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Outcomes of children with congenital heart disease implanted with ventricular assist devices: An analysis of the Pediatric Interagency Registry for Mechanical Circulatory Support (Pedimacs)

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Abstract

BACKGROUND—Reported ventricular assist device (VAD) experience in the pediatric congenital heart disease (CHD) population is limited. We sought to describe contemporary use and outcomes of VADs in children with CHD and compare outcomes to children without CHD.

METHODS—Patients enrolled in Pedimacs between September 19, 2012 through June 30, 2017 were included. CHD was classified as biventricular vs single ventricle (stage 1, 2 or 3). Outcomes were compared between groups and multivariable analysis was used to identify factors associated with mortality on device.

RESULTS—Among 471 patients enrolled, 108 (24%) had CHD (45 biventricular and 63 single ventricle). CHD patients were younger (5.7 years \pm 5.7 vs 9.8 years \pm 6.5; $p < 0.0001$) and smaller (0.8 m² \pm 0.5 vs 1.2 m² \pm 0.7; $p < 0.0001$) compared to non-CHD patients. CHD patients were

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more likely to receive a paracorporeal continuous VAD (36.1% vs 12.9%; $p<0.0001$) and less likely to receive an implantable continuous VAD (27.8% vs 55.0%; $p<0.0001$) compared to non-CHD patients. After six months on VAD, CHD patients had higher mortality (36.4% vs 12.1%) and lower percent transplanted (29.1% vs 59.9%) than non-CHD patients ($p<0.0001$). In multivariable analysis, CHD was the factor most strongly associated with mortality on VAD (HR 2.9, $p<0.0001$) while implantable continuous device and high volume center were protective (HR 0.3, $p<0.0001$; HR 0.6, $p=0.02$).

CONCLUSIONS—VAD use in children with CHD is associated with increased mortality and decreased transplant rates compared to children without CHD. For the subgroup of children with CHD who received implantable continuous flow VADs, survival rates were higher and comparable to children without CHD. Increased experience is correlated with better survival in pediatric VADs.

BACKGROUND

Congenital heart disease (CHD) is the most common etiology of heart failure in hospitalized children and accounts for approximately 40% of all pediatric heart transplants.^{1, 2} CHD is one of the strongest risk factors associated with waiting list mortality for children listed for heart transplant.^{3, 4} Despite the overall growth and progress made in supporting pediatric heart failure patients with ventricular assist devices (VADs), VAD use in CHD is limited and outcomes reported, thus far, have been suboptimal.⁵⁻⁸ There is no consensus as to whether, when and how VADs should be utilized in this complex and high-risk population.⁹ The specific aims of this study were to (1) describe the contemporary use, characteristics and outcomes of children with CHD implanted with VADs and (2) compare VAD outcomes of children with and without CHD.

METHODS

Pedimacs

The Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) is a national prospective database of >20,000 patients supported on devices.¹⁰ The Pediatric Interagency Registry for Mechanical Circulatory Support (Pedimacs), the pediatric component of INTERMACS, began enrolling pediatric patients with pediatric-specific data elements on September 19, 2012. Pedimacs contains data on all devices used in pediatric patients (age <19 years at device implantation) and was collecting data from 45 centers at the time of this analysis. The registry is a collaboration between the Society of Thoracic Surgery (STS), National Heart, Lung, and Blood Institute (NHLBI), the Food and Drug Administration, the Centers for Medicare and Medicaid Services, industry and implanting centers.

Between September 19, 2012 and June 30, 2017, patients prospectively enrolled in Pedimacs provided the study cohort. Patients with prior heart transplant who underwent VAD implant for graft failure were excluded. Patients were enrolled at the time of their implantation and follow-up was collected at specified intervals. Patients were censored when they met a study endpoint defined as death, transplant, recovery, or cessation of support.

Definitions

Patients with CHD were identified by searching the following Pedimacs variables: “primary diagnosis”; “secondary diagnosis”; “previous cardiac operation”; “previous congenital cardiac surgery”; and “concomitant surgery.” CHD was classified as biventricular or single ventricle. Single ventricle patients were further grouped into stage 1 (e.g. unrepaired, banded, or shunted), stage 2 (e.g. status post superior cavopulmonary anastomosis, “Glenn”) or stage 3 (e.g. status post total cavopulmonary anastomosis, “Fontan”). For this study, VAD denotes a device implanted into the systemic ventricle (or adjacent atrium) regardless of the underlying morphology. RVAD denotes a device implanted into the subpulmonary ventricle (or right atrium). Each study patient was reviewed by pediatric cardiologists (DMP and SJK) to ensure that the diagnoses were accurate. If there were incongruities or missing data, the inputting center was contacted to clarify data. Previously reported Pedimacs adverse event definitions were used.¹¹ With respect to center volume, “high volume” was defined as enrolling ≥15 patients and “low volume” was defined as enrolling <15 patients during the study period.

Statistical Analysis

Baseline characteristics for pediatric patients were presented as mean ± standard deviation or count (percent). Comparisons were made using chi-square test for categorical variables or Fisher’s exact test where appropriate and one-way ANOVA for continuous variables. Survival after device implantation among groups was compared using Kaplan-Meier survival analysis. The mutually exclusive patient outcomes of death, transplant, or alive on a device were analyzed using competing outcomes methods. Adverse event rates were calculated within 3 months (“early”) and post 3 months (“late”) after implant. Risk factors for death on device were examined using Cox proportional hazard. Covariables for the multivariable analysis were chosen a priori by the authors based on clinical experience and they included: age, gender, race, body surface area, patient profile, device classification, device strategy, albumin, bilirubin, sodium, blood urea nitrogen, creatinine, estimated glomerular filtration rate (eGFR), white blood cell count, platelet count, CHD, single ventricle CHD, any previous ECMO, ECMO during implant hospitalization, pulmonary disease, history of malnutrition, and high volume center. Data were analyzed using statistical software SAS statistical software version 9.4 (SAS Institute Inc, Cary, NC). All statistical tests were two-sided and a p-value <0.05 was considered statistically significant.

RESULTS

Study population and contemporary practice

Among the 471 patients enrolled in Pedimacs during the study period, 21 were excluded with graft failure. In the remaining 450 patients, 108 had CHD and 342 did not have CHD. Of the 108 CHD patients, 45 had biventricular CHD and 63 had single ventricle CHD. There were 23 stage 1 patients, 21 stage 2 patients, and 19 stage 3 patients.

Compared with non-CHD patients at the time of VAD implant, CHD patients were younger (5.7 years ± 5.7 vs 9.8 years ± 6.5; p<0.0001), more likely to be male (65.7% vs 54.7%; p=0.04), smaller (0.8 m² ± 0.5 vs 1.2 m² ± 0.7; p<0.0001) and more likely to have had

previous cardiac operation (93.5% vs 25.7%; $p < 0.0001$). CHD patients had higher hemoglobin ($12.8 \text{ g/dL} \pm 2.1$ vs $11.4 \text{ g/dL} \pm 1.9$; $p < 0.0001$), bilirubin ($2.9 \text{ mg/dL} \pm 4.9$ vs 1.5 ± 2.0 ; $p < 0.0001$), sodium ($139.7 \text{ mEq/L} \pm 7.8$ vs $137.0 \text{ mEq/L} \pm 6.1$; $p = 0.0002$) and INR (1.6 ± 0.9 vs 1.4 ± 0.5 ; $p = 0.0008$). Of note, CHD and non-CHD patients had similar renal function, prior mechanical circulatory support use, INTERMACS patient profile and device strategy (bridge to transplant, bridge to candidacy, destination therapy, etc.) CHD patients were more likely to receive a paracorporeal continuous device (36.1% vs 12.9%; $p < 0.0001$) and less likely to receive an implantable continuous device (27.8% vs 55.0%; $p < 0.0001$) compared to non-CHD patients. Over the last several years, fewer paracorporeal pulsatile devices and more implantable continuous devices have been used in CHD patients (Supplemental Table 1). Complete pre-implant characteristics for CHD and non-CHD patients are shown in Table 1a.

Within the CHD group, single ventricle patients were younger ($3.8 \text{ years} \pm 4.6$ vs $8.4 \text{ years} \pm 6.2$; $p < 0.0001$), were smaller ($0.6 \text{ m}^2 \pm 0.4$ vs $1.0 \text{ m}^2 \pm 0.6$; $p < 0.0001$), had higher hemoglobin ($13.6 \text{ g/dL} \pm 1.9$ vs $11.6 \text{ g/dL} \pm 1.9$; $p < 0.0001$), and had worse renal function ($74.7 \text{ mL/min/1.73m}^2 \pm 34.9$ vs $96.4 \text{ mL/min/1.73m}^2 \pm 42.5$; $p = 0.005$) compared with biventricular CHD patients at baseline. Single ventricle patients received more paracorporeal continuous devices (50.8% vs 15.6%; $p = 0.003$) and fewer implantable continuous devices (20.6% vs 37.8%; $p = 0.003$) than the biventricular group. Pre-implant characteristics divided by single vs biventricular CHD are listed in Table 1b. Among single ventricle patients, stage 1 patients were most likely to have had previous ECMO (30.4% vs 14.3% vs 0%; $p = 0.03$) and be in critical cardiogenic shock (59.1% vs 28.6% vs 21.1%; $p = 0.01$) compared with stage 2 and 3 patients. There were no statistically significant differences in device strategy across the CHD patient subgroups. Table 1c details the pre-implant characteristics of single ventricle patients divided by palliative stage. There were 35 CHD patients <1 year old and 26 of them had single ventricles. Their baseline characteristics are summarized in Table 1d.

A total of 45 centers enrolled patients. Ten of the 45 (22%) centers were high volume and enrolled 275 patients (61%) of the study cohort. The remaining 175 patients (39%) were enrolled at low volume centers. Between the two groups there were no significant differences with respect to CHD diagnosis, age, size or patient profile (Supplemental Table 2). However, high volume centers used proportionally more implantable continuous and paracorporeal pulsatile devices and fewer paracorporeal pulsatile devices ($p = 0.002$).

Outcomes

In competing outcomes analysis, CHD patients were more likely to have died (36.4% vs 12.1%, $p < 0.0001$) and less likely to be transplanted (29.1% vs 59.9%, $p < 0.0001$) than non-CHD patients after six months on device (Figure 1). In analyzing only bridge-to-transplant patients, the disparity in percent transplanted at six months was even more pronounced in favor of non-CHD patients (32.0% vs 74.0%, $p < 0.0001$).

Overall, CHD patients had higher mortality than non-CHD patients ($p < 0.0001$, Figure 2a). There was no difference in survival between single ventricle CHD and biventricular CHD patients ($p = 0.86$, Figure 2b). Among single ventricle patients, stage 3 patients had significantly higher survival compared with stage 1 and 2 patients ($p = 0.003$, Figure 2c).

Comparing stage 1 vs. 2, 2 vs. 3, and 1 vs. 3, the p-values were 0.4, 0.002, and 0.002, respectively. Excluding all stage 1 and 2 patients, the difference in survival between CHD and non-CHD patients narrowed but remained statistically significant ($p=0.01$, Supplemental Figure 1).

We performed similar analyses excluding patients with critical cardiogenic shock (Supplemental Figure 2), any previous ECMO (Supplemental Figure 3), ECMO during VAD implantation hospitalization (Supplemental Figure 4), bilirubin >2 mg/dL (Supplemental Figure 5), implanted with a non-LVAD (BIVAD, TAH, other, Supplemental Figure 6) and low volume centers (Supplemental Figure 7) and compared survival between CHD and non-CHD patients. After excluding each of these factors, the difference in survival between CHD and non-CHD patients remained statistically significant.

Compared with non-CHD patients, CHD patients had worse survival with paracorporeal pulsatile devices ($p=0.05$) and similar survival with implantable continuous devices ($p=0.5$) and paracorporeal continuous devices ($p=0.1$, Figure 3).

Eleven out of 26 (42%) single ventricle CHD infants (<1 year old) died during the study period (Table 2). Of the 20 single ventricle infants on paracorporeal continuous device support, 13 (65%) achieved a favorable outcome. Four of the 5 single ventricle infants supported with paracorporeal pulsatile devices died (Table 2).

CHD patients had more early respiratory failure compared with non-CHD patients ($p<0.001$ Table 3). In subgroup analyses of device classifications, CHD patients also had higher rates of “other” serious adverse events on implantable continuous devices ($p=0.009$) and paracorporeal continuous devices ($p=0.001$) though the number of events was small overall (Supplemental Tables 3-5). No statistically significant differences in rates of bleeding, infection, and neurological dysfunction were detected between CHD and non-CHD patients.

In multivariable modeling for risk of death on device for all patients, CHD, female gender and decreased eGFR were associated with increased mortality. Implantable continuous devices and high volume center were independently associated with improved survival (Table 4).

DISCUSSION

In this Pedimacs analysis, 24% of children supported with VADs had CHD. CHD was associated with worse outcomes overall. CHD was found to be an independent risk factor for mortality after VAD implant and CHD patients were less likely to receive a transplant compared with non-CHD patients. Implantable continuous devices and high volume centers were independently associated with better survival. Compared with non-CHD, CHD patients who received implantable continuous devices had similarly high survival.

To date, this report is the largest analysis of VAD use in children with CHD. Approximately one in four children who received VADs had CHD in this study. This is an increase from previous pediatric reports where the percent of VADs with CHD ranged from 16-17.5%.^{5, 12}

We found that paracorporeal continuous devices were commonly used in CHD, especially in smaller single ventricle patients. Unadjusted mortality was highest for this device class but this is likely confounded by the young age, small size, acuity and complexity of these patients. In this high-risk population, recent outcomes have most likely improved with paracorporeal continuous flow devices in comparison to the very poor survival previously reported with paracorporeal pulsatile support.^{7, 13, 14} Still, the mortality remains high and more studies and experience are needed to determine optimal support strategies for the smaller single ventricle population.

Stage 2 patients present a unique challenge for VAD support for many reasons including their dichotomous systemic venous return, collateral burden and hypoxemia. Given the superior outcomes in stage 3 patients, stage 2 patients with severe systolic dysfunction should be considered for concomitant Fontan operation and VAD implantation (i.e. “mechanically assisted Fontan completion”) which has been reported previously.¹⁵ Further study is warranted to see if this approach can improve VAD outcomes for stage 2 patients.

Fewer CHD patients received implantable continuous devices presumably due to their smaller size and complex anatomy. However, the CHD patients who did receive implantable continuous devices had similarly high survival as compared with non-CHD patients, which is consistent with the favorable implantable continuous VAD outcomes in the adult CHD population.¹⁶ In the multivariable model of the overall cohort, implantable continuous devices were significantly associated with improved survival. This finding likely reflects improving VAD technology but is also confounded by the characteristics of the patients that did, and did not, receive implantable continuous devices.

CHD was found to be an independent risk factor for mortality, along with lower eGFR and female gender. The gender disparity in outcomes has also been observed in large adult studies and warrants further investigation in the pediatric population.^{10, 17} CHD and worse renal function have been previously linked with higher mortality in pediatric VAD studies.^{7, 8, 18} Our analysis does not explain exactly why CHD patients are at higher risk for mortality despite attempts to control for known risk factors. The reasons for worse survival are certainly multifactorial. There was no difference in overall survival between biventricular and single ventricle which demonstrates that the increased risk was not unique to the single ventricle patients. Anatomic complexity, chronic circulatory abnormalities, previous surgeries, and related end-organ effects may all contribute to the worse VAD outcomes seen in CHD.

Of note, we found that CHD patients were much less likely to have been transplanted at 6 months compared with non-CHD patients. The explanation for these findings likely includes differences in age and wait times, early post-VAD mortality, sensitization and clinical status post-VAD implant the two groups.

We were not surprised to find high volume center associated with better survival. Morales and colleagues reported similar findings and also showed that high volume centers had lower associated costs.¹⁹ In our analysis comparing low and high volume centers, there were detectable differences in how devices were utilized. These findings support the idea that

there is a steep learning curve in pediatric VAD therapy and that experience and expertise can improve outcomes. In response, the pediatric heart failure and VAD community has recently launched *Action* (the Advanced Cardiac Therapies Improving Outcomes Network) to foster more active sharing and collaboration between centers and to ultimately drive improvement in critical outcomes collectively.

Limitations

There are important limitations to this study. Pedimacs only captures patients from participating centers and there is likely center-to-center variability in the accuracy and completeness of the reporting. Due to the relatively small number of patients, the analysis was mostly descriptive in nature and only the strongest associations were detectable in multivariable modeling. Because of the limited numbers of patients, heterogeneity and inability to adequately decouple the effects of age, size and device, we did not perform analysis for risk factors for mortality within the CHD group and subgroups. In the future, this analysis will be possible if Pedimacs enrollment continues to increase over time. Due to significant inconsistencies in the data, we were unable to accurately analyze and compare device malfunction/pump thrombosis and rehospitalizations in this study.

In conclusion, children with CHD experience higher mortality and a lower rate of transplant compared with children without CHD after VAD implant. Still, CHD patients supported with implantable continuous devices have demonstrated good survival. The experience and expertise gained at larger volume centers have resulted in improved outcomes. Further collaboration and study are warranted to better identify and support the CHD population at highest risk.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

Funding and Conflict of Interest Statement

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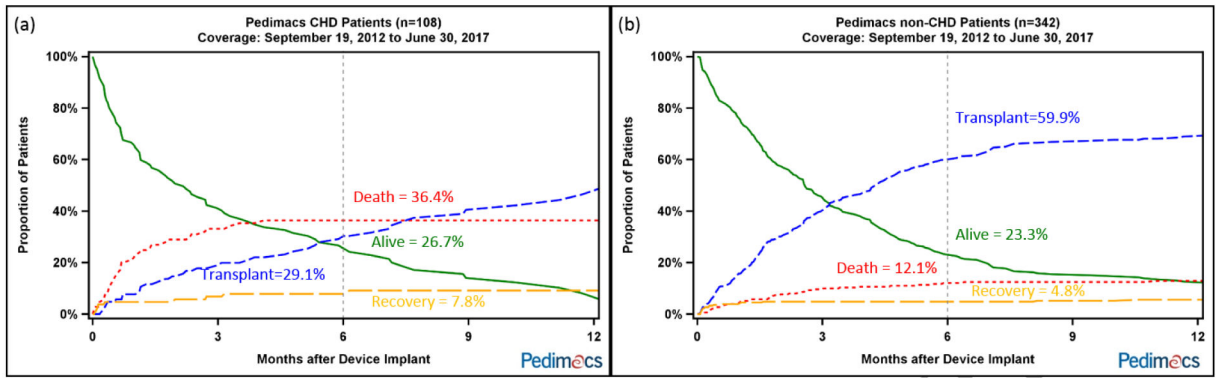


Figure 1. Competing outcomes analysis, including alive with device in place, death before transplant, transplant and explant to recovery after VAD implant for (a) CHD and (b) non-CHD patients.

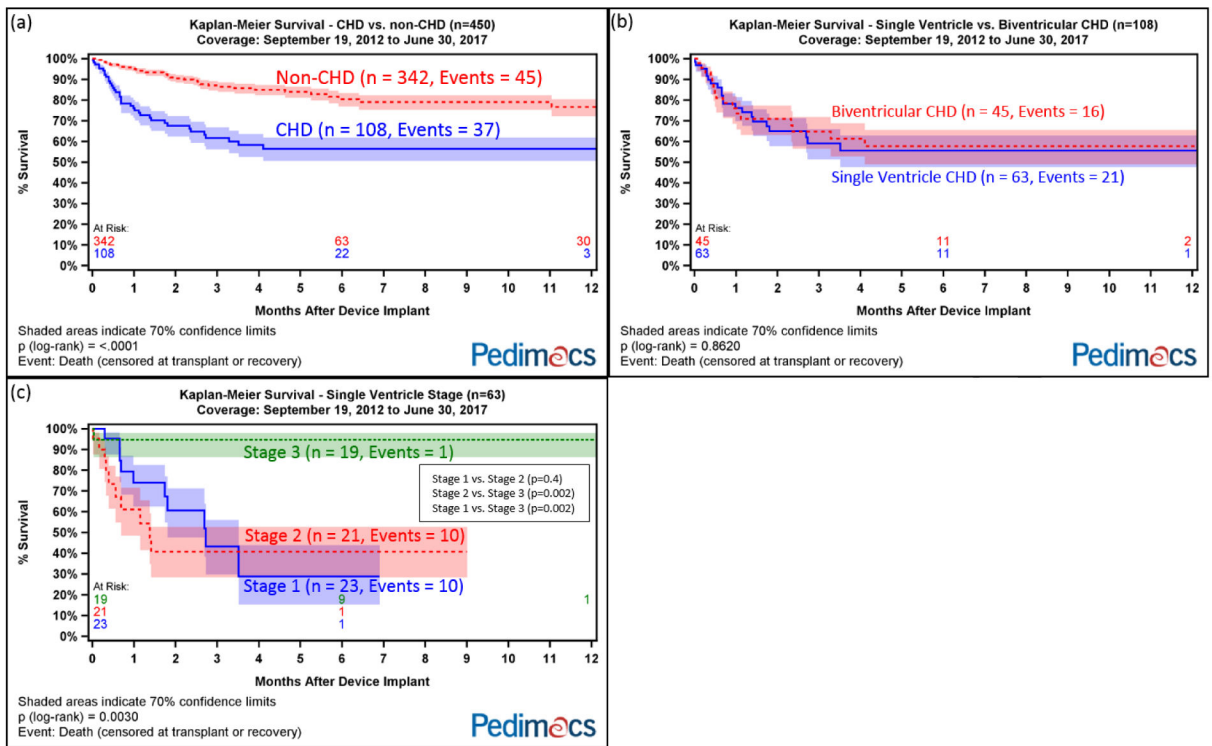


Figure 2. Kaplan-Meier survival after VAD implant divided by (a) CHD vs non-CHD patients; (b) single ventricle CHD vs biventricular CHD; (c) single ventricle stage.

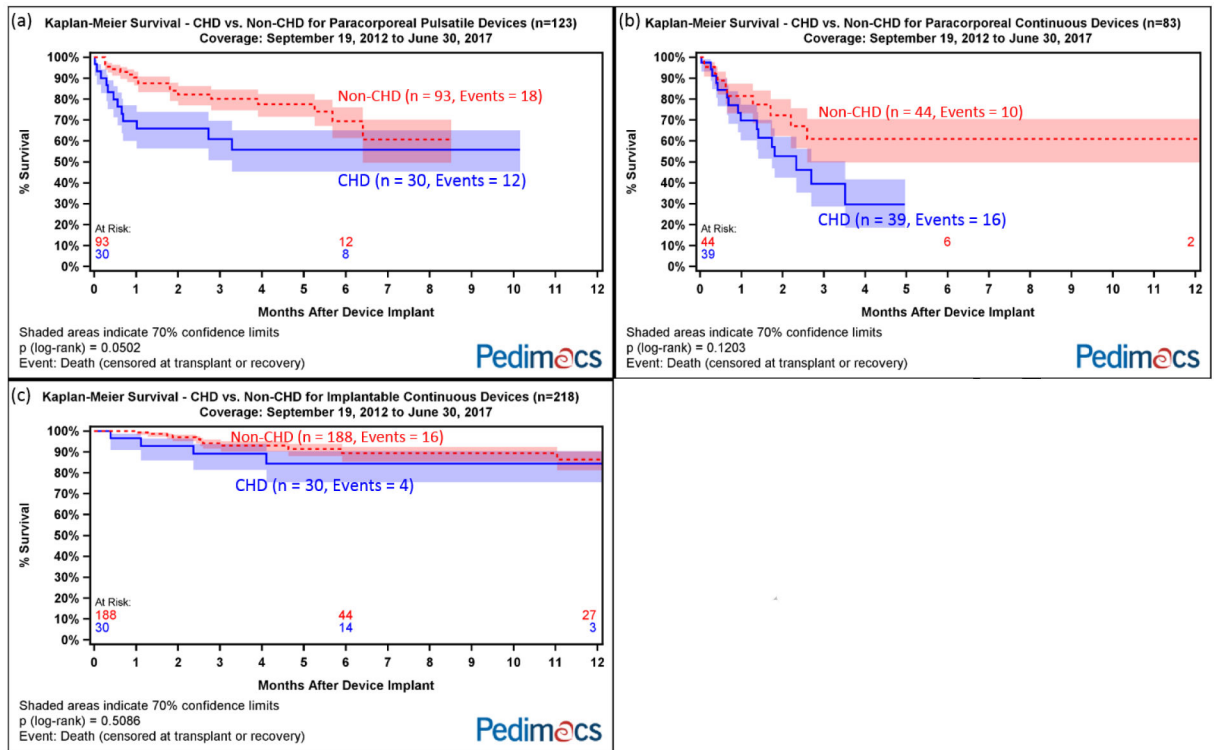


Figure 3. Kaplan-Meier survival after VAD implant for CHD vs non-CHD patients for (a) paracorporeal pulsatile devices; (b) paracorporeal continuous devices); (c) implantable continuous devices.

Table 1a:

Patient Characteristics for CHD vs. Non-CHD Patients (n=450). Pedimacs Patients, September 19, 2012 to June 30, 2017

Baseline Characteristics	CHD Patients (n=108)	non-CHD Patients (n=342)	p-value
Age (y)	5.7 +/- 5.7 (n= 108)	9.8 +/- 6.5 (n= 342)	<.0001
Age (y)			<.0001
< 1	35 (32.4)	55 (16.1)	
1-5	31 (28.7)	65 (19.0)	
6-10	20 (18.5)	44 (12.9)	
11-19	22 (20.4)	178 (52.0)	
Female	37 (34.3)	155 (45.3)	0.04
Race			0.9
White	63 (58.3)	203 (59.4)	
African American	22 (20.4)	73 (21.3)	
Other	23 (21.3)	66 (19.3)	
Body Surface Area (m ²)	0.8 +/- 0.5 (n= 106)	1.2 +/- 0.7 (n= 334)	<.0001
Blood Urea Nitrogen (mg/dL)	28.6 +/- 17.8 (n= 108)	25.1 +/- 16.4 (n= 342)	0.06
Sodium (mEq/L)	139.7 +/- 7.8 (n= 108)	137.0 +/- 6.1 (n= 342)	0.0002
Potassium (mEq/L)	3.8 +/- 0.7 (n= 108)	3.8 +/- 0.6 (n= 342)	1.0
Aspartate Aminotransferase (u/L)	214.7 +/- 1012.3 (n= 101)	223.8 +/- 845.7 (n= 334)	0.9
Alanine Aminotransferase (u/L)	183.2 +/- 897.2 (n= 101)	203.5 +/- 618.4 (n= 336)	0.8
Brain Natriuretic Peptide (pg/mL)	1998.3 +/- 1722.2 (n= 44)	2121.5 +/- 1672.0 (n= 162)	0.7
Pro Brain Natriuretic Peptide (pg/mL)	12783 +/- 13909 (n= 19)	12996 +/- 11596 (n= 95)	0.9
Albumin (g/dL)	3.4 +/- 0.8 (n= 104)	3.4 +/- 0.7 (n= 334)	1.0
Pre-Albumin (mg/L)	163.8 +/- 83.8 (n= 27)	182.8 +/- 71.5 (n= 116)	0.2
White Blood Cell Count (x10 ³ /μL)	12.0 +/- 6.6 (n= 107)	11.1 +/- 4.8 (n= 341)	0.1
Hemoglobin (g/L)	127.8 +/- 21.2 (n= 108)	113.5 +/- 19.3 (n= 341)	<.0001
Platelet Count (x10 ³ /μL)	199.8 +/- 115.2 (n= 107)	229.4 +/- 113.7 (n= 338)	0.02
INR (international units)	1.6 +/- 0.9 (n= 96)	1.4 +/- 0.5 (n= 312)	0.0008
Uric Acid (mg/dL)	7.4 +/- 4.0 (n= 20)	7.8 +/- 3.2 (n= 98)	0.6
Lymphocyte Count (%)	17.1 +/- 12.5 (n= 79)	23.7 +/- 14.0 (n= 253)	0.0002
Creatinine (mg/dL)	0.6 +/- 0.4 (n= 108)	0.8 +/- 0.5 (n= 341)	0.009
eGFR (mL/min/1.73m ²)	83.9 +/- 39.6 (n= 106)	87.5 +/- 48.0 (n= 336)	0.5
Bilirubin (mg/dL)	2.9 +/- 4.9 (n= 95)	1.5 +/- 2.0 (n= 304)	<.0001
Previous Cardiac Operation	101 (93.5)	88 (25.7)	<.0001
Previous ECMO	22 (20.4)	47 (13.7)	0.1
Previous MCSD	4 (3.7)	16 (4.7)	0.7
Patient Profile			0.2
1. Critical Cardiogenic Shock	23 (37.1)	17 (38.6)	
2. Progressive Decline	33 (53.2)	19 (43.2)	
3. Stable but Inotrope Dependent	6 (9.7)	5 (11.4)	

Baseline Characteristics	CHD Patients (n=108)	non-CHD Patients (n=342)	p-value
4.-7. Resting Symptoms or Less Sick		3 (6.8)	
Pre-Implant Device Strategy		/	0.3
Bridge to Transplant - Listed	37 (58.7)	21 (46.7)	
Bridge to Candidacy	15 (23.8)	18 (40.0)	
Destination Therapy	1 (1.6)		
Bridge to Recovery	6 (9.5)	5 (11.1)	
Other	4 (6.3)	1 (2.2)	
Device Classification			<.0001
Implantable Continuous	30 (27.8)	188 (55.0)	
Paracorporeal Continuous	39 (36.1)	44 (12.9)	
Paracorporeal Pulsatile	30 (27.8)	93 (27.2)	
Percutaneous	7 (6.5)	14 (4.1)	
TAH	2 (1.9)	3 (0.9)	
Pre-Implant Device Type			0.0004
LVAD	95 (88.0)	290 (84.8)	
BiVAD	11 (10.2)	48 (14.0)	
RVAD		1 (0.3)	
TAH	2 (1.9)	3 (0.9)	

eGFR = Estimated Glomerular Filtration Rate; ECMO = Extracorporeal Membrane Oxygenation; MCS = Mechanical Circulatory Support Device; TAH = Total Artificial Heart; LVAD = Left Ventricular Assist Device; RVAD = Right Ventricular Assist Device; BiVAD = Biventricular Assist Device

Table 1b:

Patient Characteristics for Single Ventricle vs. Biventricular CHD Patients (n=108). Pedimacs Patients, September 19, 2012 to June 30, 2017

Baseline Characteristics	Single Ventricle CHD (n=63)	Biventricular CHD (n=45)	p-value
Age (y)	3.8 +/- 4.6 (n= 63)	8.4 +/- 6.2 (n= 45)	<.0001
Age (y)			0.0005
< 1	26 (41.3)	9 (20.0)	
1-5	22 (34.9)	9 (20.0)	
6-10	10 (15.9)	10 (22.2)	
11-19	5 (7.9)	17 (37.8)	
Female	24 (38.1)	13 (28.9)	0.3
Race			0.3
White	33 (52.4)	30 (66.7)	
African American	15 (23.8)	7 (15.6)	
Other	15 (23.8)	8 (17.8)	
Body Surface Area (m ²)	0.6 +/- 0.4 (n= 61)	1.0 +/- 0.6 (n= 45)	<.0001
Blood Urea Nitrogen (mg/dL)	32.1 +/- 19.1 (n= 63)	23.9 +/- 14.8 (n= 45)	0.02
Sodium (mEq/L)	139.1 +/- 7.9 (n= 63)	140.5 +/- 7.7 (n= 45)	0.4
Potassium (mEq/L)	3.8 +/- 0.7 (n= 63)	3.8 +/- 0.7 (n= 45)	0.5
Aspartate Aminotransferase (u/L)	123.4 +/- 275.3 (n= 57)	332.9 +/- 1503.1 (n= 44)	0.3
Alanine Aminotransferase (u/L)	87.2 +/- 259.9 (n= 57)	307.6 +/- 1325.1 (n= 44)	0.2
Brain Natriuretic Peptide (pg/mL)	2051.2 +/- 1668.3 (n= 27)	1914.2 +/- 1853.6 (n= 17)	0.8
Pro Brain Natriuretic Peptide (pg/mL)	13389 +/- 12327 (n= 9)	12237 +/- 15848 (n= 10)	0.9
Albumin (g/dL)	3.3 +/- 0.9 (n= 61)	3.5 +/- 0.7 (n= 43)	0.2
Pre-Albumin (mg/L)	153.0 +/- 54.9 (n= 14)	175.5 +/- 108.0 (n= 13)	0.5
White Blood Cell Count (x10 ³ /μL)	11.3 +/- 3.5 (n= 62)	13.0 +/- 9.3 (n= 45)	0.2
Hemoglobin (g/L)	136.0 +/- 18.7 (n= 63)	116.4 +/- 19.3 (n= 45)	<.0001
Platelet Count (x10 ³ /g/L)	218.4 +/- 126.8 (n= 62)	174.1 +/- 92.1 (n= 45)	0.05
INR (international units)	1.9 +/- 1.1 (n= 52)	1.3 +/- 0.3 (n= 44)	0.001
Uric Acid (mg/dL)	7.7 +/- 3.1 (n= 11)	7.1 +/- 5.1 (n= 9)	0.8
Lymphocyte Count (%)	18.6 +/- 13.7 (n= 42)	15.5 +/- 11.0 (n= 37)	0.3
Creatinine (mg/dL)	0.6 +/- 0.5 (n= 63)	0.6 +/- 0.4 (n= 45)	1.0
eGFR (mL/min/1.73m ²)	74.7 +/- 34.9 (n= 61)	96.4 +/- 42.5 (n= 45)	0.005
Bilirubin (mg/dL)	2.9 +/- 4.1 (n= 55)	2.9 +/- 5.9 (n= 40)	1.0
Previous Cardiac Operation	61 (96.8)	40 (88.9)	0.1
Previous ECMO	10 (15.9)	12 (26.7)	0.2
Previous MCSD	2 (3.2)	2 (4.4)	0.7
Patient Profile			0.2
1. Critical Cardiogenic Shock	23 (37.1)	17 (38.6)	
2. Progressive Decline	33 (53.2)	19 (43.2)	
3. Stable but Inotrope Dependent	6 (9.7)	5 (11.4)	

Baseline Characteristics	Single Ventricle CHD (n=63)	Biventricular CHD (n=45)	p-value
4.-7. Resting Symptoms or Less Sick		3 (6.8)	
Pre-Implant Device Strategy			0.3
Bridge to Transplant - Listed	37 (58.7)	21 (46.7)	
Bridge to Candidacy	15 (23.8)	18 (40.0)	
Destination Therapy	1 (1.6)		
Bridge to Recovery	6 (9.5)	5 (11.1)	
Other	4 (6.3)	1 (2.2)	
Device Classification			0.003
Implantable Continuous	13 (20.6)	17 (37.8)	
Paracorporeal Continuous	32 (50.8)	7 (15.6)	
Paracorporeal Pulsatile	15 (23.8)	15 (33.3)	
Percutaneous	3 (4.8)	4 (8.9)	
TAH		2 (4.4)	
Pre-Implant Device Type			0.0004
LVAD	62 (98.4)	33 (73.3)	
BiVAD	1 (1.6)	10 (22.2)	
TAH		2 (4.4)	

eGFR = Estimated Glomerular Filtration Rate; ECMO = Extracorporeal Membrane Oxygenation; MCS = Mechanical Circulatory Support Device; TAH = Total Artificial Heart; LVAD = Left Ventricular Assist Device; BiVAD = Biventricular Assist Device;

Table 1c:

Patient Characteristics for Single Ventricle Patients Divided by Stage of Palliation (n=63). Pedimacs Patients, September 19, 2012 to June 30, 2017

Baseline Characteristics	Stage 1 (n=23)	Stage 2 (n=21)	Stage 3 (n=19)	p-value
Age (y)	1.1 +/- 2.4 (n= 23)	2.6 +/- 3.1 (n= 21)	8.3 +/- 4.7 (n= 19)	<.0001
Age (y)				<.0001
< 1	17 (73.9)	9 (42.9)		
1-5	5 (21.7)	9 (42.9)	8 (42.1)	
6-10	1 (4.3)	2 (9.5)	7 (36.8)	
11-19		1 (4.8)	4 (21.1)	
Female	8 (34.8)	10 (47.6)	6 (31.6)	0.5
Race				0.3
White	15 (65.2)	9 (42.9)	9 (47.4)	
African American	3 (13.0)	5 (23.8)	7 (36.8)	
Other	5 (21.7)	6 (23.8)	3 (15.8)	
Body Surface Area (m ²)	0.3 +/- 0.2 (n= 23)	7 (23.8)	1.0 +/- 0.4 (n= 18)	<.0001
Blood Urea Nitrogen (mg/dL)	34.4 +/- 19.0 (n= 23)	8 (23.8)	28.8 +/- 21.8 (n= 19)	0.6
Sodium (mEq/L)	141.3 +/- 5.9 (n= 23)	9 (23.8)	134.8 +/- 8.6 (n= 19)	0.02
Potassium (mEq/L)	3.7 +/- 0.6 (n= 23)	10 (23.8)	3.8 +/- 0.6 (n= 19)	0.8
Aspartate Aminotransferase (u/L)	91.0 +/- 114.1 (n= 21)	11 (23.8)	195.0 +/- 464.5 (n= 18)	0.4
Alanine Aminotransferase (u/L)	43.3 +/- 41.2 (n= 21)	12 (23.8)	173.8 +/- 452.9 (n= 18)	0.2
Brain Natriuretic Peptide (pg/mL)	910.8 +/- 713.1 (n= 4)	13 (23.8)	2134.2 +/- 1631.6 (n= 13)	0.3
Pro Brain Natriuretic Peptide (pg/mL)	20320 +/- 12284 (n= 5)	14 (23.8)	614.0 +/- 643.5 (n= 2)	0.1
Albumin (g/dL)	3.1 +/- 1.3 (n= 22)	15 (23.8)	3.5 +/- 0.4 (n= 18)	0.5
Pre-Albumin (mg/L)	152.0 +/- 53.0 (n= 4)	16 (23.8)	125.2 +/- 48.0 (n= 5)	0.3
White Blood Cell Count (x10 ³ /μL)	10.9 +/- 4.0 (n= 22)	17 (23.8)	10.1 +/- 3.0 (n= 19)	0.03
Hemoglobin (g/L)	133.0 +/- 17.3 (n= 23)	18 (23.8)	140.0 +/- 18.1 (n= 19)	0.5
Platelet Count (x10 ³ /μL)	155.7 +/- 103.6 (n= 22)	19 (23.8)	258.6 +/- 102.8 (n= 19)	0.01
INR (international units)	1.6 +/- 0.7 (n= 18)	20 (23.8)	2.6 +/- 1.4 (n= 16)	0.008
Uric Acid (mg/dL)	7.7 +/- 4.2 (n= 5)	21 (23.8)	7.3 +/- 1.7 (n= 3)	1.0
Lymphocyte Count (%)	13.6 +/- 9.2 (n= 11)	22 (23.8)	17.7 +/- 10.0 (n= 16)	0.2
Creatinine (mg/dL)	0.5 +/- 0.3 (n= 23)	23 (23.8)	0.8 +/- 0.4 (n= 19)	0.06
eGFR (mL/min/1.73m ²)	63.5 +/- 30.2 (n= 23)	24 (23.8)	76.6 +/- 29.7 (n= 18)	0.1
Bilirubin (mg/dL)	4.6 +/- 6.0 (n= 22)	25 (23.8)	2.1 +/- 1.0 (n= 15)	0.03
Previous Cardiac Operation	21 (91.3)	26 (23.8)	19 (100)	0.2
Previous ECMO	7 (30.4)	27 (23.8)	0 (0.0)	0.03
Previous MCSD	1 (4.3)	28 (23.8)	1 (5.3)	0.6
Patient Profile				0.01
1. Critical Cardiogenic Shock	13 (59.1)	6 (28.6)	4 (21.1)	
2. Progressive Decline	5 (22.7)	14 (66.7)	14 (73.7)	
3. Stable but Inotrope Dependent	4 (18.2)	1 (4.8)	1 (5.3)	

Baseline Characteristics	Stage 1 (n=23)	Stage 2 (n=21)	Stage 3 (n=19)	p-value
Pre-Implant Device Strategy				0.2
Bridge to Transplant - Listed	13 (56.5)	11 (52.4)	13 (68.4)	
Bridge to Candidacy	7 (30.4)	5 (23.8)	3 (15.8)	
Destination Therapy		1 (4.8)		
Bridge to Recovery	3 (13.0)	3 (14.3)		
Other		1 (4.8)	3 (15.8)	
Device Classification				0.0006
Implantable Continuous	1 (4.3)	2 (9.5)	10 (52.6)	
Paracorporeal Continuous	18 (78.3)	10 (47.6)	4 (21.1)	
Paracorporeal Pulsatile	4 (17.4)	7 (33.3)	4 (21.1)	
Percutaneous		2 (9.5)	1 (5.3)	
TAH		2 (4.4)		
Pre-Implant Device Type				0.4
LVAD	22 (95.7)	21 (100)	19 (100)	
BiVAD	1 (4.3)			

eGFR = Estimated Glomerular Filtration Rate; ECMO = Extracorporeal Membrane Oxygenation; MCSD = Mechanical Circulatory Support Device; LVAD = Left Ventricular Assist Device; BiVAD = Biventricular Assist Device;

Table 1d:

Patient Characteristics for CHD Patients <1 Year of Age (n=35). Pedimacs Patients, September 19, 2012 to June 30,

Baseline Characteristics	CHD Patients < 1 Year (n=35)
Age (y)	0.4 +/- 0.3 (n= 35)
Female	11 (31.4)
Race	
White	21 (60.0)
African American	6 (17.1)
Other	8 (22.9)
Body Surface Area (m ²)	0.3 +/- 0.1 (n= 35)
Blood Urea Nitrogen (mg/dL)	27.6 +/- 18.7 (n= 35)
Sodium (mEq/L)	142.3 +/- 6.6 (n= 35)
Potassium (mEq/L)	3.8 +/- 0.9 (n= 35)
Aspartate Aminotransferase (u/L)	87.6 +/- 114.3 (n= 32)
Alanine Aminotransferase (u/L)	49.8 +/- 56.7 (n= 32)
Brain Natriuretic Peptide (pg/mL)	1907.6 +/- 1884.2 (n= 9)
Pro Brain Natriuretic Peptide (pg/mL)	14841 +/- 6138.4 (n= 2)
Albumin (g/dL)	3.2 +/- 1.1 (n= 34)
Pre-Albumin (mg/L)	176.0 +/- 73.2 (n= 3)
White Blood Cell Count (x10 ³ /μL)	11.4 +/- 4.3 (n= 34)
Hemoglobin (g/L)	12.9 +/- 2.0 (n= 35)
Platelet Count (x10 ³ /μL)	190.6 +/- 127.3 (n= 34)
INR (international units)	1.4 +/- 0.4 (n= 28)
Uric Acid (mg/dL)	4.6 +/- 1.9 (n= 4)
Lymphocyte Count (%)	18.9 +/- 11.1 (n= 20)
Creatinine (mg/dL)	0.5 +/- 0.5 (n= 35)
eGFR (mL/min/1.73m ²)	74.3 +/- 38.2 (n= 35)
Bilirubin (mg/dL)	2.6 +/- 3.3 (n= 33)
Previous Cardiac Operation	30 (85.7)
Previous ECMO	12 (34.3)
Previous MCS/D	-
Patient Profile	
1. Critical Cardiogenic Shock	15 (42.9)
2. Progressive Decline	15 (42.9)
3. Stable but Inotrope Dependent	5 (14.3)
4.-7. Resting Symptoms or Less Sick	-
Pre-Implant Device Strategy	
Bridge to Transplant - Listed	17 (48.6)
Bridge to Candidacy	12 (34.3)
Destination Therapy	1 (2.9)

Baseline Characteristics	CHD Patients < 1 Year (n=35)
Bridge to Recovery	4 (11.4)
Other	1 (2.9)
Device Classification	
Implantable Continuous	-
Paracorporeal Continuous	21 (60.0)
Paracorporeal Pulsatile	13 (37.1)
Percutaneous	1 (2.9)
TAH	-
Pre-Implant Device Type	
LVAD	32 (91.4)
BiVAD	3 (8.6)
RVAD	-
TAH	-

eGFR = Estimated Glomerular Filtration Rate; ECMO = Extracorporeal Membrane Oxygenation; MCS = Mechanical Circulatory Support Device; TAH = Total Artificial Heart; LVAD = Left Ventricular Assist Device; RVAD = Right Ventricular Assist Device; BiVAD = Biventricular Assist Device

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Table 2:

Outcomes for CHD Patients <1 year of age as of June 30, 2017 (n=35). Pedimacs Patients, September 2012 through June 2017

Outcome	SV (Paracorporeal Continuous)	SV (Paracorporeal Pulsatile)	SV (Percutaneous)	BV (Paracorporeal Continuous)	BV (Paracorporeal Pulsatile)
Alive	4 (20%)	1 (20%)			
Transplanted	4 (20%)		1 (100%)	1 (100%)	6 (75%)
Death	7 (35%)	4 (80%)			1 (12%)
Recovery	5 (25%)				1(12%)

SV = single ventricle; BV = biventricular

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Table 3:

Adverse Events for CHD vs. Non-CHD Patients. Pedimacs Patients, September 19, 2012 to June 30, 2017

Event	Period ^a	Pedimacs CHD				Pedimacs Non-CHD				Rate Ratio ^c	p-value ^d
		Events	Patient Count	Patient Percent	Rate ^b	Events	Patient Count	Patient Percent	Rate ^b		
Arterial Non-CNS Thromboembolism	Early					3	3	1%	0.5		
Bleeding	Early	33	24	22%	17.9	131	89	26%	19.9	0.9	0.6
	Late	5	4	4%	3.2	12	10	3%	1.4	2.3	0.1
Cardiac Arrhythmia	Early	11	8	7%	6	30	24	7%	4.6	1.3	0.4
	Late					2	2	1%	0.2		
Infection	Early	33	23	21%	17.9	93	70	20%	14.1	1.3	0.2
	Late	9	6	6%	5.8	38	26	8%	4.5	1.3	0.5
Neurological Dysfunction	Early	33	25	23%	17.9	87	71	21%	13.2	1.4	0.1
	Late	4	4	4%	2.6	20	12	4%	2.3	1.1	0.9
Other SAE	Early	33	22	20%	17.9	113	68	20%	17.2	1	0.8
	Late	6	5	5%	3.8	19	14	4%	2.2	1.7	0.2
Pericardial Drainage	Early	5	5	5%	2.7	18	16	5%	2.7	1	1.0
Psychiatric Episode	Early	3	3	3%	1.6	21	20	6%	3.2	0.5	0.3
	Late	1	1	1%	0.6	2	2	1%	0.2	2.7	0.4
Renal Dysfunction	Early	12	11	10%	6.5	23	23	7%	3.5	1.9	0.08
	Late	1	1	1%	0.6	2	1	0%	0.2	2.7	0.4
Respiratory Failure	Early	35	23	21%	19	41	34	10%	6.2	3	<.001
	Late	2	2	2%	1.3	3	3	1%	0.4	3.6	0.1
Venous Thromboembolism	Early					6	6	2%	0.9		
Wound Dehiscence	Early	1	1	1%	0.5	2	2	1%	0.3	1.8	0.6
	Late					1	1	0%	0.1		

^aEarly = within three months of device implant, Late = more than three months after device implant^bRates are reported per 100 patient months^cRate Ratio is comparing CHD rates to non-CHD rates for the given time period^dp-value is comparing CHD rates to non-CHD rates for the given time period

Table 4:

Multivariable model for mortality on a device (n=450). Pedimacs Patients, September 19, 2012 to June 30, 2017

Pre-Implant Characteristics	Hazard Ratio	95% CI		p-value
Implantable Continuous Device	0.3	0.2	0.5	<0.0001
CHD	2.9	1.8	4.5	<0.0001
eGFR (20 unit increase)	0.9	0.8	1.0	0.01
Female	1.7	1.1	2.6	0.02
High Volume Center	0.6	0.4	0.9	0.02

CHD = Congenital Heart Disease; eGFR = Estimated Glomerular Filtration Rate;

High Volume Center is defined as enrolling 15 patients in Pedimacs.

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