3.2** shows the trend per centre, with Birmingham and Manchester having the most marked increases in implantations over the decade. Last year's activity is shown by centre and device type in **Figure 3.3**. The highest numbers of implantations were performed by Harefield, followed by Newcastle and Birmingham.

Figure 3.1 Number of adult long-term bridging device implants in the UK, by financial year and device type, 1 April 2007 to 31 March 2017

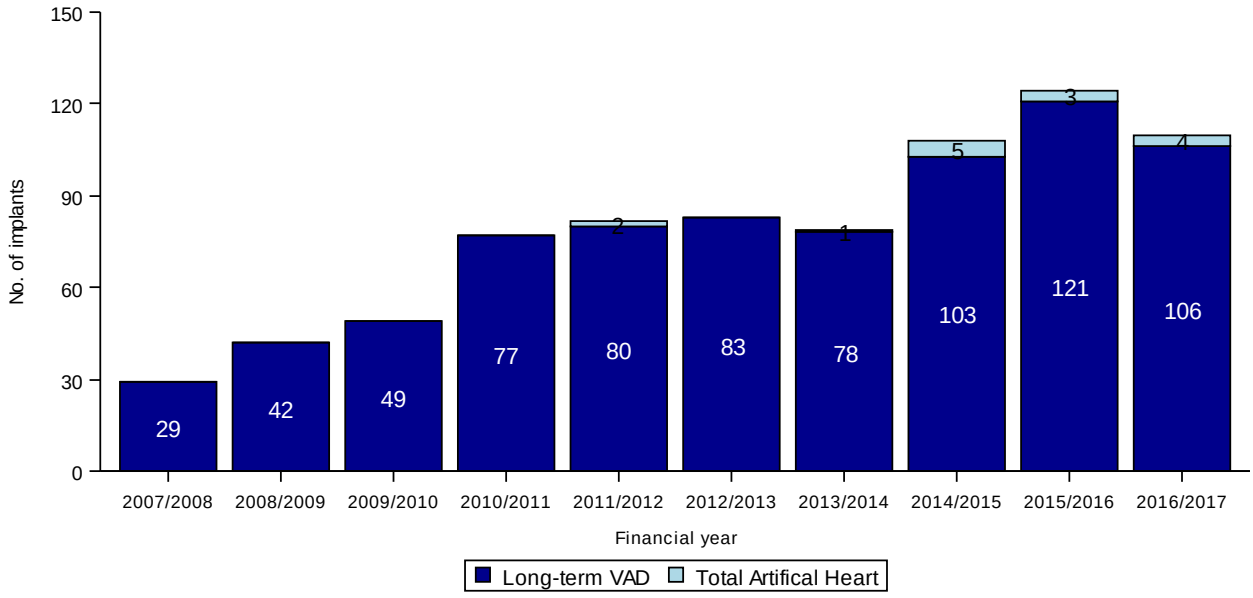


Figure 3.2 Number of adult long-term bridging device implants in the UK, by financial year, centre and device type, 1 April 2007 to 31 March 2017

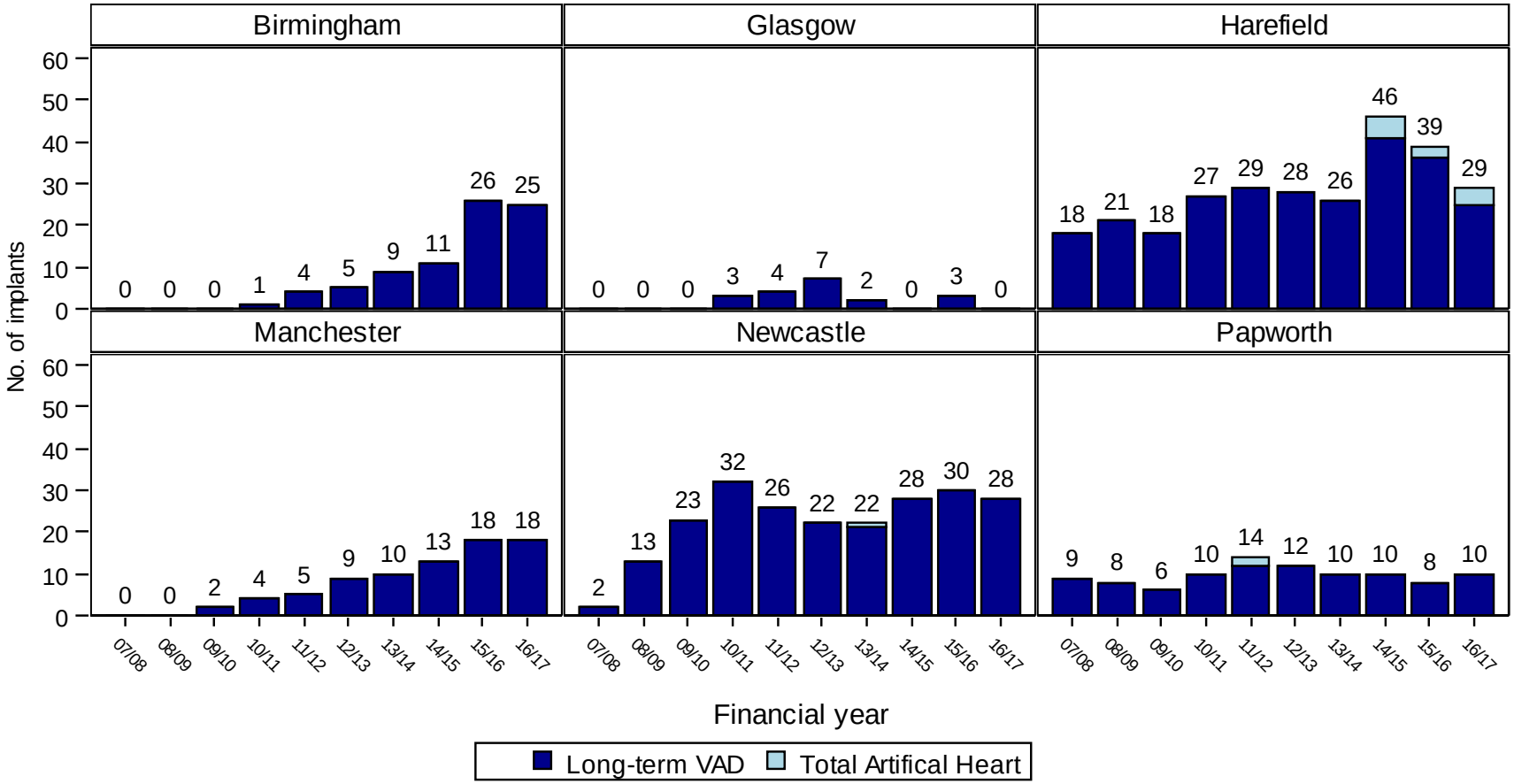


Figure 3.3 Number of adult long-term bridging device implants in the UK, by centre and device type, 1 April 2016 to 31 March 2017

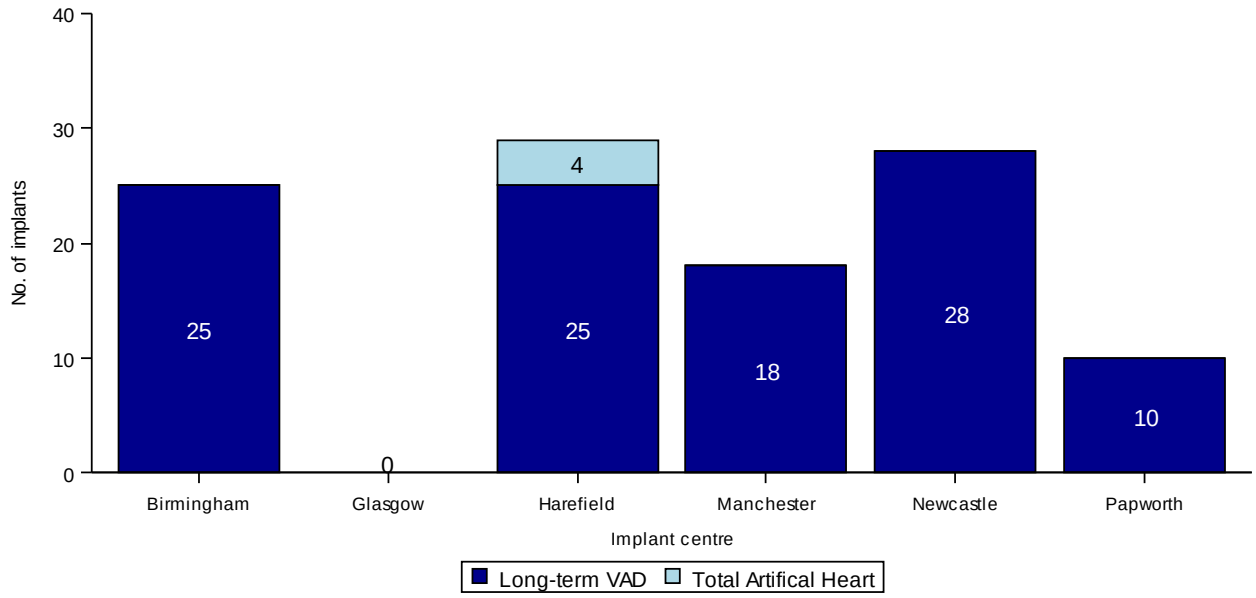
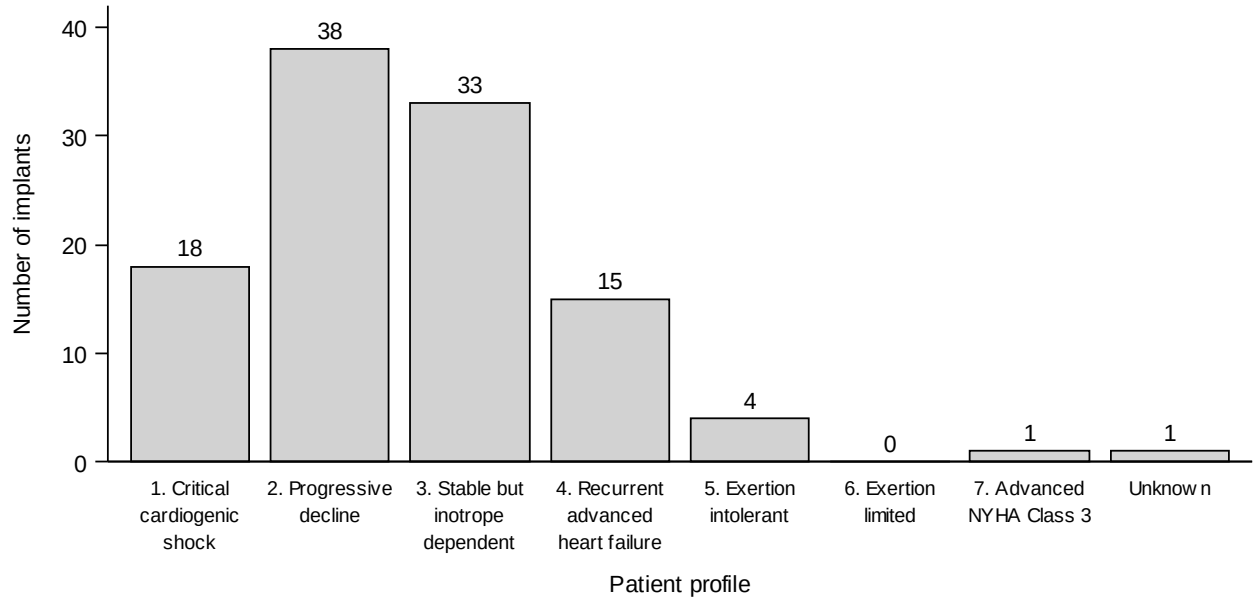


Figure 3.4 shows the INTERMACS patient profile at time of long-term VAD implantation for patients implanted during 2016/2017. Most patients implanted were either level 2 (progressive decline) or level 3 (stable but inotrope dependent).

Figure 3.4 INTERMACS patient profile of adult patients receiving long-term bridging device implants during 1 April 2016 – 31 March 2017



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 device was a continuous-flow long-term VAD. It excludes any patients who received short-term support prior to long-term support. Patients who received a Total Artificial Heart are considered separately in Section 4.5. Patients are analysed on a per-patient basis.

4.1 Duration on support

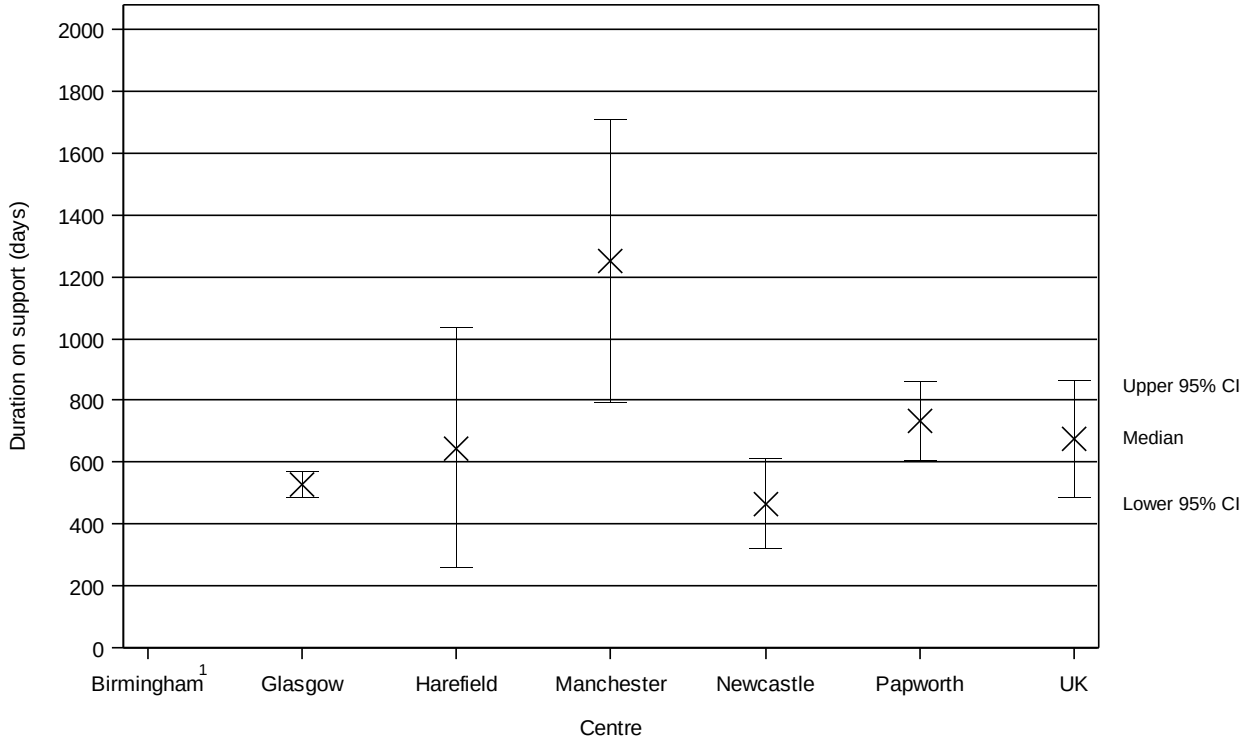
Table 4.1 shows the median duration on long-term VAD support for patients implanted in a recent three year period, both nationally and by centre. The medians and confidence intervals are estimated using the Kaplan-Meier method since not all patients have come to the end of their support and this method allows these (censored) patients to be included in the analysis. Transplant, explant or death signify end of support. If a patient was subsequently given a short-term device, only time on the long-term device is counted. Nationally, the median time on long-term support was 675 days and ranged from 467 days at Newcastle to 1250 days at Manchester (log-rank p=0.04).

Table 4.1 Median duration on long-term VAD support for adult patients implanted between 1 April 2013 and 31 March 2016, by centre

Centre	Number of patients	Time on support (days) Median	(95% confidence interval)
Birmingham[1]	37	-	-
Glasgow	3	527	485 - 569
Harefield	75	645	258 - 1032
Manchester	30	1250	792 - 1708
Newcastle	73	467	321 - 613
Papworth	26	734	605 - 863
Overall	**244**	**675**	**486 - 864**

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

Figure 4.1 Median duration on long-term VAD support for adult patients implanted between 1 April 2013 and 31 March 2016



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

4.2 Rate of transplant listing

Figure 4.2 and **Table 4.2** show the rate of transplant listing for patients first implanted between 1 April 2012 and 31 March 2016, by centre. This includes listing on the super-urgent, urgent or non-urgent heart transplant lists (whichever occurred first). Overall, 46% of patients were listed prior to implant, but this proportion ranged from 26% at Harefield to 76% at Papworth (chi-square p<0.0001). The proportion still on a VAD at one year and not listed was 23% overall and ranged from 3% at Papworth to 46% at Manchester (chi-square p<0.0001).

Figure 4.2 Heart transplant listing status with respect to long-term VAD implantation for adult patients receiving a first device 1 April 2012 – 31 March 2016, by centre and overall

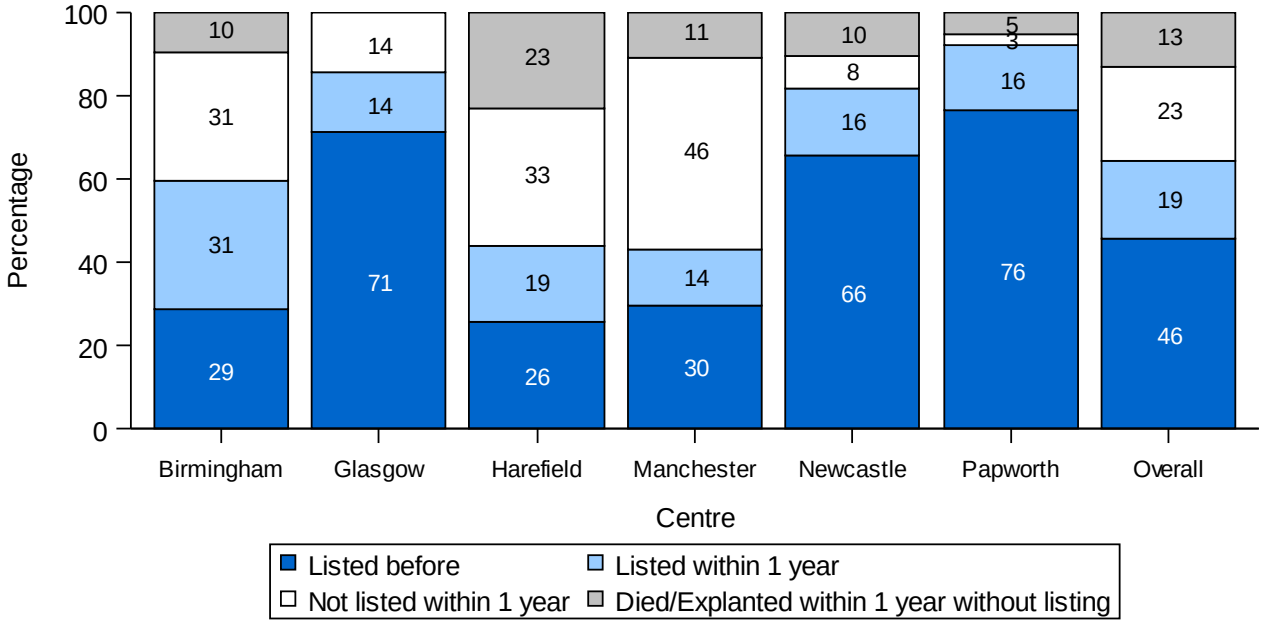


Table 4.2 Heart transplant listing status with respect to long-term VAD implantation for adult patients receiving a first device 1 April 2012 – 31 March 2016, by centre and overall

Centre	Number of patients	Listed before VAD implant	Listed within 1 year	Not listed within 1 year	Died/explanted within 1 year without listing
	N	N (%)	N (%)	N (%)	N (%)
Birmingham	42	12 (29)	13 (31)	13 (31)	4 (10)
Glasgow	7	5 (71)	1 (14)	1 (14)	0 (0)
Harefield	86	22 (26)	16 (19)	28 (33)	20 (23)
Manchester	37	11 (30)	5 (14)	17 (46)	4 (11)
Newcastle	87	57 (66)	14 (16)	7 (8)	9 (10)
Papworth	38	29 (76)	6 (16)	1 (3)	2 (5)
Overall	**297**	**136 (46)**	**55 (19)**	**67 (23)**	**39 (13)**

4.3 Competing risks

Whilst on VAD support, patients are susceptible to different outcomes. Death on support, transplant, and explant without transplant (with or without recovery) are all possible outcomes. **Figure 4.3** shows the cumulative incidence of each of these outcomes occurring from time of implantation, for the cohort of patients receiving a first long-term device between 1 April 2012 and 31 March 2017. This is calculated using the Aalen-Johansen method to account for competing risks. 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. Any subsequent VAD support post-explant is not counted and any such patients are classed simply as explanted. If a patient is moved from one device to another (of any type) without a period free of support, they are counted as still on support.

For this cohort, at one year post- long-term implant, 59% of patients remained alive on support, 30% died on support, 8% received a heart transplant and 2% had their device explanted. At two years, the incidence of transplantation rose to 18%, however so did the incidence of death, to 38%, with the remaining 38% of patients still alive on support and 6% explanted. At three years, the incidence of death on support rose to 46%, the incidence of transplant rose to 27%, 7% had been explanted and 20% 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 2012 to 31 March 2017

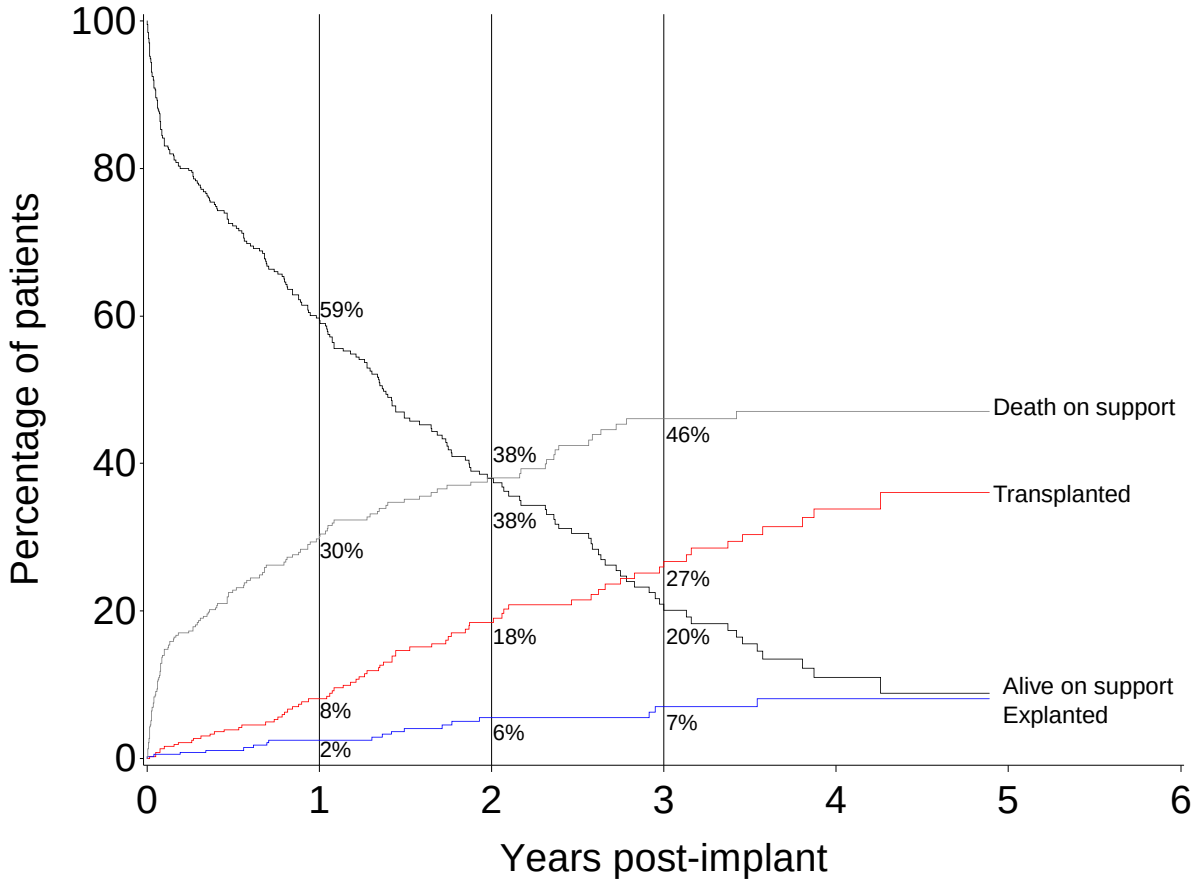


Table 4.3 shows the centre-specific one-year estimates for each competing outcome. The incidence of each outcome varies across centres.

Table 4.3 Cumulative incidence of each outcome at 1 year, by centre, for adult patients implanted with a first long-term VAD, 1 April 2012 to 31 March 2017

Centre	Number of patients	Transplanted %	Explanted %	Alive on support %	Death on support %
Birmingham	62	6	3	66	25
Glasgow	7	0	0	57	43
Harefield	99	15	4	45	36
Manchester	53	4	0	81	15
Newcastle	108	9	3	56	32
Papworth	44	3	0	66	31
Overall	**373**	**8**	**2**	**59**	**30**

4.4 Patient survival from implant

This analysis looks at the rate of survival from the point of first long-term VAD implant regardless of any other interventions the patient may have received, such as transplant. This incorporates data from the UK Transplant Registry on post-transplant survival. For example, if a patient received a long-term VAD, was later transplanted and followed-up for two years, this entire time is considered. Any additional survival time recorded on the VAD Database for patients explanted is also counted, so if a patient was implanted, explanted and then survived for another year, this entire time is included. Any 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, then died, 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, 1 year and 3 years post-implant and are based on those patients recorded as receiving a first device between 1 April 2007 and 31 March 2016 where information on survival post-implant is known. **Figure 4.4** shows a comparison between implants performed in the earlier 5 years and implants performed in the latter 4 years. The national survival rates in the recent era were 87.1%, 70.2% and 46.6% at 30 days, 1 year and 3 years respectively.

In **Tables 4.5**-**4.7** and **Figures 4.5**-**4.7** the centre-specific survival rates for implants in the most recent era, 1 April 2012 to 31 March 2016, are presented for 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 in **Table 4.8** which displays the baseline characteristics of the 295 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.

Figure 4.4 Unadjusted patient survival after long-term VAD implant for adult patients implanted 1 April 2007 – 31 March 2016, by era

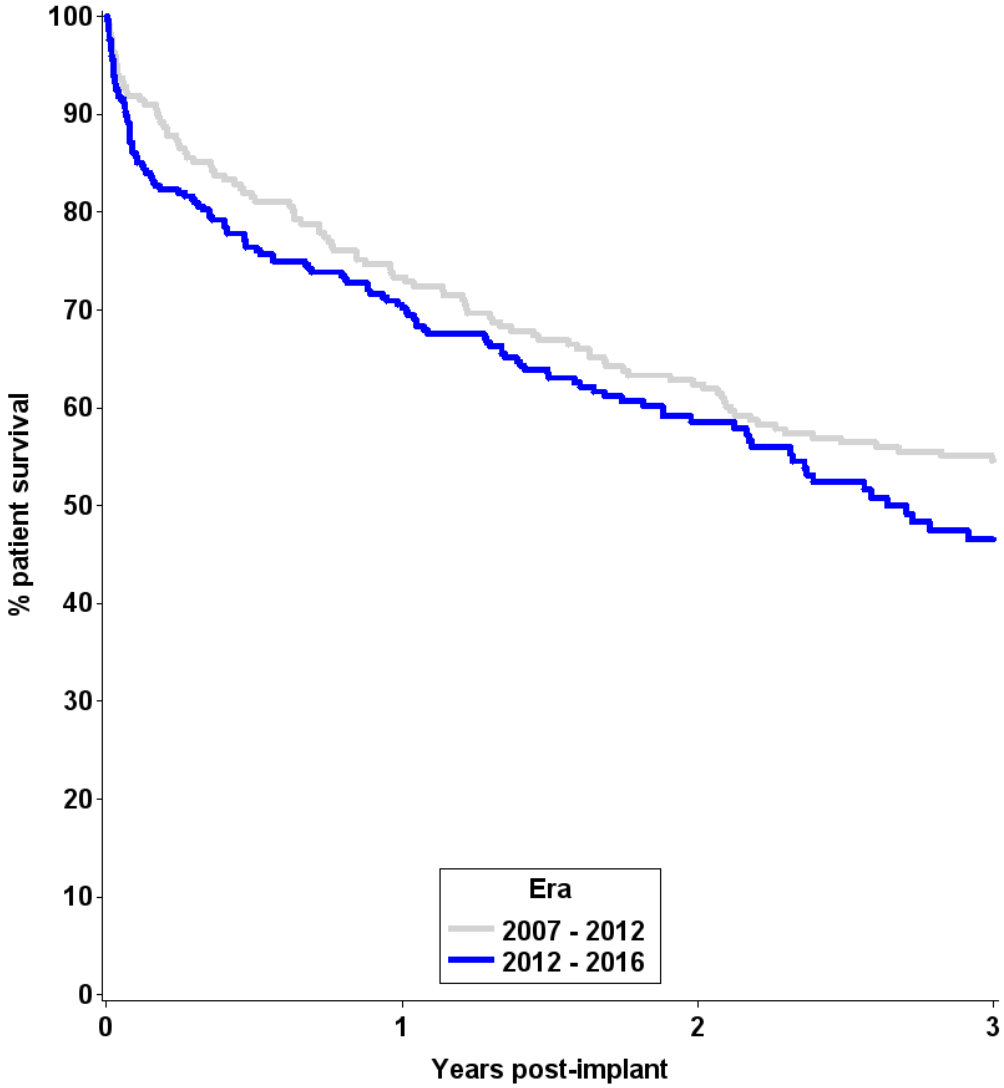


Table 4.4 Patient survival rates after long-term VAD implant for adult patients implanted 1 April 2007 – 31 March 2016, by era

Era	Number of patients	% 30-day survival (95% CI)	% 1-year survival (95% CI)	% 3-year survival (95% CI)
1 Apr 2007 – 31 Mar 2012	222	91.9 (87.4 - 94.8)	73.3 (67.0 - 78.7)	54.6 (47.8 - 60.9)
1 Apr 2012 – 31 Mar 2016	295	87.1 (82.7 - 90.4)	70.2 (64.5 - 75.1)	46.6 (39.3 - 53.5)
Log-rank p-value		**0.09**	**0.3**	**0.2**

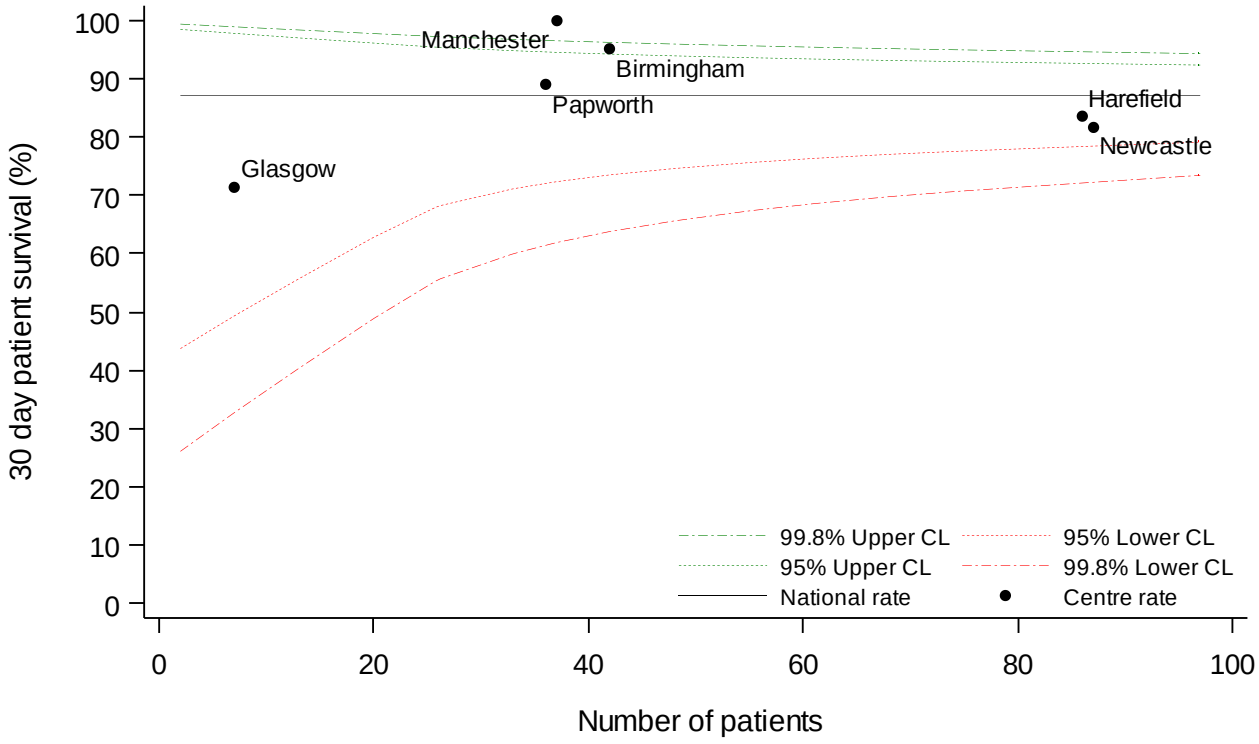
The unadjusted centre-specific 30-day survival rates for patients implanted in the recent period are shown in **Table 4.5** and **Figure 4.5**. The rate for Manchester was 100% which exceeded the upper 99.8% confidence limit for the national rate, indicating that their unadjusted rate was higher than the national rate. The rate for Birmingham was 95.2% which was between the upper 95% and 99.8% confidence limits, indicating some evidence of a higher rate.

Table 4.5 30-day patient survival rates after long-term VAD implant for adult patients implanted 1 April 2012 – 31 March 2016, by centre

Centre	Number of patients	% 30-day survival (95% CI) Unadjusted	
Birmingham	42	95.2	(82.3 - 98.8)
Glasgow	7	71.4	(25.8 - 92.0)
Harefield	86	83.7	(74.0 - 90.0)
Manchester	37	100.0	-
Newcastle	87	81.6	(71.7 - 88.3)
Papworth	36	88.9	(73.1 - 95.7)
UK	**295**	**87.1**	**(82.7 - 90.4)**

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

Figure 4.5 Unadjusted 30-day patient survival rates after long-term VAD implant for adult patients implanted 1 April 2012 – 31 March 2016, by centre



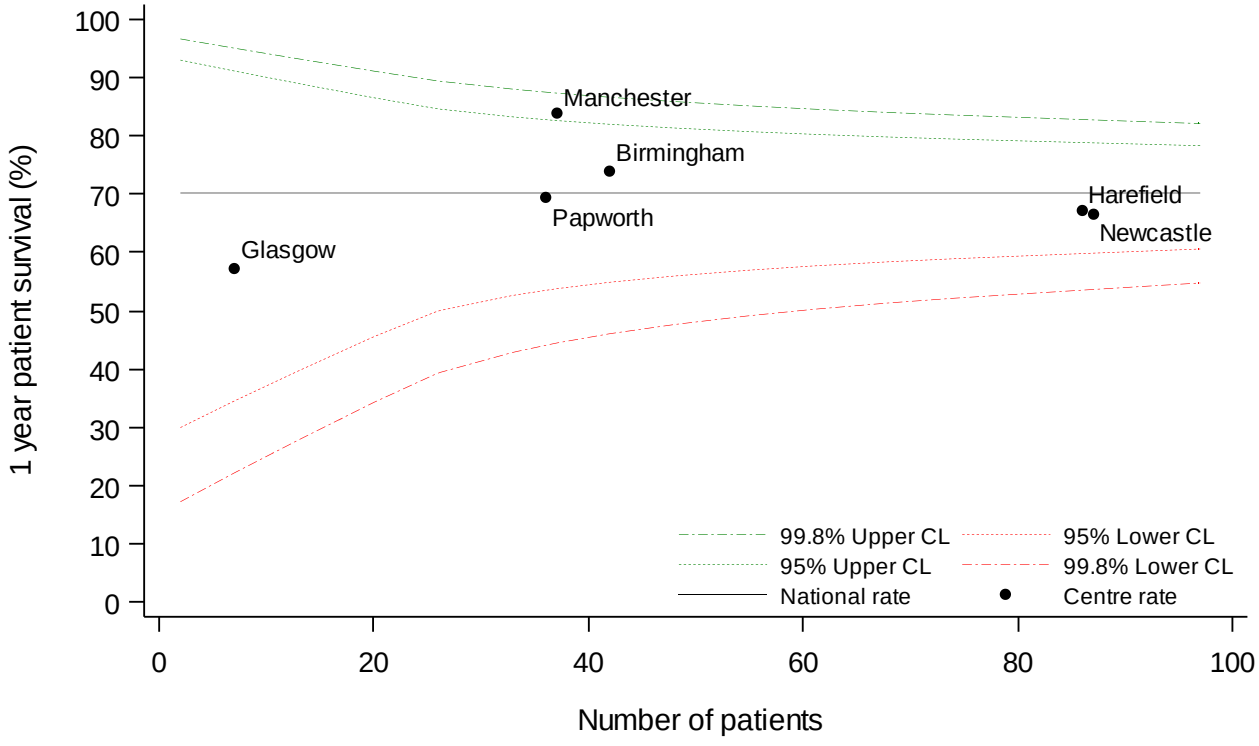
The unadjusted centre-specific 1-year survival rates are shown in **Table 4.6** and **Figure 4.6**. The centre-specific rates varied between 57.1% and 83.8% but apart from Manchester, for whom there was some evidence of a higher rate, all rates were consistent with the national rate.

Table 4.6 1-year patient survival rates after long-term VAD implant for adult patients implanted 1 April 2012 –31 March 2016, by centre

Centre	Number of patients	% 1-year survival (95% CI) Unadjusted	
Birmingham	42	73.8	(57.7 - 84.6)
Glasgow	7	57.1	(17.2 - 83.7)
Harefield	86	67.2	(55.4 - 76.5)
Manchester	37	83.8	(67.4 - 92.4)
Newcastle	87	66.6	(55.6 - 75.4)
Papworth	36	69.4	(51.7 - 81.8)
UK	**295**	**70.2**	**(64.5 - 75.1)**

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

Figure 4.6 Unadjusted 1-year patient survival rates after long-term VAD implant for adult patients implanted 1 April 2012 – 31 March 2016, by centre



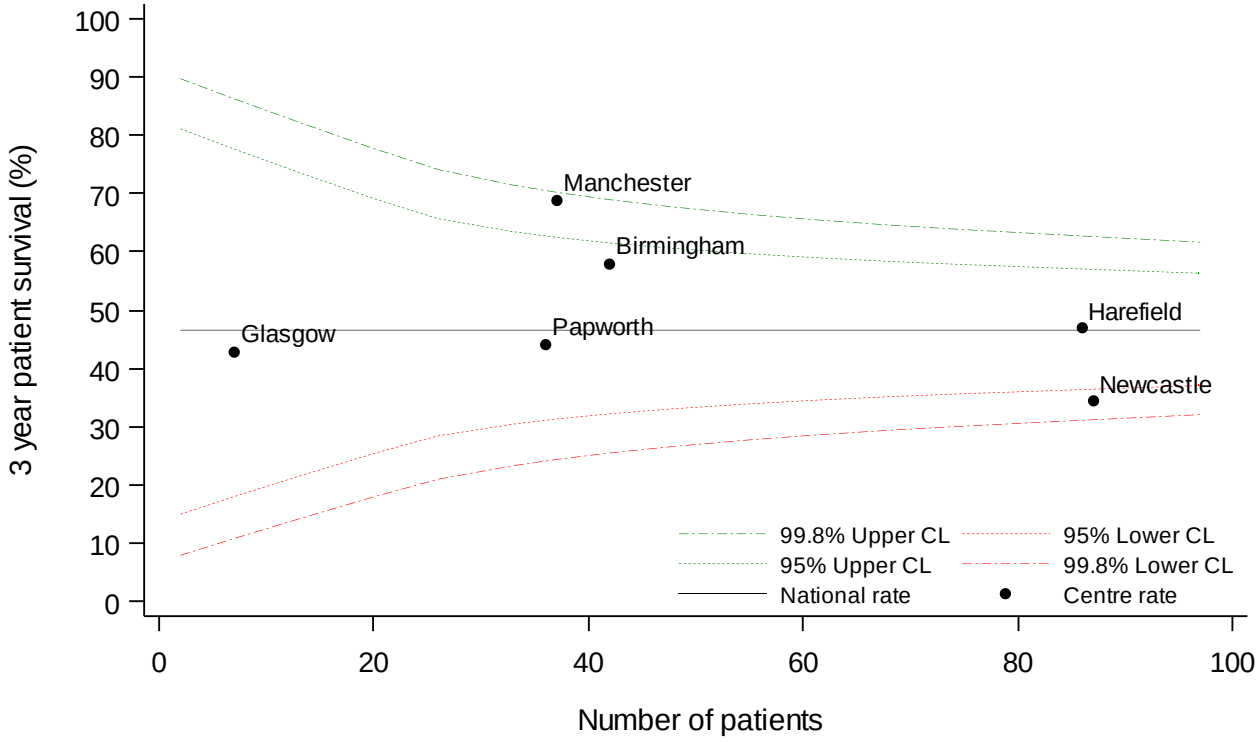
The unadjusted centre-specific 3-year survival rates are shown in **Table 4.7** and **Figure 4.7**. There was some evidence that the rate for Newcastle was lower than average and for Manchester higher than average.

Table 4.7 3-year patient survival rates after long-term VAD implant for adult patients implanted 1 April 2012 –31 March 2016, by centre

Centre	Number of patients	% 3-year survival (95% CI) Unadjusted	
Birmingham	42	57.9	(33.9 - 75.9)
Glasgow	7	42.9	(9.8 - 73.4)
Harefield	86	46.9	(30.9 - 61.3)
Manchester	37	68.9	(48.9 - 82.4)
Newcastle	87	34.5	(22.9 - 46.3)
Papworth	36	44.2	(26.1 - 60.9)
UK	**295**	**46.6**	**(39.3 - 53.5)**

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

Figure 4.7 Unadjusted 3-year patient survival rates after long-term VAD implant for adult patients implanted 1 April 2012 – 31 March 2016, by centre



The demographic characteristics of the 295 patients in the survival from implant analysis are shown below in **Table 4.8** by centre and overall. Nationally, 87% of patients were male, the median age was 53 years and 71% of patients received a Heartware device. For some characteristics, due to rounding, percentages may not add up to 100.

Table 4.8 Characteristics of patients in the long-term VAD patient survival from implant analysis, by centre

		Birmingham N (%)	Glasgow N (%)	Harefield N (%)	Manchester N (%)	Newcastle N (%)	Papworth N (%)	**Total N (%)**
Number of patients		42	7	86	37	87	36	**295**
Age at implant (years)	Median (IQR)	55 (49-60)	32 (28-54)	48 (36-57)	55 (46-56)	54 (42-60)	52 (45-56)	**53 (42-58)**
Sex	Male	37 (88)	7 (100)	70 (81)	33 (89)	78 (90)	33 (92)	**258 (87)**
	Female	5 (12)	0 (0)	16 (19)	4 (11)	9 (10)	3 (8)	**37 (13)**
Primary disease	Dilated cardiomyopathy	18 (43)	4 (57)	62 (72)	16 (43)	48 (55)	22 (61)	**170 (58)**
	Ischaemic heart disease	22 (52)	0 (0)	19 (22)	15 (41)	29 (33)	10 (28)	**95 (32)**
	Congenital heart disease	0 (0)	0 (0)	0 (0)	0 (0)	7 (8)	0 (0)	**7 (2)**
	Hypertrophic cardiomyopathy	0 (0)	2 (29)	3 (3)	1 (3)	0 (0)	3 (8)	**9 (3)**
	Restrictive cardiomyopathy	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	**1 (0)**
	Valvular heart disease	0 (0)	0 (0)	1 (1)	2 (5)	1 (1)	0 (0)	**4 (1)**
	Infiltrative heart muscle disease	0 (0)	0 (0)	0 (0)	1 (3)	2 (2)	0 (0)	**3 (1)**
	Other	2 (5)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	**3 (1)**
	Unknown	0 (0)	1 (14)	1 (1)	1 (3)	0 (0)	0 (0)	**3 (1)**
INTERMACS patient profile	1. Critical cardiogenic shock	4 (10)	1 (14)	27 (31)	2 (5)	11 (13)	0 (0)	**45 (15)**
	2. Progressive decline	11 (26)	5 (71)	38 (44)	7 (19)	31 (36)	20 (56)	**112 (38)**
	3. Stable but inotrope dependent	26 (62)	0 (0)	15 (17)	14 (38)	24 (28)	10 (28)	**89 (30)**
	4. Recurrent advanced heart failure	1 (2)	0 (0)	4 (5)	12 (32)	19 (22)	6 (17)	**42 (14)**
	5. Exertion intolerant	0 (0)	0 (0)	0 (0)	2 (5)	2 (2)	0 (0)	**4 (1)**
	6. Exertion limited	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**0 (0)**
	7. Advanced NYHA Class 3	0 (0)	1 (14)	2 (2)	0 (0)	0 (0)	0 (0)	**3 (1)**
First VAD device name	Heartmate II	38 (90)	4 (57)	2 (2)	29 (78)	0 (0)	0 (0)	**73 (25)**
	Heartware	0 (0)	3 (43)	84 (98)	1 (3)	84 (97)	36 (100)	**208 (71)**
	Heartware MVAD	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)	0 (0)	**3 (1)**
	HeartMate III	4 (10)	0 (0)	0 (0)	7 (19)	0 (0)	0 (0)	**11 (4)**

4.5 TAH outcomes

Table 4.9 shows the outcomes of the 15 patients who received a TAH as a bridge to transplant in the time period. All patients are considered, including those who received other MCS therapy prior to the TAH, however one patient who received a TAH post-transplant is excluded. Three centres have used TAH in the time period. The 30-day post-implant survival rate for these patients was 53.3% (95% confidence interval: 26.3 - 74.4%), 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 2007 to 31 March 2017

Centre	Number of patients N	Died without listing N (%)	Died with listing N (%)	Survived to transplant N (%)
Harefield	12	8 (67)	1 (8)	3 (25)
Newcastle	1	0 (0)	1 (100)	0 (0)
Papworth	2	1 (50)	0 (0)	1 (50)
Overall	**15**	**9 (60)**	**2 (13)**	**4 (27)**

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 2016/2017 there were 65 implantations; 8 more than 2015/2016. There were more ECMO procedures compared with short-term VADs in 2012/2013 and 2013/2014 but in the last three years there have been more short-term VADs. The highest activity was recorded in 2014/2015. **Figure 5.2** shows the trend per centre, with Birmingham, Manchester and Papworth all having their highest activity in 2014/2015. Last year's implant activity is shown by centre and device type in **Figure 5.3**. The highest number of ECMO procedures last year were performed by Harefield. Note that the ECMO activity for Newcastle is incomplete as there has been an issue with under reporting of this treatment since 2013.

Figure 5.1 Number of adult short-term bridging device implants in the UK, by financial year and device type, 1 April 2007 to 31 March 2017

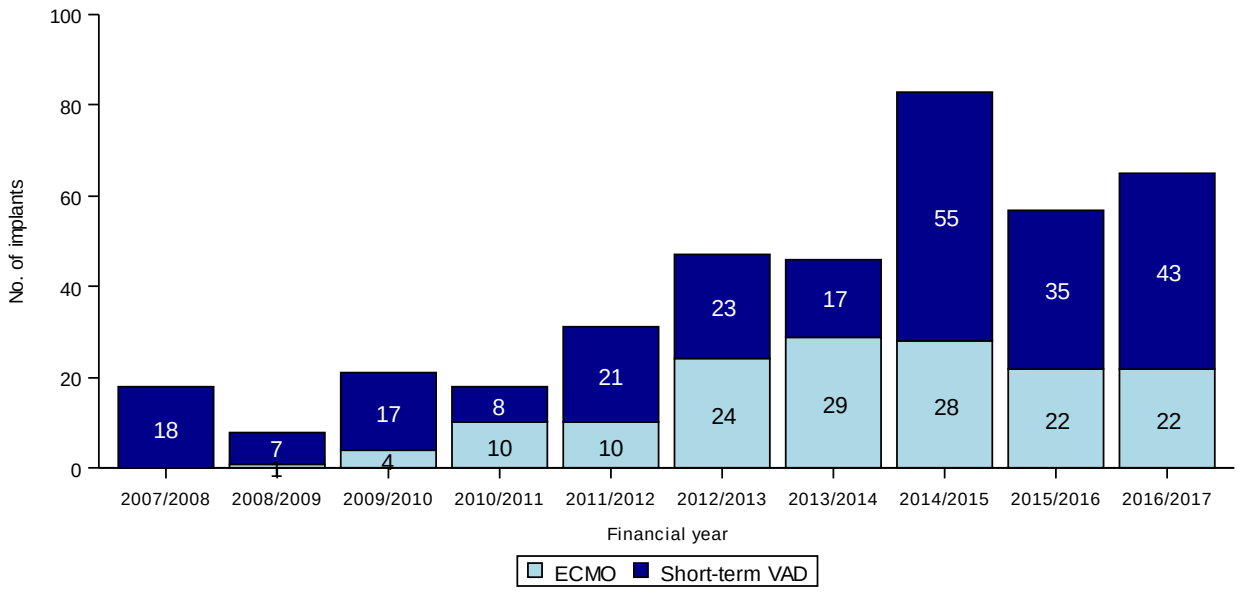


Figure 5.2 Number of adult short-term bridging device implants in the UK, by financial year, centre and device type, 1 April 2007 to 31 March 2017

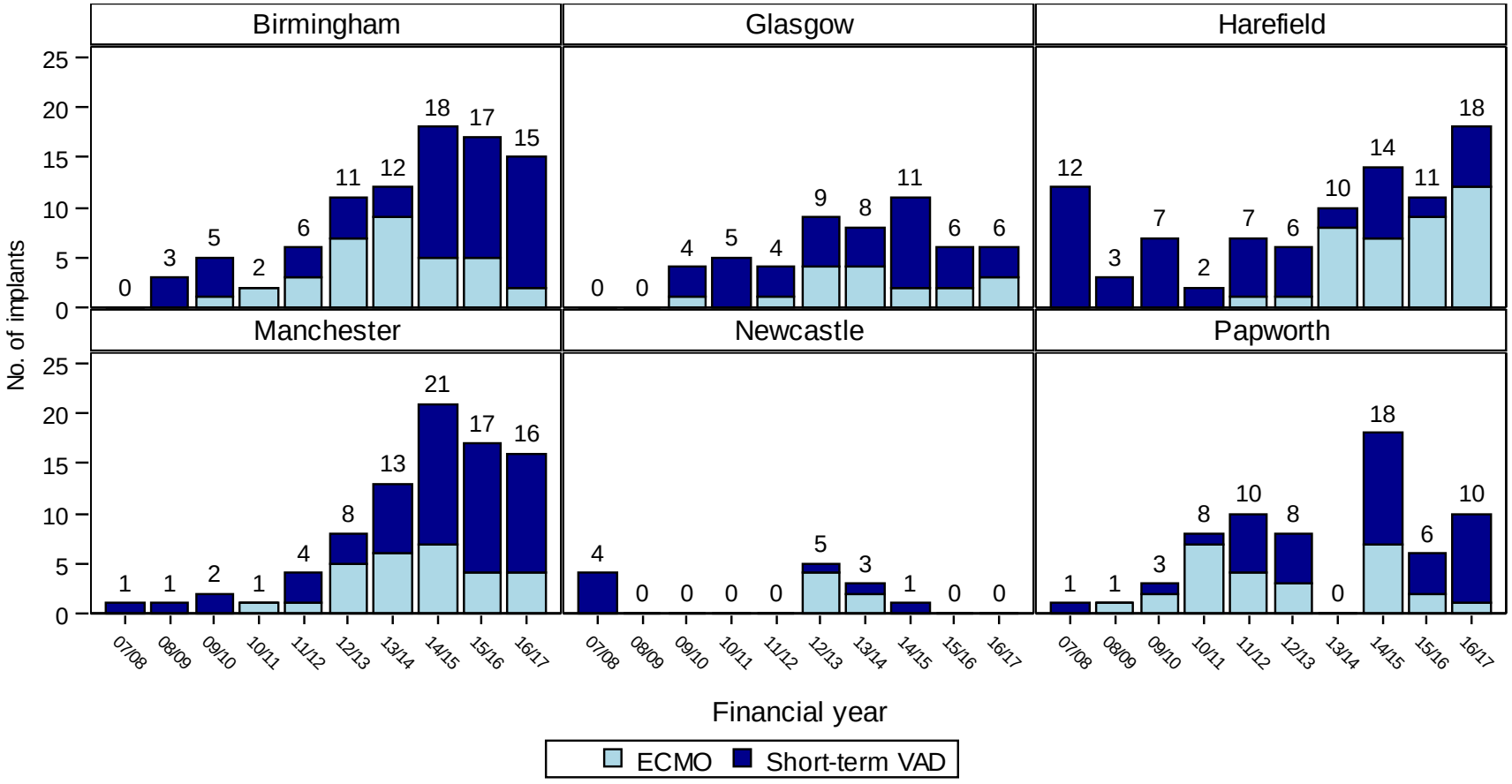


Figure 5.3 Number of adult short-term bridging device implants in the UK, by centre and device type, 1 April 2016 to 31 March 2017

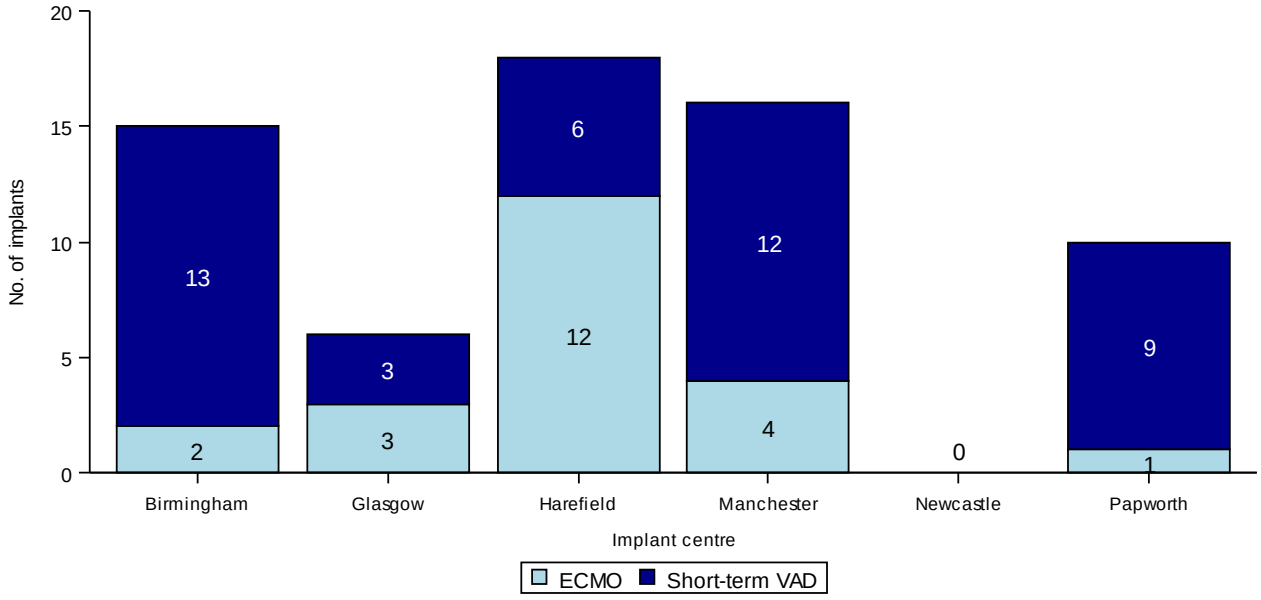
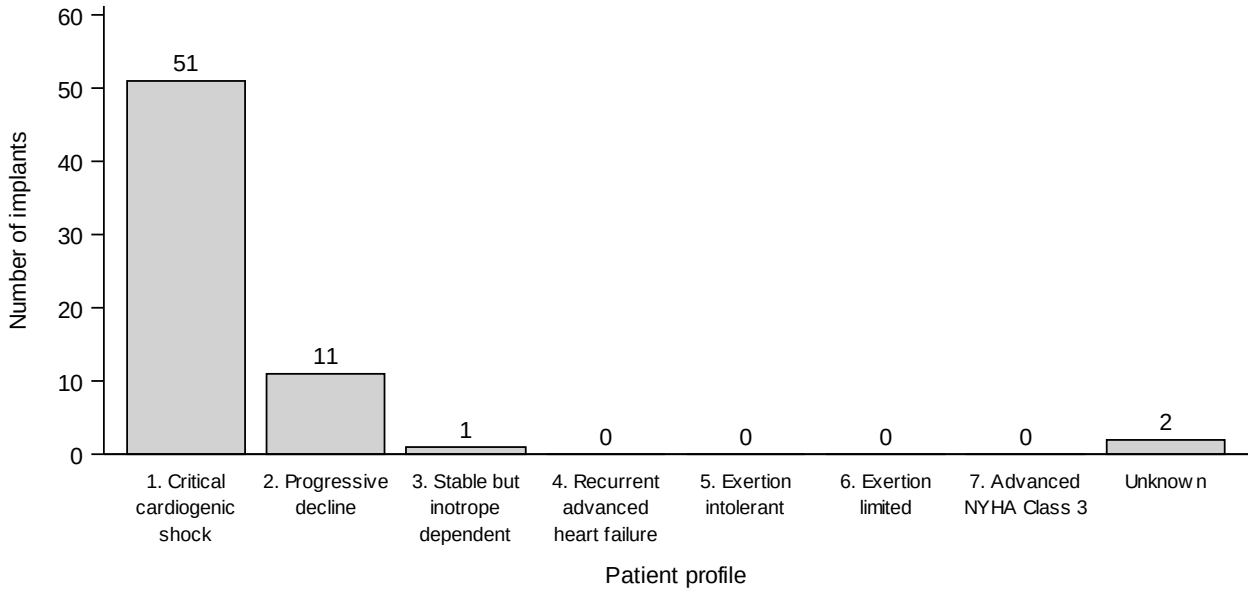


Figure 5.4 shows the INTERMACS patient profile at receipt of short-term support for patients implanted during 2016/2017. Most patients were profile 1 (critical cardiogenic shock).

Figure 5.4 INTERMACS patient profile for all short-term bridging device implants in adult patients in the UK, 1 April 2016 to 31 March 2017



ADULT SHORT TERM DEVICES USED FOR BRIDGING

Patient Outcomes

6 Outcomes of adult patients receiving short-term bridging devices

This section only considers patients whose first device was a short-term device (including ECMO). If a patient previously received a long-term device they are excluded. Patients are analysed on a per-patient basis, as opposed to per implant.

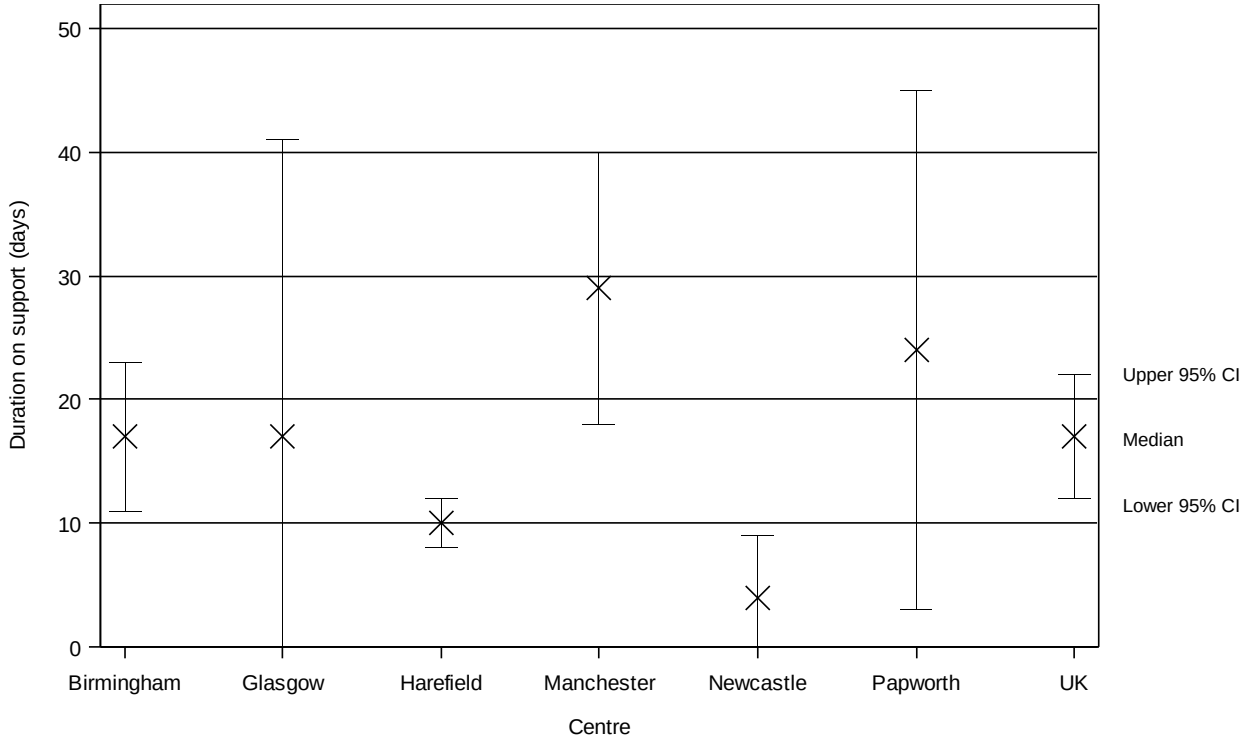
6.1 Duration on support

Table 6.1 shows the median duration on short-term support for patients implanted in a recent three-year period, both nationally and by centre. The medians and confidence intervals are estimated using the Kaplan-Meier method. Transplant, explant, death or transfer to a long-term device signify end of short-term support. If a patient went from ECMO to short-term VAD, all this time is counted. Nationally, the median time on support was 17 days and ranged from 4 days at Newcastle to 29 days at Manchester (log-rank p= 0.001).

Table 6.1 Median duration on short-term bridging device support for adult patients implanted between 1 April 2013 and 31 March 2016, by centre

Centre	Number of patients	Time on support (days) Median	(95% confidence interval)
Birmingham	35	17	11 - 23
Glasgow	22	17	0 - 41
Harefield	26	10	8 - 12
Manchester	41	29	18 - 40
Newcastle	3	4	0 - 9
Papworth	16	24	3 - 45
Overall	**143**	**17**	**12 - 22**

Figure 6.1 Median duration on short-term bridging device support for adult patients implanted between 1 April 2013 and 31 March 2016



6.2 Rate of transplant listing

Figure 6.2 and **Table 6.2** show the rate of transplant listing for patients first implanted between 1 April 2012 and 31 March 2016, 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, 19% of patients were listed prior to short-term implant, which was a smaller proportion than that observed for long-term implants (46%). This proportion ranged between 9% at Manchester and 30% at Glasgow (chi-square p=0.3). The proportion listed within 1 month was 22% overall and was similar across centres (chi-square p=0.4).

Figure 6.2 Heart transplant listing status with respect to short-term device implantation for adult patients receiving a first bridging device 1 April 2012 – 31 March 2016, by centre and overall

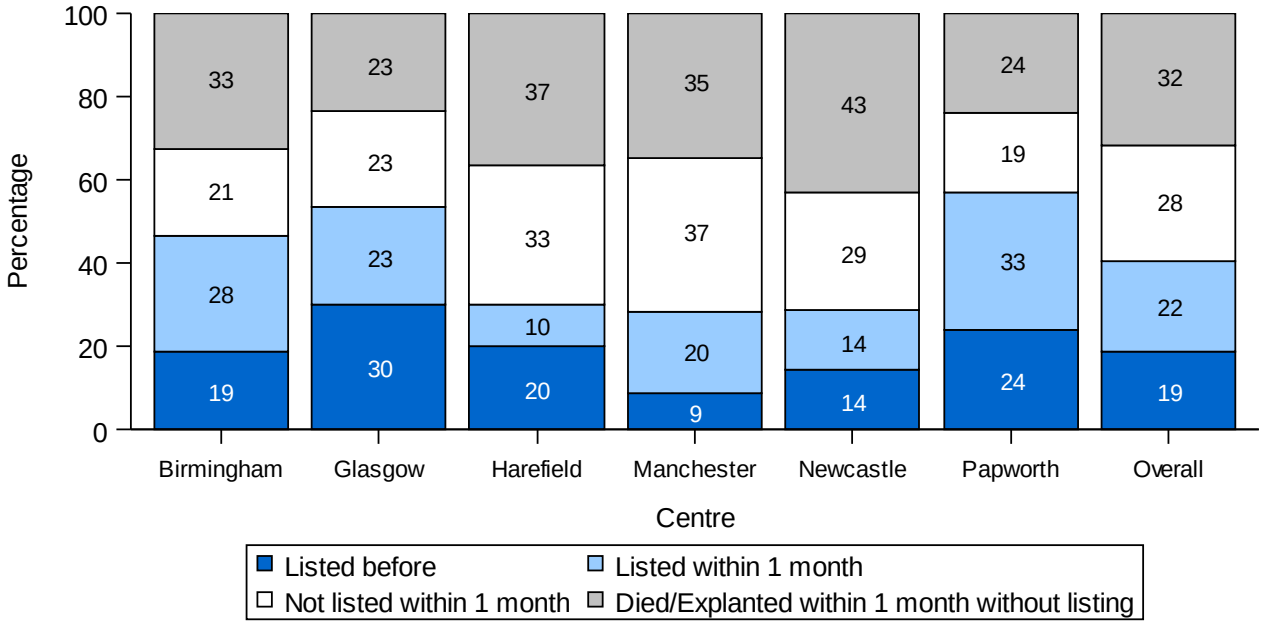


Table 6.2 Heart transplant listing status with respect to short-term device implantation for adult patients receiving a first bridging device 1 April 2012 – 31 March 2016, by centre and overall

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	43	8 (19)	12 (28)	9 (21)	14 (33)
Glasgow	30	9 (30)	7 (23)	7 (23)	7 (23)
Harefield	30	6 (20)	3 (10)	10 (33)	11 (37)
Manchester	46	4 (9)	9 (20)	17 (37)	16 (35)
Newcastle	7	1 (14)	1 (14)	2 (29)	3 (43)
Papworth	21	5 (24)	7 (33)	4 (19)	5 (24)
Overall	**177**	**33 (19)**	**39 (22)**	**49 (28)**	**56 (32)**

6.3 Competing risks

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 2012 and 31 March 2017. This is calculated using the Aalen-Johansen method to account for competing risks. 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. Any subsequent VAD support post-explant is not counted and any such patients are classed simply as explanted. If a patient is moved from one short-term device to another without a period free of support, they are counted as still on support.

For this cohort, one month after receipt of a short-term device, 28% of patients died on short-term support, 26% of patients remained alive on support, 19% received a transplant, 18% were transferred to a long-term device and 9% were explanted. 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 11%. The subsequent outcomes of those patients that were transferred to a long-term device are shown in Section 6.5.

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 2012 to 31 March 2017

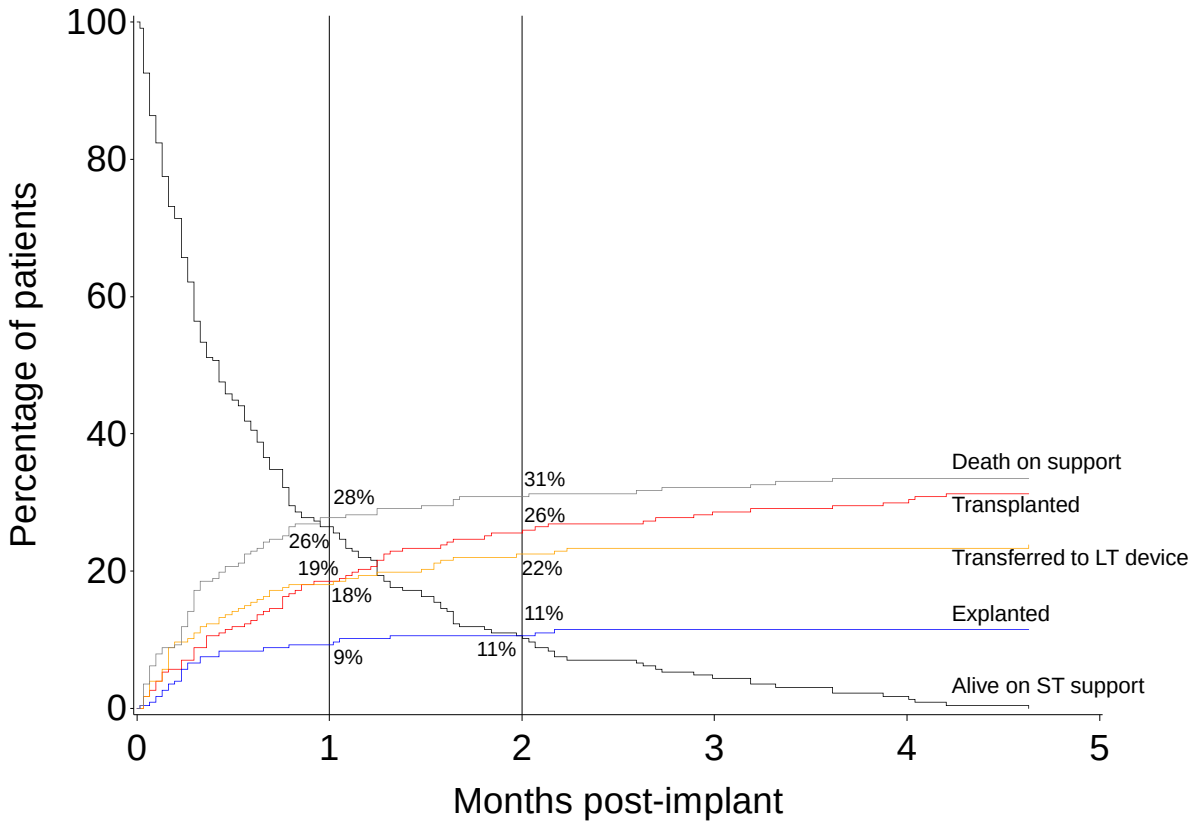


Table 6.3 shows the centre-specific 30-day estimates for each competing outcome. The incidence of each outcome varies across centres, however the estimates are based on small groups of particularly high risk patients so it is expected that each individual patient's condition would have a strong influence on these statistics.

Table 6.3 Cumulative incidence of each outcome at 30 days, by centre, for adult patients implanted with a first short-term bridging device, 1 April 2012 to 31 March 2017

Centre	Number of patients	Transplanted %	Transferred to LT device %	Explanted %	Alive on support %	Death on support %
Birmingham	57	30	11	9	14	37
Glasgow	33	15	9	21	33	21
Harefield	42	10	52	5	7	26
Manchester	59	10	8	7	47	27
Newcastle	7	0	43	43	0	14
Papworth	29	34	7	0	34	24
Overall	**227**	**19**	**18**	**9**	**26**	**28**

6.4 Patient survival from implant

This analysis looks at the rate of survival from the point of first short-term device implant regardless of any other interventions the patient may have received, such as transplant. This incorporates data from the UK Transplant Registry on post-transplant survival. For example, if a patient received a short-term device, was later transplanted and followed-up for two years, this entire time is considered. Any additional survival time recorded on the VAD Database for patients explanted is also counted, so if a patient was implanted, explanted and then survived for another year this entire time is included. Any time on additional devices is also counted, so for example if a patient was bridged to a long-term device but later died on 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 post-implant and are based on those patients recorded as receiving a first device between 1 April 2007 and 31 March 2016 where information on survival post-implant is known. **Figure 6.4** shows a comparison between implants performed in the earlier 5 years and implants performed in the latter 4 years. The national survival rates in the recent era were 67.0%, 54.2% and 44.8% at 30 days, 90 days and 1 year respectively.

In **Tables 6.5**-**6.7** and **Figures 6.5**-**6.7** the centre-specific survival rates for implants in the most recent era, 1 April 2012 to 31 March 2016, 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 6.8** which displays the baseline characteristics of the 177 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.

Figure 6.4 Unadjusted patient survival after short-term bridging device implant for adult patients implanted 1 April 2007 – 31 March 2016, by era

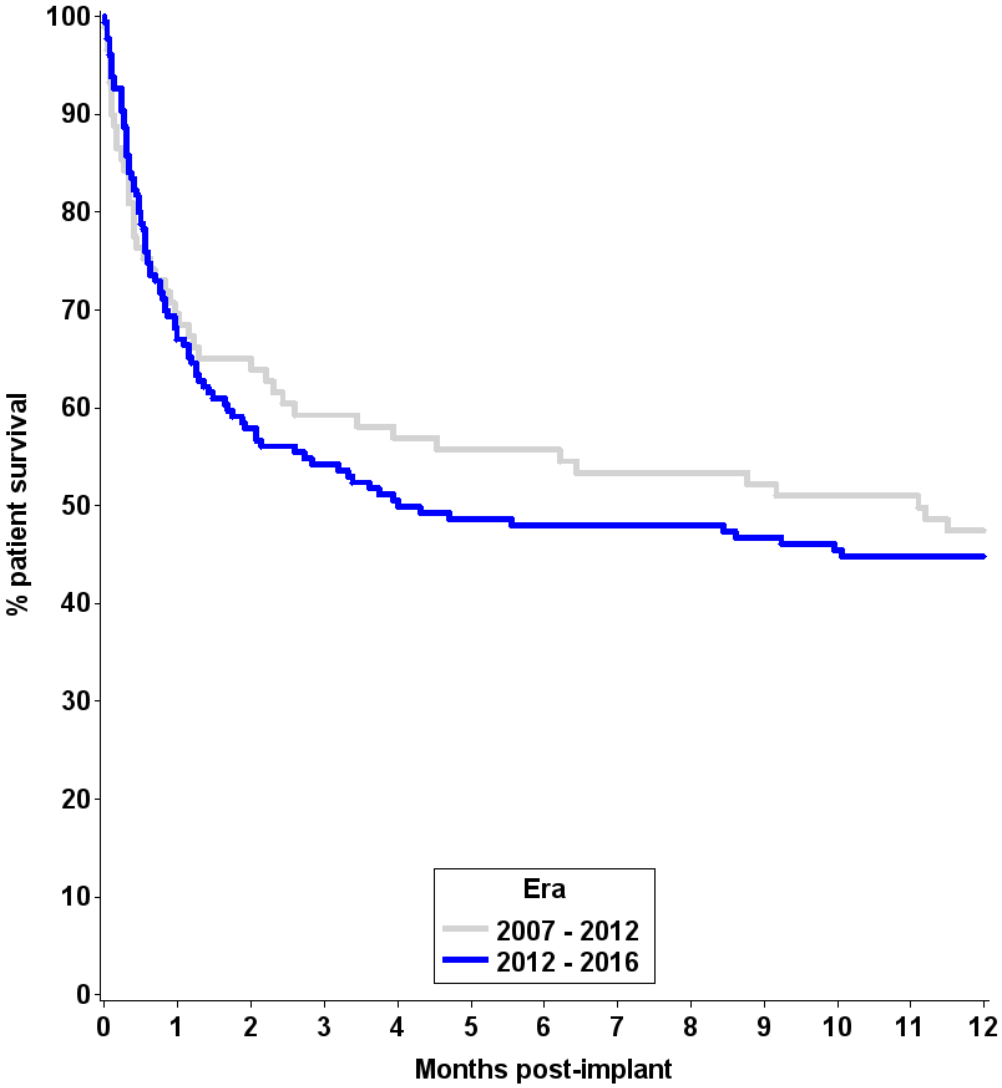


Table 6.4 Patient survival rates after short-term bridging device implant for adult patients implanted 1 April 2007 – 31 March 2016, by era

Era	Number of patients	% 30-day survival (95% CI)	% 90-day survival (95% CI)	% 1-year survival (95% CI)
1 Apr 2007 – 31 Mar 2012	89	69.6 (58.9 - 78.0)	59.2 (48.2 - 68.7)	47.4 (36.6 - 57.5)
1 Apr 2012 – 31 Mar 2016	177	67.0 (59.4 - 73.5)	54.2 (46.4 - 61.4)	44.8 (37.1 - 52.2)
Log-rank p-value		**0.8**	**0.6**	**0.7**

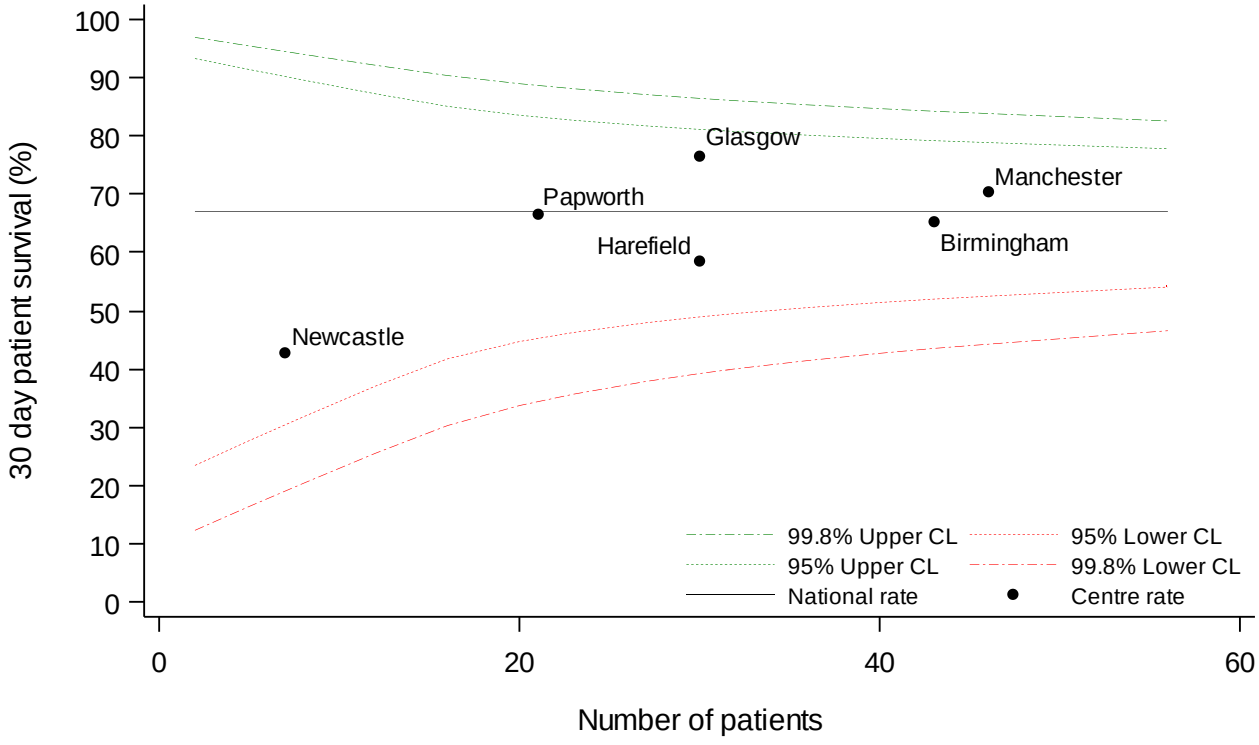
The unadjusted centre-specific 30-day survival rates for patients in the recent era are shown in **Table 6.5** and **Figure 6.5**. By centre, this ranged from 42.9% at Newcastle (based on small numbers) to 76.7% at Glasgow, however all rates were within the confidence limits for the national rate indicating that the variation observed was no more than expected by chance.

Table 6.5 30-day patient survival rates after short-term bridging device implant for adult patients implanted 1 April 2012 – 31 March 2016, by centre

Centre	Number of patients	% 30-day survival (95% CI) Unadjusted	
Birmingham	43	65.1	(49.0 - 77.3)
Glasgow	30	76.7	(57.2 - 88.1)
Harefield	30	58.6	(38.7 - 74.1)
Manchester	46	70.5	(54.6 - 81.7)
Newcastle	7	42.9	(5.8 - 77.7)
Papworth	21	66.7	(42.5 - 82.5)
UK	**177**	**67.0**	**(59.4 - 73.5)**

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

Figure 6.5 Unadjusted 30-day patient survival rates after short-term bridging device implant for adult patients implanted 1 April 2012 – 31 March 2016, by centre



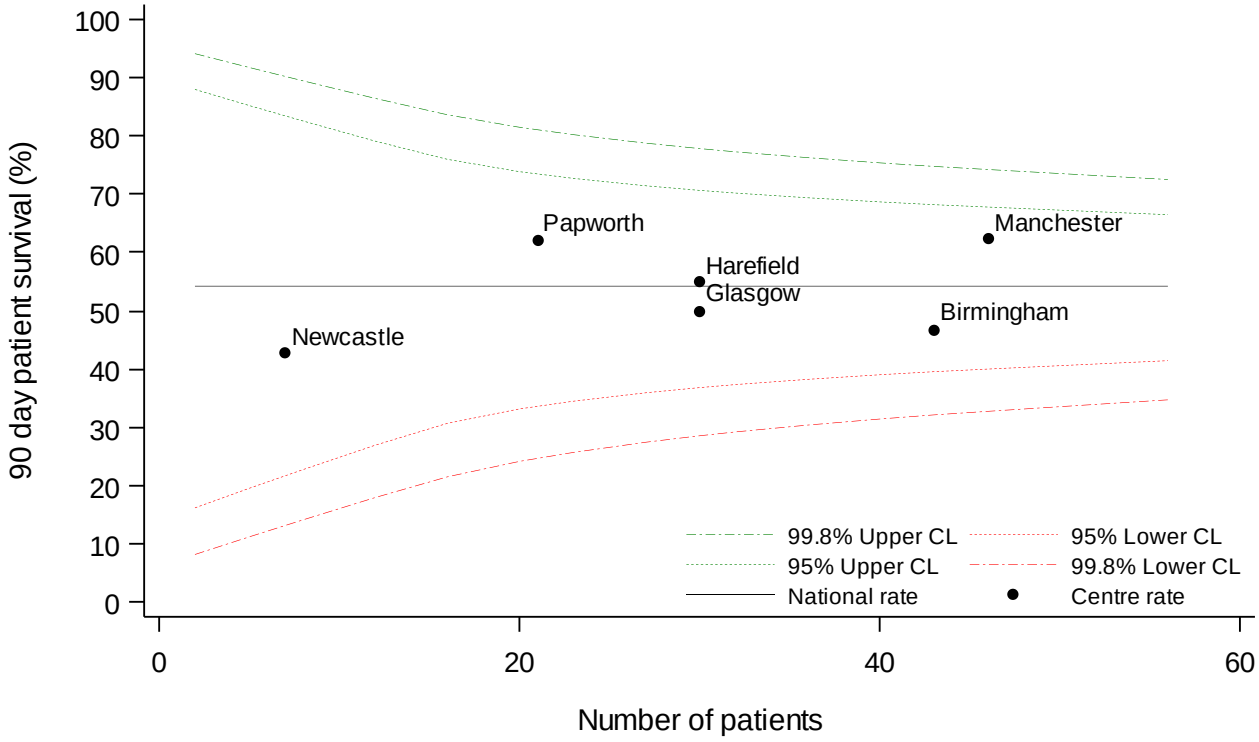
The unadjusted centre-specific 90-day survival rates are shown in **Table 6.6** and **Figure 6.6**. The rates are all within the confidence limits for the national rate indicating consistency with the national rate of 54.2%.

Table 6.6 90-day patient survival rates after short-term bridging device implant for adult patients implanted 1 April 2012 – 31 March 2016, by centre

Centre	Number of patients	% 90-day survival (95% CI) Unadjusted	
Birmingham	43	46.5	(31.2 - 60.4)
Glasgow	30	50.0	(31.3 - 66.1)
Harefield	30	55.0	(35.3 - 70.9)
Manchester	46	62.5	(46.0 - 75.2)
Newcastle	7	42.9	(5.8 - 77.7)
Papworth	21	61.9	(38.1 - 78.8)
UK	**177**	**54.2**	**(46.4 - 61.4)**

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

Figure 6.6 Unadjusted 90-day patient survival rates after short-term bridging device implant for adult patients implanted 1 April 2012 – 31 March 2016, by centre



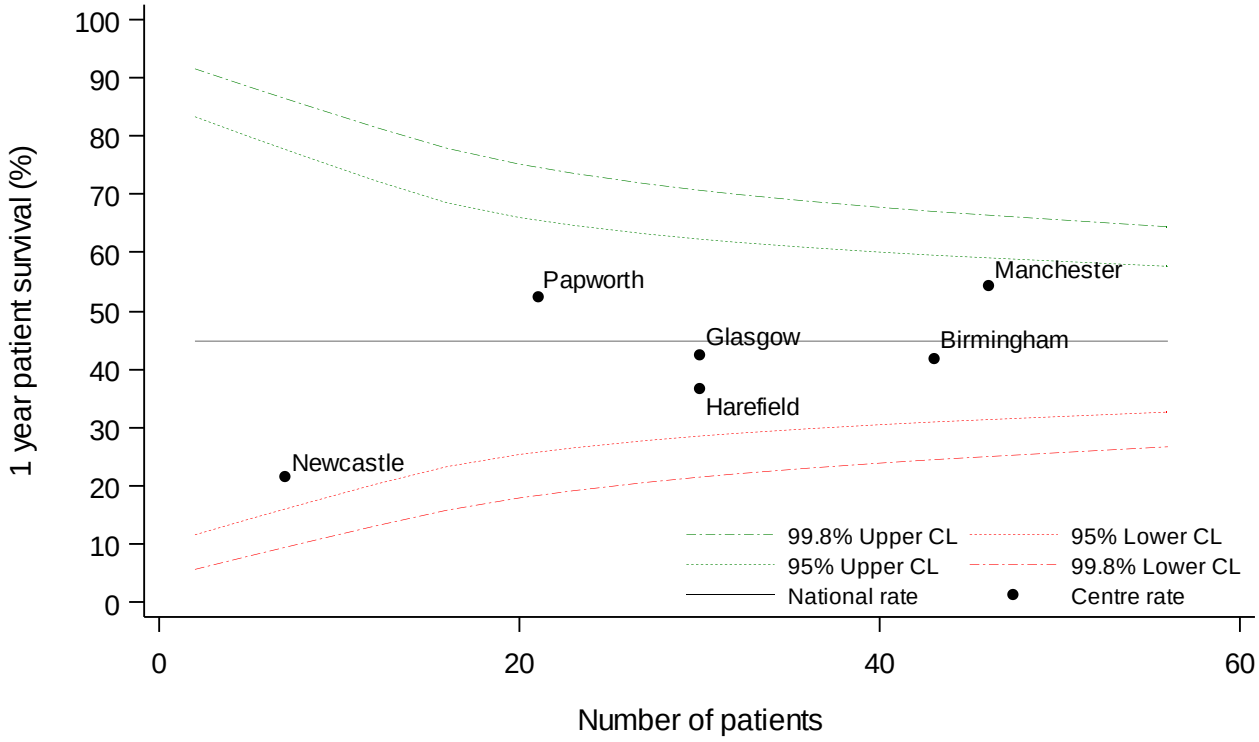
The unadjusted centre-specific 1-year survival rates are shown in **Table 6.7** and **Figure 6.7**. The rates are all within the confidence limits for the national rate.

Table 6.7 1-year patient survival rates after short-term bridging device implant for adult patients implanted 1 April 2012 – 31 March 2016, by centre

Centre	Number of patients	% 1-year survival (95% CI) Unadjusted	
Birmingham	43	41.9	(27.1 - 55.9)
Glasgow	30	42.4	(24.4 - 59.3)
Harefield	30	36.7	(19.5 - 54.0)
Manchester	46	54.3	(37.8 - 68.2)
Newcastle	7	21.4	(0.9 - 60.5)
Papworth	21	52.4	(29.7 - 70.9)
UK	**177**	**44.8**	**(37.1 - 52.2)**

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 6.7 Unadjusted 1-year patient survival rates after short-term bridging device implant for adult patients implanted 1 April 2012 – 31 March 2016, by centre



The demographic characteristics of the 177 patients in the survival from implant analysis are shown below in **Table 6.8** by centre and overall. Nationally, 70% of patients were male, the median age was 44 years and 53% of patients received an ECMO only. For some characteristics, due to rounding, percentages may not add up to 100.

Table 6.8 Characteristics of patients in the short-term bridging survival from implant analysis, by centre

		Birmingham N (%)	Glasgow N (%)	Harefield N (%)	Manchester N (%)	Newcastle N (%)	Papworth N (%)	**Total N (%)**
Number of patients		43	30	30	46	7	21	**177**
Age at implant (years)	Median (IQR)	47 (30-55)	43 (36-49)	48 (29-53)	40 (27-52)	50 (37-63)	42 (25-52)	**44 (30-53)**
Recipient sex	Male	29 (67)	16 (53)	21 (70)	33 (72)	5 (71)	20 (95)	**124 (70)**
	Female	14 (33)	14 (47)	9 (30)	13 (28)	2 (29)	1 (5)	**53 (30)**
Primary disease	Dilated cardiomyopathy	22 (51)	14 (47)	15 (50)	26 (57)	0 (0)	13 (62)	**90 (51)**
	Ischaemic heart disease	13 (30)	5 (17)	11 (37)	15 (33)	3 (43)	8 (38)	**55 (31)**
	Congenital heart disease	1 (2)	0 (0)	1 (3)	0 (0)	2 (29)	0 (0)	**4 (2)**
	Hypertrophic cardiomyopathy	1 (2)	2 (7)	1 (3)	0 (0)	0 (0)	0 (0)	**4 (2)**
	Valvular heart disease	2 (5)	1 (3)	1 (3)	1 (2)	0 (0)	0 (0)	**5 (3)**
	Infiltrative heart muscle disease	2 (5)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**2 (1)**
	Other	0 (0)	5 (17)	0 (0)	3 (7)	2 (29)	0 (0)	**10 (6)**
	Unknown	2 (5)	3 (10)	1 (3)	1 (2)	0 (0)	0 (0)	**7 (4)**
INTERMACS patient profile	1. Critical cardiogenic shock	34 (79)	15 (50)	25 (83)	41 (89)	6 (86)	14 (67)	**135 (76)**
	2. Progressive decline	8 (19)	14 (47)	2 (7)	4 (9)	1 (14)	7 (33)	**36 (20)**
	3. Stable but inotrope dependent	0 (0)	1 (3)	1 (3)	0 (0)	0 (0)	0 (0)	**2 (1)**
	4. Recurrent advanced heart failure	1 (2)	0 (0)	1 (3)	0 (0)	0 (0)	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)	1 (3)	0 (0)	0 (0)	0 (0)	**1 (1)**
	Unknown	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	**1 (1)**
First VAD device name	Impella	5 (12)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**5 (3)**
	Centrimag	15 (35)	18 (60)	9 (30)	26 (57)	1 (14)	10 (48)	**79 (45)**
	ECMO only	23 (53)	12 (40)	21 (70)	20 (43)	6 (86)	11 (52)	**93 (53)**

6.5 Bridge to long-term device

As seen in **Figure 6.3**, a proportion of patients that receive short-term support are later transferred to a long-term device. The median duration on short-term support for the subgroup of patients implanted with a short-term device between 1 April 2012 and 31 March 2016 and bridged to a long-term device was 10 days (95% confidence interval: 7 - 13 days). Patient survival from the point of first short-term device implant, including time on long-term support and any subsequent treatment, is shown in **Figure 6.8** with the corresponding survival rates at 30 days, 90 days and 1 year in **Table 6.9**. Survival for this subgroup is superior to that of the full cohort of patients whose first device was a short-term device.

Figure 6.8 Unadjusted patient survival from point of short-term device implant for adult patients implanted 1 April 2012 – 31 March 2016 and bridged to a long-term device

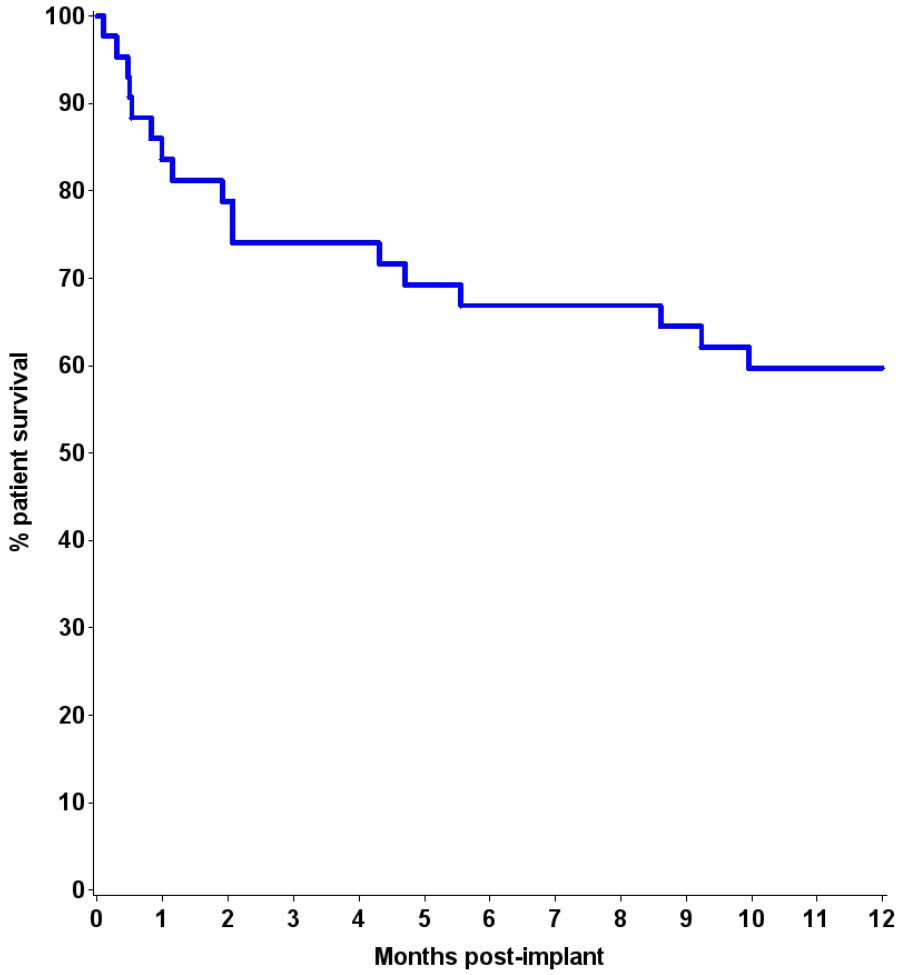


Table 6.9 Patient survival rates after short-term device implant for adult patients bridged to a long-term device 1 April 2012 – 31 March 2016

Number of patients	% 30-day survival (95% CI)	% 90-day survival (95% CI)	% 1-year survival (95% CI)
43	83.6 (68.6 - 91.8)	74.0 (58.0 - 84.7)	59.7 (43.4 - 72.7)

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 (which could be for the same transplant or a different transplant) each implant is included. Short-term devices used for rejection more than 30 days post-heart transplant are excluded (six recorded in the time period) as are long-term devices used post-transplant (three Berlin Hearts by Newcastle and one TAH by Harefield).

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 2016/2017 there were 33 implantations, 4 more than 2015/2016 and 3 times higher than in 2007/2008. Since 2010/2011, 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 Manchester and Birmingham had the highest activity in 2016/2017. Note that the ECMO activity for Newcastle is incomplete as there has been an issue with under reporting of this treatment since 2013.

Figure 7.1 Number of adult short-term device implants for PGD in the UK, by financial year and device type, 1 April 2007 to 31 March 2017

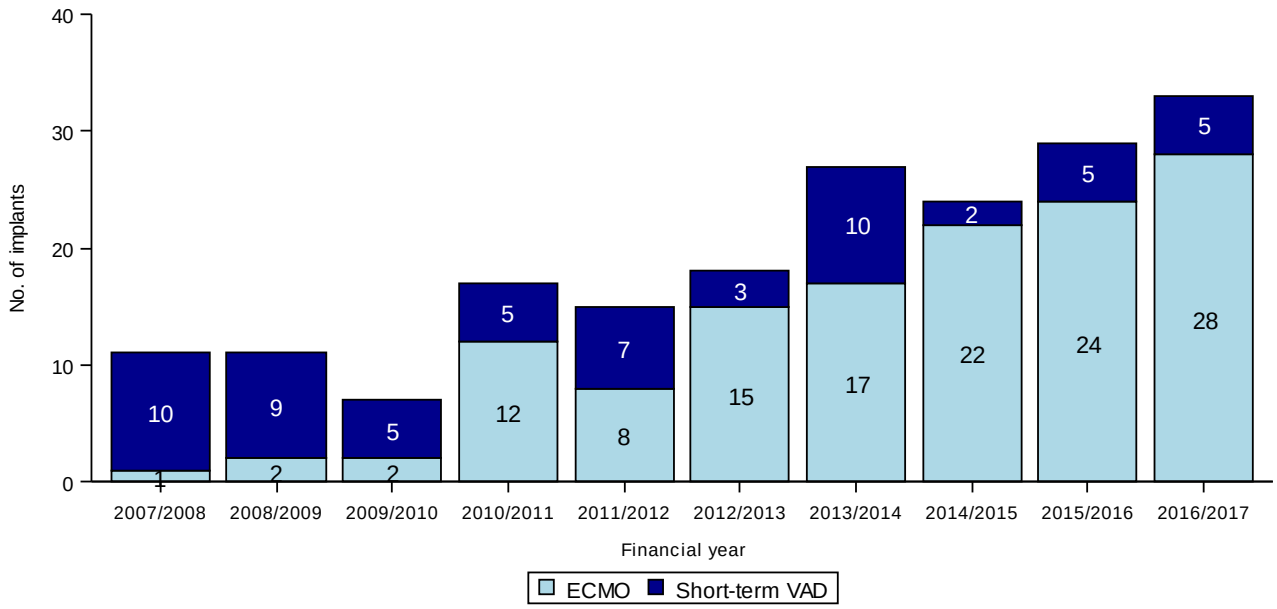


Figure 7.2 Number of adult short-term device implants for PGD in the UK, by financial year, centre and device type, 1 April 2007 to 31 March 2017

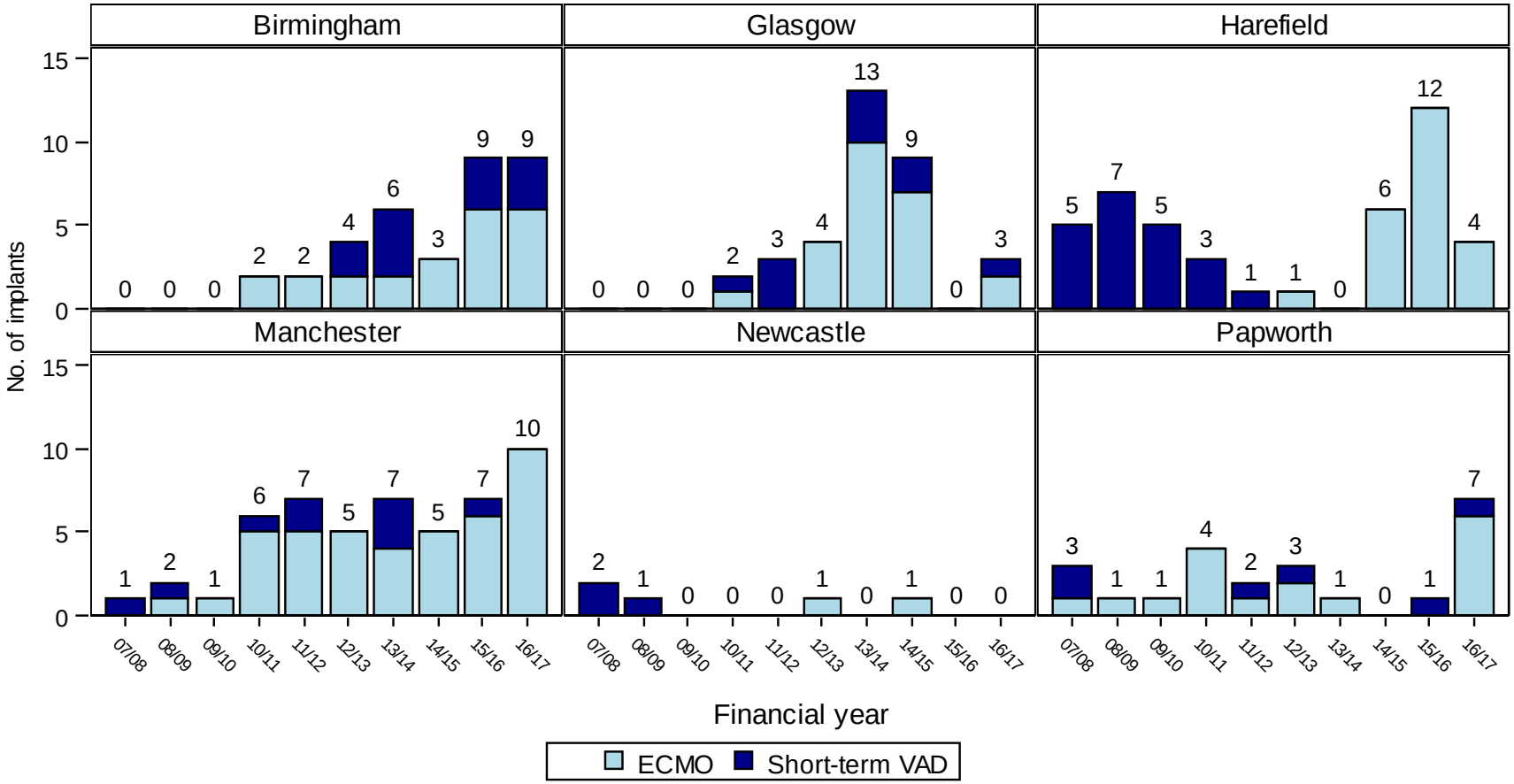


Figure 7.3 Number of adult short-term device implants for PGD in the UK, by centre and device type, 1 April 2016 to 31 March 2017

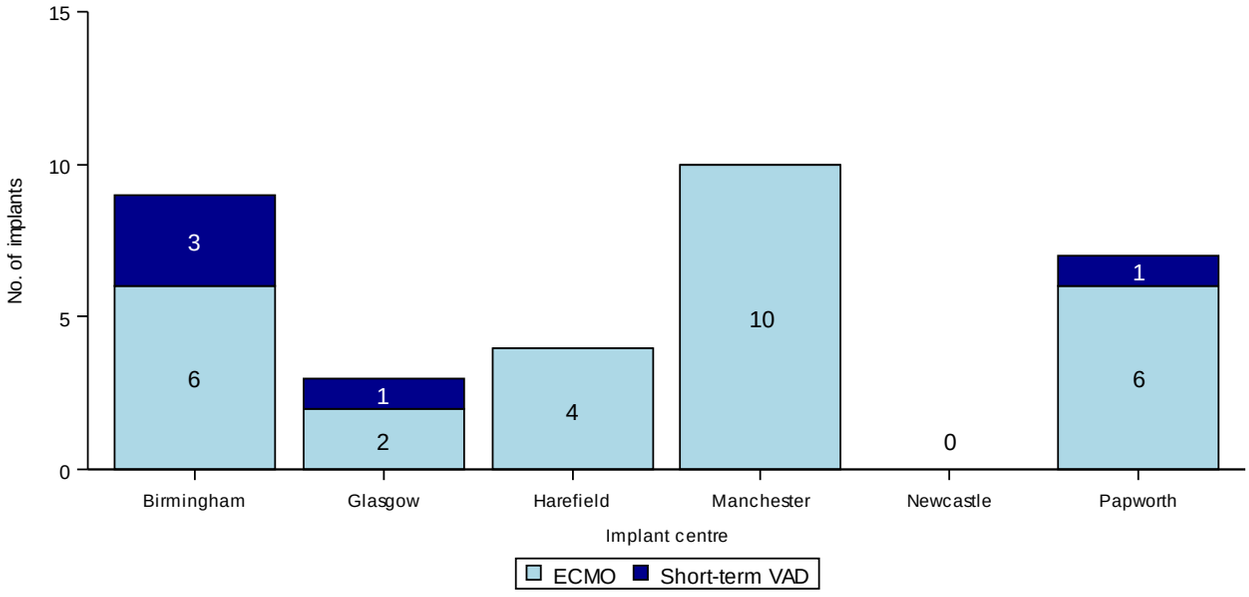
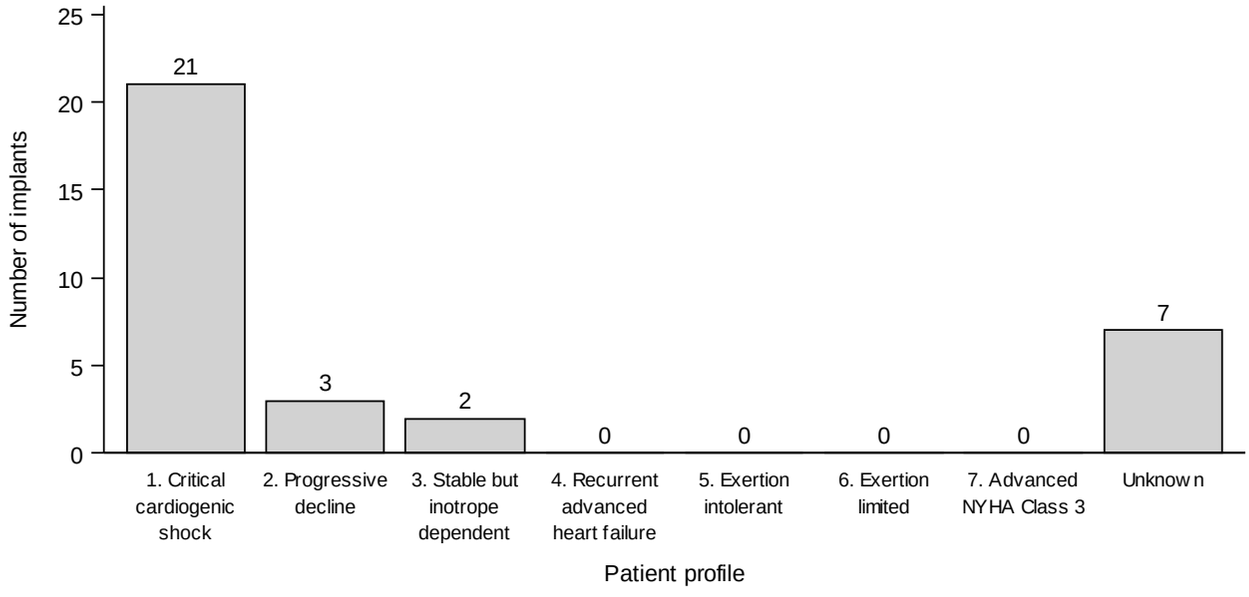


Figure 7.4 shows the INTERMACS patient profile at receipt of short-term support for patients implanted during 2016/2017. Most patients were profile 1 (critical cardiogenic shock) but there were some missing data.

Figure 7.4 INTERMACS patient profile for all short-term device implants for PGD in adult patients in the UK, 1 April 2016 to 31 March 2017



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 Duration on support

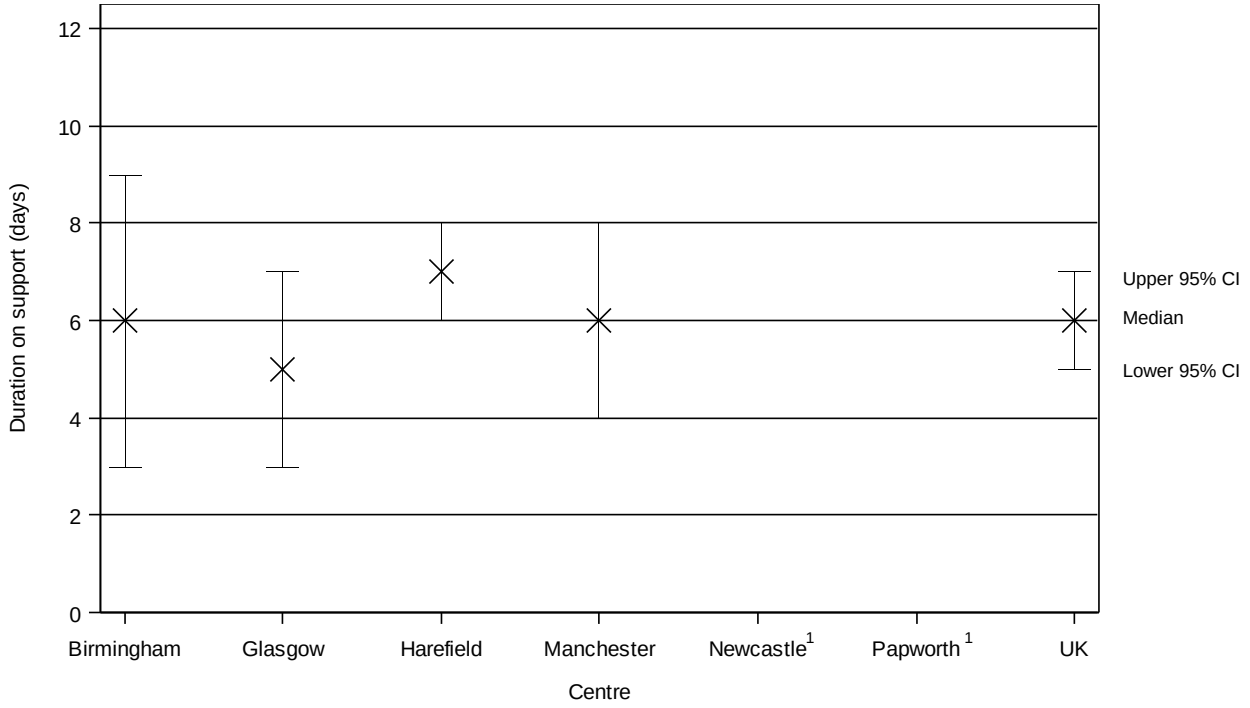
Table 8.1 shows the median duration on short-term support for patients implanted in a recent three-year period, both nationally and by centre. The medians and confidence intervals are estimated using the Kaplan-Meier method. This includes time spent on any short-term device post-transplant so if a patient went from ECMO to short-term VAD, all this time is counted. Nationally, the median time on support was 6 days and was similar across all centres (where estimable).

Table 8.1 Median duration on short-term device support for PGD for adult patients implanted between 1 April 2013 and 31 March 2016, by centre

Centre	Number of patients	Time of support (days) Median	(95% confidence interval)
Birmingham	16	6	3 - 9
Glasgow	17	5	3 - 7
Harefield	16	7	6 - 8
Manchester	15	6	4 - 8
Newcastle[1]	1	-	-
Papworth[1]	2	-	-
Overall	**67**	**6**	**5 - 7**

[1] Median duration on support cannot be estimated due to small numbers of patients

Figure 8.1 Median duration on short-term device support for PGD for adult patients implanted between 1 April 2013 and 31 March 2016



[1] Median duration on support cannot be estimated due to small numbers of patients

8.2 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 on post-transplant survival. Survival rates are calculated using the Kaplan-Meier method where times are censored if the patient was still alive at last known follow-up. The rates are estimated at 30 days, 90 days and 1 year and are based on the 83 patients recorded as receiving a short-term device for PGD between 1 April 2012 and 31 March 2016 where information on survival post-implant is known. Survival rates are given nationally and for individual centres. Note that the centre-specific rates are unadjusted for potential differences in risk between patients treated at different centres.

The unadjusted 30-day, 90-day and 1-year survival rates for patients in the time period are shown in **Tables 8.2**, **8.3** and **8.4**, respectively. The national rates of survival were 59.2%, 54.1% and 44.1%, respectively. **Table 8.5** displays the baseline characteristics of the 83 patients included in this analysis.

Table 8.2 30-day patient survival rates after short-term device implant for PGD for adult patients implanted 1 April 2012 – 31 March 2016, by centre

Centre	Number of patients	Number of deaths	% 30-day survival (95% CI) Unadjusted	
Birmingham	19	7	62.0	(36.3 - 79.8)
Glasgow	20	8	60.0	(35.7 - 77.6)
Harefield	17	10	35.3	(14.5 – 57.0)
Manchester	20	5	73.1	(46.8 - 87.9)
Newcastle[1]	2	2	-	-
Papworth[1]	5	0	-	-
UK	**83**	**32**	**59.2**	**(47.6 – 69.0)**

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

Table 8.3 90-day patient survival rates after short-term device implant for PGD for adult patients implanted 1 April 2012 – 31 March 2016, by centre

Centre	Number of patients	Number of deaths	% 90-day survival (95% CI) Unadjusted	
Birmingham	19	7	62.0	(36.3 - 79.8)
Glasgow	20	8	60.0	(35.7 - 77.6)
Harefield	17	13	23.5	(7.3 - 44.9)
Manchester	20	7	61.9	(36.1 - 79.8)
Newcastle[1]	2	2	-	-
Papworth[1]	5	0	-	-
UK	**83**	**37**	**54.1**	**(42.6 - 64.3)**

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

Table 8.4 1-year patient survival rates after short-term device implant for PGD for adult patients implanted 1 April 2012 – 31 March 2016, by centre

Centre	Number of patients	Number of deaths	% 1-year survival (95% CI) Unadjusted	
Birmingham	19	12	33.8	(13.9 - 55.1)
Glasgow	20	10	50.0	(27.1 - 69.2)
Harefield	17	13	23.5	(7.3 - 44.9)
Manchester	20	8	56.3	(31.1 - 75.3)
Newcastle[1]	2	2	-	-
Papworth[1]	5	0	-	-
UK	**83**	**45**	**44.1**	**(33.0 - 54.5)**

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

The demographic characteristics of the 83 patients in the survival from implant analysis are shown below in **Table 8.5** by centre and overall. Nationally, 77% of patients were male, the median age was 49 years and 88% of patients received ECMO only. For some characteristics, due to rounding, percentages may not add up to 100.

Table 8.5 Characteristics of patients in the short-term PGD survival from implant analysis, by centre

		Birmingham N (%)	Glasgow N (%)	Harefield N (%)	Manchester N (%)	Newcastle N (%)	Papworth N (%)	**Total N (%)**
Number of patients		19	20	17	20	2	5	**83**
Age at implant (years)	Median (IQR)	52 (30-58)	46 (37-54)	49 (32-55)	51 (41-58)	40 (38-42)	42 (36-50)	**49 (36-55)**
Sex	Male	16 (84)	15 (75)	11 (65)	18 (90)	0 (0)	4 (80)	**64 (77)**
	Female	3 (16)	5 (25)	6 (35)	2 (10)	2 (100)	1 (20)	**19 (23)**
Primary disease	Dilated cardiomyopathy	9 (47)	9 (45)	7 (41)	12 (60)	1 (50)	1 (20)	**39 (47)**
	Ischaemic heart disease	6 (32)	4 (20)	4 (24)	5 (25)	0 (0)	2 (40)	**21 (25)**
	Congenital heart disease	1 (5)	0 (0)	0 (0)	0 (0)	1 (50)	0 (0)	**2 (2)**
	Hypertrophic cardiomyopathy	1 (5)	2 (10)	2 (12)	0 (0)	0 (0)	1 (20)	**6 (7)**
	Restrictive cardiomyopathy	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)	**2 (2)**
	Valvular heart disease	0 (0)	1 (5)	2 (12)	1 (5)	0 (0)	0 (0)	**4 (5)**
	Other	0 (0)	3 (15)	1 (6)	2 (10)	0 (0)	1 (20)	**7 (8)**
	Unknown	1 (5)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	**2 (2)**
INTERMACS patient profile	1. Critical cardiogenic shock	17 (89)	15 (75)	10 (59)	4 (20)	2 (100)	4 (80)	**52 (63)**
	2. Progressive decline	1 (5)	3 (15)	1 (6)	6 (30)	0 (0)	1 (20)	**12 (14)**
	3. Stable but inotrope dependent	1 (5)	2 (10)	0 (0)	2 (10)	0 (0)	0 (0)	**5 (6)**
	4. Recurrent advanced heart failure	0 (0)	0 (0)	0 (0)	5 (25)	0 (0)	0 (0)	**5 (6)**
	5. Exertion intolerant	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**0 (0)**
	6. Exertion limited	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**0 (0)**
	7. Advanced NYHA Class 3	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**0 (0)**
	Unknown	0 (0)	0 (0)	6 (35)	3 (15)	0 (0)	0 (0)	**9 (11)**
First LVAD device name	Impella	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**1 (1)**
	Centrimag	6 (32)	1 (5)	0 (0)	0 (0)	0 (0)	2 (40)	**9 (11)**
	ECMO only	12 (63)	19 (95)	17 (100)	20 (100)	2 (100)	3 (60)	**73 (88)**

PAEDIATRIC DEVICES USED FOR BRIDGING

Activity

9 Mechanical circulatory support in paediatrics

This section considers all paediatric (age less than 16 years) patients who received mechanical circulatory support as a bridge to heart transplantation between 1 April 2013 and 31 March 2017. Devices used post-transplant are excluded. 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.

Figure 9.1 shows the total number of bridging device implants each year nationally by device type (long-term and short-term). During 2016/2017 there were 19 implantations; 4 fewer than 2015/2016. The highest activity was recorded in 2014/2015. Overall, there were 97 implants, with long-term device implants making up 71%. **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 2017

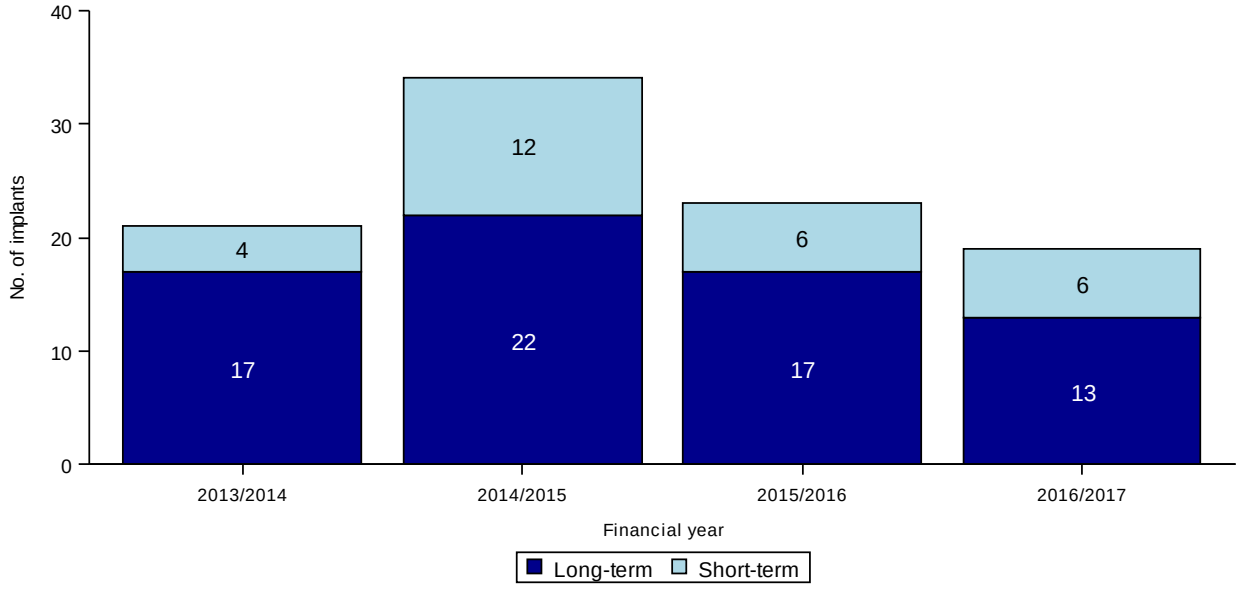


Figure 9.2 Number of paediatric bridging device implants in the UK, by financial year, centre and device type, 1 April 2013 to 31 March 2017

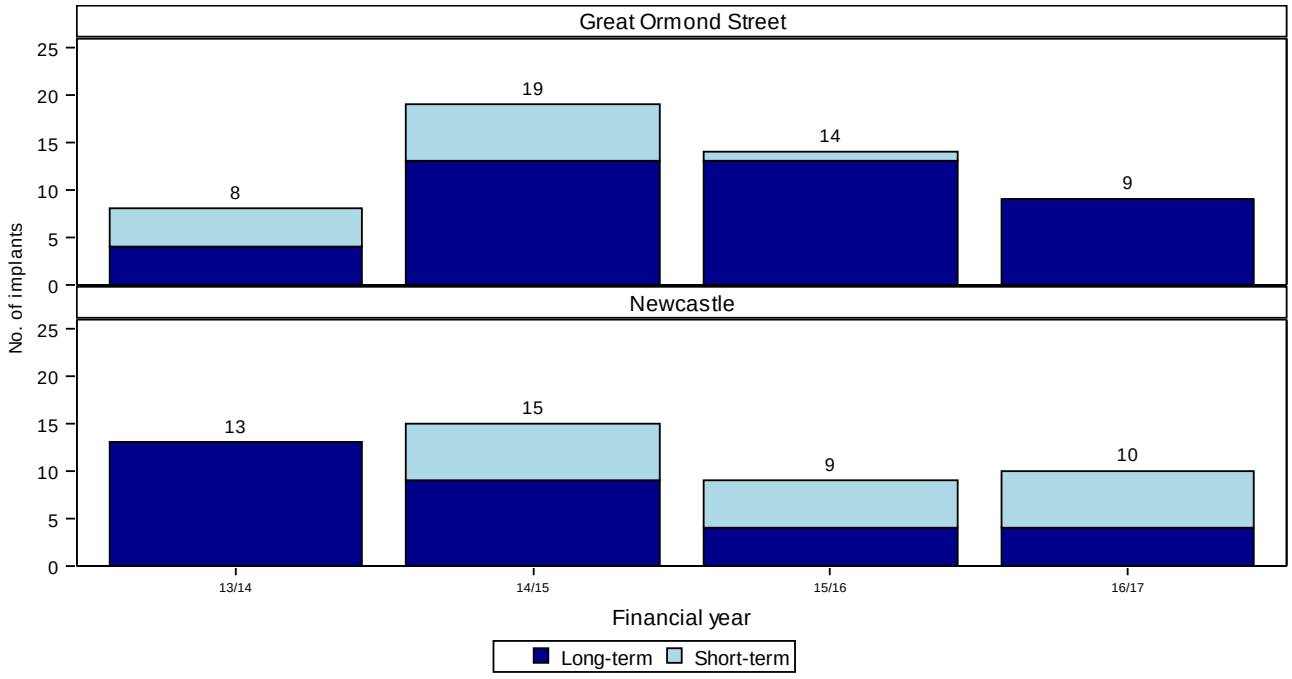
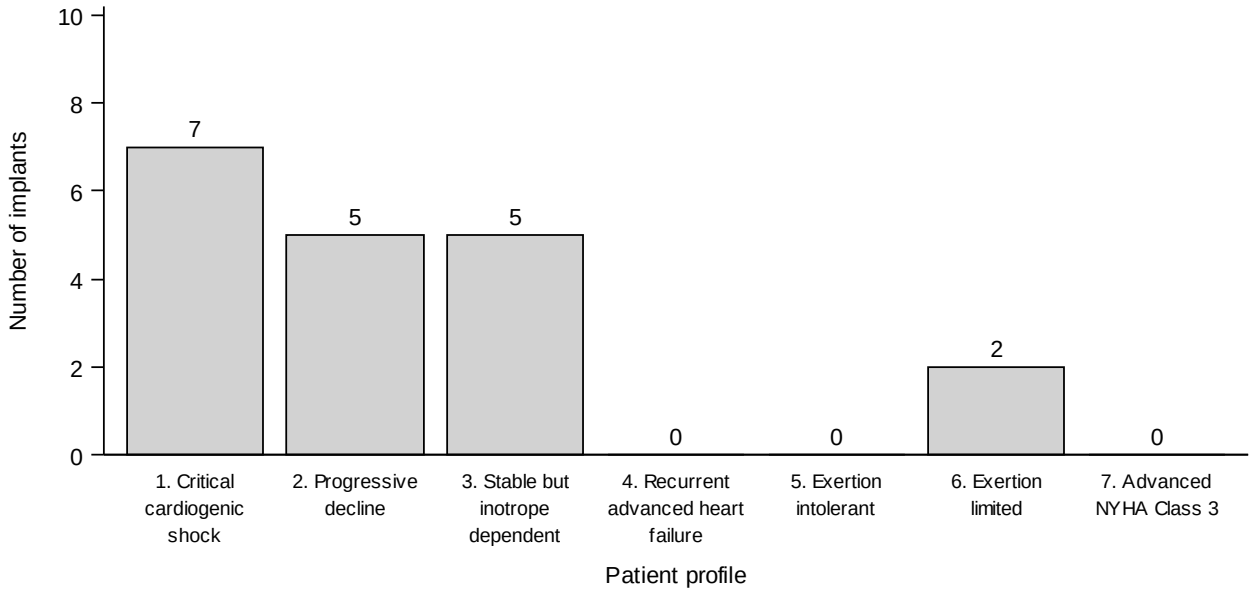


Figure 9.3 Number of paediatric bridging device implants in the UK, by centre and device type, 1 April 2016 to 31 March 2017

Figure 9.4 shows the INTERMACS patient profile at implant for paediatric patients implanted during 2016/2017. There was a range of profiles reported.

Figure 9.4 INTERMACS patient profile for all bridging devices used in paediatric patients in the UK, 1 April 2016 to 31 March 2017



PAEDIATRIC DEVICES USED FOR BRIDGING

Patient Outcomes

10 Outcomes of paediatric patients receiving bridging devices

This section considers all paediatric patients who received any type of support for bridging. If a patient was moved from a short-term device to a long-term device, for example, the entire time they were on support is considered. Patients are analysed on a per-patient basis, as opposed to per implant.

10.1 Duration on support

Table 10.1 shows the median duration on support for patients implanted in a recent three-year period, both nationally and by centre. The medians and confidence intervals are estimated using the Kaplan-Meier method since not all patients may have come to the end of support and this method allows these (censored) patients to be included in the analysis. Transplant, explant or death signify end of support. Nationally, the median time on support was 59 days. Great Ormond Street used a higher proportion of long-term devices, explaining their longer median duration of 104 days.

Table 10.1 Median duration on support for paediatric patients implanted with a bridging device between 1 April 2013 and 31 March 2016, by centre

Centre	Number of patients	Time on support (days) Median	(95% confidence interval)
Great Ormond Street	32	104	40 - 168
Newcastle	36	31	24 - 38
Overall	**68**	**59**	**20 - 98**

Note: Great Ormond Street used a higher proportion of long-term devices, explaining their longer durations

Figure 10.1 Median duration on support for paediatric patients implanted with a bridging device between 1 April 2013 and 31 March 2016

Note: Great Ormond Street used a higher proportion of long-term devices, explaining their longer durations

10.2 Rate of transplant listing

Figure 10.2 and **Table 10.2** show the rate of transplant listing for patients implanted between 1 April 2013 and 31 March 2016 by centre. This includes listing on the urgent or non-urgent heart transplant lists (whichever occurred first). Overall, 74% of patients were listed prior to implant, with a further 19% listed after implant and 7% 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 2013 – 31 March 2016, by centre and overall

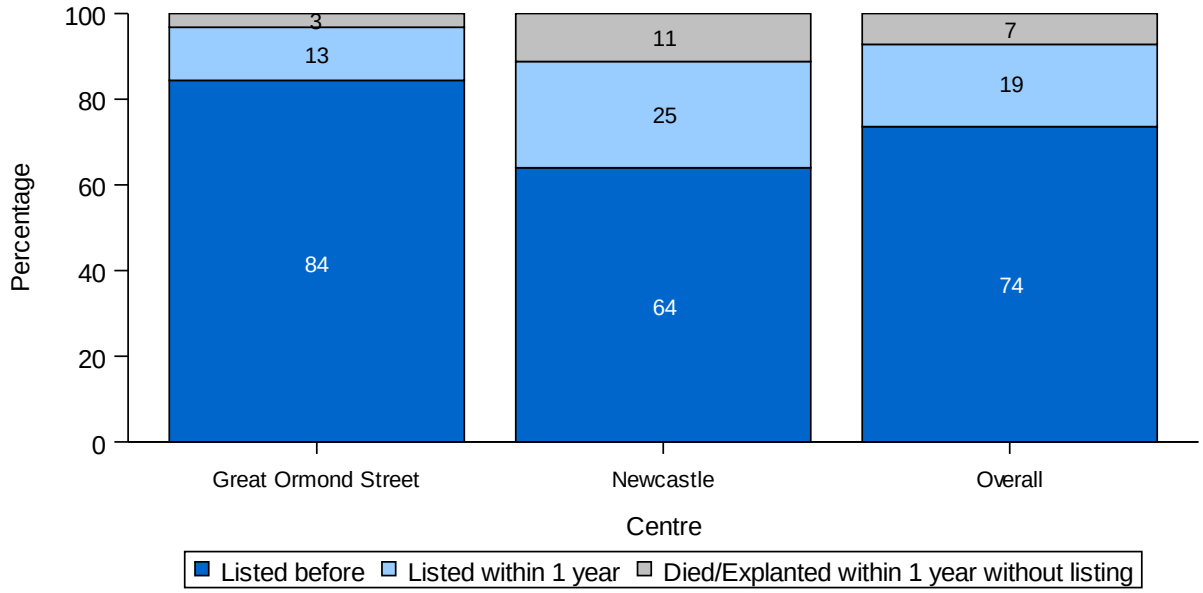


Table 10.2 Heart transplant listing status with respect to bridging device implantation for paediatric patients implanted 1 April 2013 – 31 March 2016, by centre and overall

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	32	27 (84)	4 (13)	0 (-)	1 (3)
Newcastle	36	23 (64)	9 (25)	0 (-)	4 (11)
Overall	**68**	**50 (74)**	**13 (19)**	**0 (-)**	**5 (7)**

10.3 Competing risks

Whilst on short-term support, patients are susceptible to different outcomes. Death on support, transplant and explant without transplant (with or without recovery) are all possible outcomes. **Figure 10.3** shows the cumulative incidence of each of these outcomes occurring from time of implantation, for the cohort of paediatric patients receiving a first device between 1 April 2013 and 31 March 2017. This is calculated using the Aalen-Johansen method to account for competing risks. 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. Any subsequent VAD support post-explant is not counted and any such patients are classed simply as explanted. If a patient is moved from one device to another (of any type) without a period free of support, they are counted as still on support.

For this cohort, one month after receipt of a device, 62% of patients remained alive on support, 29% received a heart transplant, 5% died on support and 5% had their device explanted. At three months, the incidence of transplantation rose to 46%, the incidence of death rose slightly, to 7%, and the proportion explanted became 8%, leaving 38% left on support.

Figure 10.3 Cumulative incidence functions for transplant, death and explant for paediatric patients receiving a bridging device, 1 April 2013 to 31 March 2017

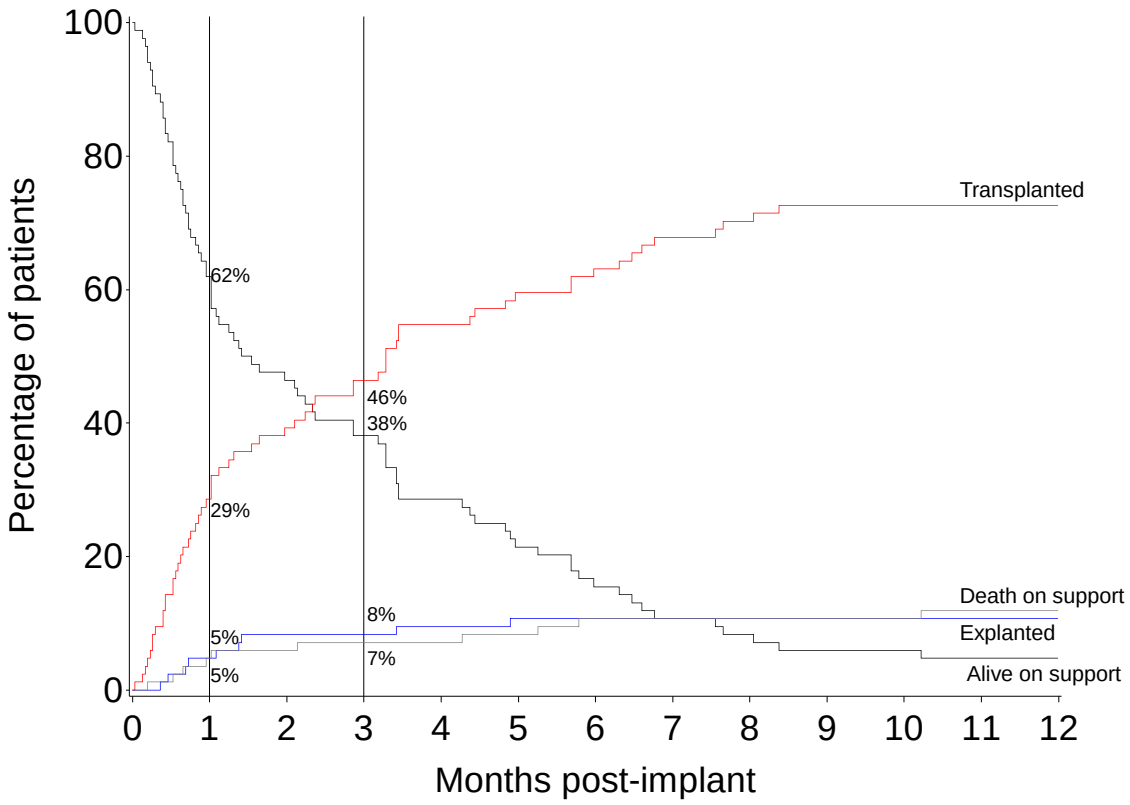


Table 10.3 shows the centre-specific 90-day estimates for each competing outcome. A slightly higher proportion of patients had received a transplant at 90 days at Newcastle (51%) compared with Great Ormond Street (41%).

Table 10.3 Cumulative incidence of each outcome at 90 days, by centre, for paediatric patients implanted with a first bridging device, 1 April 2013 to 31 March 2017

Centre	Number of patients	Transplanted %	Explanted %	Alive on support %	Death on support %
Great Ormond Street	41	41	5	49	5
Newcastle	43	51	12	28	9
Overall	**84**	**46**	**8**	**38**	**7**

10.4 Patient survival from implant

This analysis looks at the rate of survival from the point of first device implant regardless of any other interventions the patient may have received, such as transplant. This incorporates data from the UK Transplant Registry on post-transplant survival. For example, if a patient received a long-term VAD, was later transplanted and followed-up for two years, this entire time is considered. Any additional survival time recorded on the VAD Database for patients explanted in also counted, so if a patient was implanted, explanted and then survived for another year, this entire time is included. Any 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, then died, 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 based on the 68 patients recorded as receiving a bridging device between 1 April 2013 and 31 March 2016 where information on survival post-implant is known. Survival rates are given nationally and for individual centres. 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 period are shown in **Tables 10.4**, **10.5** and **10.6**, respectively. The national rate of survival at each time point was 91.2%, 86.7% and 79.1%, respectively. **Table 10.7** displays the baseline characteristics of the 68 patients included in this analysis.

Table 10.4	30-day patient survival rates after bridging device implant for paediatric patients implanted 1 April 2013 – 31 March 2016, by centre			
Centre	Number of patients	Number of deaths	% 30-day survival (95% CI) Unadjusted	
Great Ormond Street	32	2	93.8	(77.3 - 98.4)
Newcastle	36	4	88.9	(73.1 - 95.7)
UK	**68**	**6**	**91.2**	**(81.4 - 95.9)**

Table 10.5	90-day patient survival rates after bridging device implant for paediatric patients implanted 1 April 2013 – 31 March 2016, by centre			
Centre	Number of patients	Number of deaths	% 90-day survival (95% CI) Unadjusted	
Great Ormond Street	32	4	87.5	(70.0 - 95.1)
Newcastle	36	4	86.0	(69.6 - 93.9)
UK	**68**	**8**	**86.7**	**(76.0 - 92.8)**

Table 10.6	1-year patient survival rates after bridging device implant for paediatric patients implanted 1 April 2013 – 31 March 2016, by centre			
Centre	Number of patients	Number of deaths	% 1-year survival (95% CI) Unadjusted	
Great Ormond Street	32	5	84.4	(66.5 - 93.2)
Newcastle	36	9	74.3	(56.4 - 85.8)
UK	**68**	**14**	**79.1**	**(67.2 – 87.0)**

The demographic characteristics of the 68 patients in the survival from implant analysis are shown below in **Table 10.7** by centre and overall. Nationally, 49% of patients were male, the median age was 3 years and 46% of patients received a Berlin Heart Excor device. For some characteristics, due to rounding, percentages may not add up to 100.

Table 10.7 Characteristics of patients in the paediatric survival from implant analysis, by centre

		Great Ormond Street N (%)	Newcastle N (%)	**Total** **N (%)**
Number of patients		32	36	**68**
Age at implant (years)	Median (IQR)	6 (2-11)	1 (0-6)	**3 (0-9)**
	Missing	0	0	**0**
Sex	Male	15 (47)	18 (50)	**33 (49)**
	Female	17 (53)	18 (50)	**35 (51)**
Primary disease	Dilated cardiomyopathy	24 (75)	25 (69)	**49 (72)**
	Congenital heart disease	0 (0)	7 (19)	**7 (10)**
	Restrictive cardiomyopathy	3 (9)	2 (6)	**5 (7)**
	Other	5 (16)	2 (6)	**7 (10)**
INTERMACS patient profile	1. Critical cardiogenic shock	6 (19)	31 (86)	**37 (54)**
	2. Progressive decline	21 (66)	4 (11)	**25 (37)**
	3. Stable but inotrope dependent	4 (13)	1 (3)	**5 (7)**
	4. Recurrent advanced heart failure	1 (3)	0 (0)	**1 (1)**
	5. Exertion intolerant	0 (0)	0 (0)	**0 (0)**
	6. Exertion limited	0 (0)	0 (0)	**0 (0)**
	7. Advanced NYHA Class 3	0 (0)	0 (0)	**0 (0)**
First VAD device name	Berlin Heart Excor	17 (53)	14 (39)	**31 (46)**
	Heartware	6 (19)	11 (31)	**17 (25)**
	Centrimag	4 (13)	4 (11)	**8 (12)**
	Levitronix with BH cannulae	0 (0)	7 (19)	**7 (10)**
	ECMO only	5 (16)	0 (0)	**5 (7)**

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 2007 – 31 March 2017	• Introduction/Activity	None	783 (implants)
1 April 2013 – 31 March 2016	• Duration on support	• TAH and pulsatile devices • Patients who had a previous short-term device	244 (patients)
1 April 2012 – 31 March 2016	• Rate of transplant listing	• TAH and pulsatile devices • Patients who had a previous short-term device	297 (patients)
1 April 2012 – 31 March 2017	• Competing risks	• TAH and pulsatile devices • Patients who had a previous short-term device	373 (patients)
1 April 2012 – 31 March 2016	• Patient survival from implant	• TAH and pulsatile devices • Patients who had a previous short-term device • Patients with missing survival data	295 (patients)
1 April 2007 – 31 March 2017	• TAH outcomes	• Patients who received a TAH post-transplant	15 (patients)
Adult – Short-term bridging			
1 April 2007 – 31 March 2017	• Introduction/Activity	None	394 (implants)
1 April 2013 – 31 March 2016	• Duration on support	• Patients who had a previous long-term device	143 (patients)
1 April 2012 – 31 March 2016	• Rate of transplant listing	• Patients who had a previous long-term device	177 (patients)
1 April 2012 – 31 March 2017	• Competing risks	• Patients who had a previous long-term device	227 (patients)
1 April 2012 – 31 March 2016	• Patient survival from implant	• Patients who had a previous long-term device • Patients with missing survival data	177 (patients)
Adult – Short-term post-transplant			
1 April 2007 – 31 March 2017	• Introduction/Activity	• Implants for rejection • Long-term devices used post-transplant	192 (implants)
1 April 2013 – 31 March 2016	• Duration on support	• Implants for rejection • Long-term devices used post-transplant	67 (patients)
1 April 2012 – 31 March 2016	• Patient survival from implant	• Implants for rejection • Long-term devices used post-transplant • Patients with missing survival data	98 (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 2017	• Introduction/Activity	None	97 (implants)
1 April 2013 – 31 March 2016	• Duration on support • Rate of transplant listing	None	68 (patients)
1 April 2013 – 31 March 2017	• Competing risks	None	84 (patients)
1 April 2013 – 31 March 2016	• Patient survival from implant	• Patients with missing survival data	68 (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".
- 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.

Table A1.3 details the device history of patients reported as receiving a bridging device between 1 April 2007 and 31 March 2017 and the section of the report each type of patient is included in. For example, 580 adult patients received a single long-term device implant, of which 580 are included in the activity section of the long-term part of the report, and 553 are included in the outcome section (since 27 pulsatile device recipients are excluded). **Table A1.4** shows the same information for post-transplant device recipients.

Table A1.3 Device history of adult and paediatric patients receiving bridging device implants, 1 April 2007 – 31 March 2017, and the section of the report patients are included in

Age group	Device history	No. patients	Long-term section		Short-term section	
			Activity	Outcome	Activity	Outcome
Adult	LT	580	580	553		
	LT-ECMO	5	5	5	5	
	LT-ECMO-LT	1	1	1	1	
	LT-ECMO-ST-LT	1	1	1	1	
	LT-LT	41	41	35		
	LT-LT-LT	1	1	1		
	LT-LT-LT-LT	1	1	0		
	LT-LT-ST	1	1	1	1	
	LT-LT-ST-LT	1	1	0	1	
	LT-ST	5	5	5	5	
	LT-ST-LT	1	1	1	1	
	LT-TAH	2	2	2		
	LT/LT-ECMO	1	1	1	1	
	LT/LT-LT/ST	1	1	1	1	
	LT/ST[1]	1			1	
	TAH	8	8	8		
	ST	146			146	146
	ST-ECMO-ST-LT	1	1		1	1
	ST-LT	26	26		26	26
	ST-LT-LT	3	3		3	3
	ST-ST	3			3	3
	ST-ST-LT	1	1		1	1
	ST-TAH	1	1	1	1	1
	ECMO	54			54	54
	ECMO-ECMO	2			2	2
	ECMO-LT	28	28		28	28
	ECMO-LT-ECMO	1	1		1	1
	ECMO-ST	36			36	36
	ECMO-ST-LT	8	8		8	8
	ECMO-ST/LT	1	1		1	1
	ECMO-TAH	4	4	4	4	4
	ECMO/ECMO-ST	1			1	1
	ECMO/LT	1	1		1	1
	ECMO/ST	1			1	1
	Total	**969**	**725**	**620**	**336**	**318**

		No. patients	Paediatric section	
			Activity	Outcome
Paediatric	LT	56	56	56
	LT-LT	1	1	1
	LT/ECMO-LT	1	1	1
	LT/LT	1	1	1
	ST	17	17	17
	ST-LT	1	1	1
	ST-LT/ST	1	1	1
	ST/ST	1	1	1
	ECMO-LT	5	5	5
	Total	**84**	**84**	**84**

[1] Long-term implant happened prior to reporting period
LT=Long-Term, ST-Short-Term, ECMO=Extra Corporeal Membrane Oxygenation, TAH= Total Artificial Heart
LT-ST indicates that a patient received a long-term device and then a short-term device immediately following explantation of a long-term device
LT/ST indicates that a patient received a long-term device which was explanted and then a short-term device after a period of no support
Shading indicates exclusion of patients with a particular device history from a given section

Table A1.4 Device history of adult and paediatric patients receiving post-transplant device implants, 1 April 2007 – 31 March 2017, and the section of the report patients are included in

Age group	Device history	No. patients	PGD section		Rejection[1]
			Activity	Outcome	
Adult	LT	3			
	TAH/ECMO	1	1	1	
	ST	44	42	42	2
	ST-ECMO	1	1	1	
	ST-ST	1	1	1	
	ST-ST-ECMO	1	1	1	
	ST/ECMO	1	1	1	1
	ECMO	107	107	107	
	ECMO-ECMO-ST	1	1	1	
	ECMO-ST	10	9	9	1
	ECMO-ST/ECMO	1	1	1	
	ECMO/ECMO	3	3	3	1
	ECMO/ST	2	2	2	
	Total	**176**	**170**	**170**	**5**
Paediatric	LT	2			2
	Total	**2**			**2**

[1] Included in text only
LT=Long-Term, ST-Short-Term, ECMO=Extra Corporeal Membrane Oxygenation, TAH= Total Artificial Heart
LT-ST indicates that a patient received a long-term device and then a short-term device immediately following explantation of a long-term device
LT/ST indicates that a patient received a long-term device which was explanted and then a short-term device after a period of no support
Shading indicates exclusion of patients with a particular device history from a given section

A2: Methods

Analysis of geographical variation in MCS rates

Patients were assigned to Strategic Health Authorities (SHA) 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 SHA/country was obtained using mid-2015 population estimates based on the Office for National Statistics (ONS) 2011 Census figures (denominator). No SHA 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 Strategic Health Authority (SHA), 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, we introduce an additional multiplicative rate factor which varies from area to area. We 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.

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 risks
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 risks. Generally, the competing risks 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.

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 for a short period of time (days or weeks). Patients cannot leave hospital with the device.

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.

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 treated the same as bridge to transplant), 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.

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