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Outcomes of pediatric patients supported with continuous-flow ventricular assist devices: A report from the Pediatric Interagency Registry for Mechanical Circulatory Support (PediMACS)

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KEYWORDS:
pediatric;
ventricular assist devices;
mechanical circulatory support;
heart failure;
outcomes;
bridge to transplant

BACKGROUND: Continuous-flow (CF) ventricular assist devices (VADs) have largely replaced pulsatile-flow VADs in adult patients. However, there are few data on CF VADs among pediatric patients. In this study we aimed to describe the overall use, patients' characteristics and outcomes of CF VADs in this population.

METHODS: The Pediatric Interagency Registry for Mechanical Circulatory Support (PediMACS) is a national registry for U.S. Food and Drug Adminstration (FDA)-approved VADs in patients <19 years of age. Patients undergoing placement of durable CF VADs between September 2012 and June 2015 were included and outcomes were compared with those of adults from the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS).

RESULTS: CF VADs were implanted in 109 patients at 35 hospitals. The median age at implantation was 15 years (2.8 to 18.9 years) and median weight was 62 kg (range 16 to 141 kg). The underlying disease was cardiomyopathy in 89 (82%) patients. The INTERMACS level at time of implant was Level 1 in 20 (19%), Level 2 in 64 (61%) and Levels 3 to 7 in 21 (20%) patients. Most were implanted as LVADs (n = 102, 94%). Median duration of support was 2.3 months (range <1 day to 28 months). Serious adverse event rates were low, including neurologic dysfunction (early event rate 4.1 per 100 patient-months with 2 late events). Competing outcomes analysis at 6 months post-implant indicated 61% transplanted, 31% alive with device in place and 8% death before transplant. These outcomes compared favorably with the 3,894 adults supported with CF VADs as a bridge to transplant.

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CONCLUSIONS: CF VADs are commonly utilized in older children and adolescents, with excellent survival rates. Further study is needed to understand impact of patient and device characteristics on outcomes in pediatric patients.

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Historically, most pediatric patients supported with ventricular assist devices (VADs) as a bridge to transplantation have been supported with paracorporeal pulsatile devices.[1-4] Although these devices provide superior support and durability compared with extracorporeal membrane oxygenation (ECMO), there persists a high rate of serious adverse events, including stroke, infections and bleeding.[3,5]

Continuous-flow devices have largely replaced pulsatile-flow devices among adults requiring long-term mechanical circulatory support, due to improved survival and decreased adverse events.[6] Although the current generation of continuous-flow (CF) devices has not been specifically tested or approved in children, many pediatric centers have utilized these devices in recent years.[7,8] Initial reports have suggested a high rates of survival to transplant with a favorable adverse event profile[7,8]; however, there are very few data on the overall use or outcomes in this population. We aimed to describe the overall use and outcomes of CF VADs in pediatric patients and test the hypothesis that pediatric patients supported with CF VADs have comparable outcomes to those of adults supported with CF VADs.

Methods

The Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS), a National Heart, Lung and Blood Institute (NHLBI)-sponsored database, contains data on >10,000 patients supported on U.S. Food and Drug Administration (FDA)-approved devices. 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.

This longitudinal study includes patients supported with durable CF VADs in PediMACS. PediMACS contains data on all FDA-approved VADs in pediatric patients (age <19 years at device implantation). Our analysis included all patients with durable CF VADs placed from September 2012 through June 2015. INTERMACS patients age >19 years at device implantation and placed on CF VADs as a bridge to candidacy or bridge to transplantation during a similar time period were included as a comparison group. Adult patients implanted for destination therapy were excluded from the analysis as their survival is lower than in patients implanted as a bridge to candidacy or bridge to transplantation. Data collection for PediMACS is similar to that for INTERMACS and includes comprehensive demographic and clinical data at the time of implant as well as serially during follow-up.[6,9] Pediatric-specific definitions for adverse events were utilized.[10]

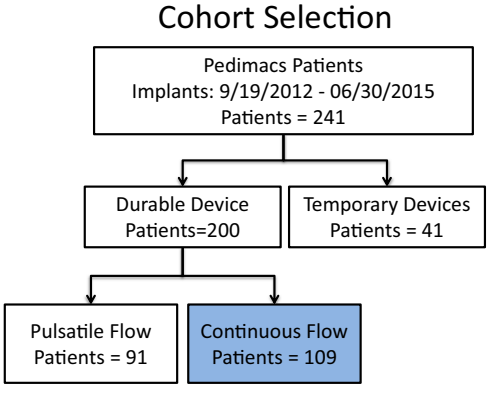


Figure 1 Cohort selection: patients receiving durable continuous-flow devices (PediMACS: September 2012 to June 2015).

Statistical analysis

Baseline demographic and clinical data are expressed as number with percent or as median value with range, as appropriate. Differences in baseline characteristics between INTERMACS and PediMACS patients were assessed with chi-square analysis or with the Mann-Whitney *U*-test, as appropriate. Kaplan-Meier survival analysis with log-rank statistics was used to assess overall survival in PediMACS and INTERMACS patients. Competing outcomes analysis was used for events post-implant to 1 of 4 outcomes, with possible events being: death; transplantation; alive on device; or device explanation for recovery.

Results

Two-hundred patients were entered into the PediMACS registry during the study period (Figure 1). Of these, 91 (46%) patients were supported with pulsatile durable devices and 109 (55%) were supported with durable CF VADs. Some patients had device exchanges and, in total, there were 109 total CF devices implanted at 35 hospitals (Figure 2). Forty-three percent of the centers implanted only 1 device and 17% of centers implanted >5 devices during the study period (see Figure S1 in Supplementary materials available online at www.jhltonline.org). The median age at implantation was 15 years (range 2.8 to 18.9 years), with 18 (16%) 6 to 10 years and 88 (81%) >10

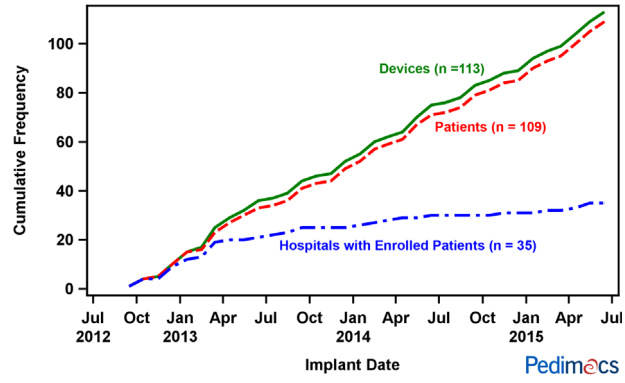


Figure 2 Hospital, patient and device enrollment of continuous-flow ventricular assist devices (PediMACS: September 2012 to June 2015).

Table 1 Patients' Baseline Characteristics at Time of VAD Implantation

Characteristics	PediMACS ($n = 109$)	INTERMACS ($n = 3,894$)	p-value
Age, median [years (range)]	15 (2.8–18.9)	56 (19.0–84.1)	<0.0001
<6 years [n (%)]	3 (3)	NA	
6–10 years [n (%)]	18 (16)	NA	
11–18 years [n (%)]	88 (81)	NA	
19–30 years [n (%)]	NA	225 (6)	
31–50 years [n (%)]	NA	1,088 (28)	
51–70 years [n (%)]	NA	2,521 (65)	
>70 years [n (%)]	NA	60 (2)	
Weight, median [kg (range)]	62 (16–141)	86 (26–258)	<0.0001
<20 kg [n (%)]	4 (4)	0 (0)	
20–40 kg [n (%)]	21 (19)	40 (1)	
41–70 kg [n (%)]	47 (43)	826 (21)	
70–100 kg [n (%)]	28 (26)	2,060 (53)	
>100 kg [n (%)]	9 (8)	963 (25)	
BSA, median [m^2 (range)]	1.7 (0.7–2.7)	2.1 (0.6–3.7)	<0.0001
Female [n (%)]	36 (33)	887 (23)	0.015
Cardiac diagnosis			<0.0001
Cardiomyopathy	89 (82)	3613 (93)	
Myocarditis	7 (6)	26 (0.7)	
Congenital heart disease	11 (10)	29 (1)	
Other	2 (2)	225 (5.8)	
Race			0.16
White	64 (59)	2553 (66)	
African American	28 (26)	939 (24)	
Other	17 (16)	402 (10)	
Previous cardiac operation	26 (24)	1,077 (28)	0.38
Previous ECMO	8 (7)	47 (1)	<0.0001
Previous temporary VAD	4 (4)	NA[a]	
Creatinine [mg/dl (range)]	0.8 (0.2–4.6)	1.2 (0.3–15.0)	<0.0001
BUN [mg/dl (range)]	20 (7–90)	24 (3–286)	0.008
Sodium [mEq/liter (range)]	136 (117–160)	135 (113–156)	0.08
Potassium [mEq/liter (range)]	3.9 (2.4–5.6)	4.1 (2.1–6.9)	0.0001
AST [U/liter (range)]	38 (12–9,234)	29 (4–5,454)	<0.0001
ALT [U/liter (range)]	45 (6–6,654)	30 (4–5,5313)	<0.0001
BNP [pg/ml (range)]	1,130 (82–6,590)	773 (4–7,500)	0.0015
NT-BNP [pg/ml (range)]	5,927 (498–34,656)	3,853 (63–60,000)	0.07
Albumin [g/dl (range)]	3.5 (2.3–4.7)	3.5 (0.1–8.0)	0.78
WBC cells [$\times 10^3/\mu l$ (range)]	9.1 (2.6–26.5)	8.0 (1.3–75.0)	0.0004
Hemoglobin [g/dl (range)]	11.5 (7.5–17.2)	11.4 (0.9–18.4)	0.59
Platelets [$\times 10^3/\mu l$ (range)]	213 (5–505)	191 (1–725)	0.09
INR (range)	1.3 (0.9–3.3)	1.2 (0.9–6.5)	0.0008
LDH [U/liter (range)]	385 (149–2,292)	277 (11.0–3,500)	0.0002
Total bilirubin [mg/dl (range)]	1.1 (0.2–7.2)	1.0 (0.1–44.4)	0.21

ALT, alanine aminotransferase; AST, aspartate aminotransferase; BNP, B-type natriuretic peptide; BSA, body surface area; BUN, blood urea nitrogen; ECMO, extracorporeal membrane oxygenation; INR, international normalized ratio; LDH, lactate dehydrogenase; NT-BNP, N-terminal pro-BNP; VAD, ventricular assist device; WBC, white blood cells.

[a]Previous temporary VAD is not recorded in INTERMACS.

years of age (Table 1). The median weight at implant was 62 kg (range 16 to 141 kg) with 4 (4%) <20 kg, 21 (19%) 20 to 40 kg and 84 (77%) >40 kg. The smallest patient had a body surface area of 0.7 m^2. The cardiac disease leading to VAD placement was cardiomyopathy in the majority of cases (82%), with congenital heart disease (CHD) present in only 10%. Comparisons to adult patients in INTERMACS are presented in Table 1.

The INTERMACS level at time of implant was Level 1 in 20 (19%), Level 2 in 64 (61%), Level 3 in 18 (17%) and Levels 4 to 7 in 3 (3%). Compared with adult patients, pediatric patients were more likely to be implanted at Levels 1 or 2 (Figure 3). When evaluating the types of CF devices placed, the majority of the devices were LVADs ($n = 102$, 94%), with only 6 BiVADs and 1 RVAD (Table 2). Previous temporary devices supported 4 (4%) patients. The device strategy at time of implant was bridge to transplant in 59 (54%), bridge to candidacy in 44 (40%) and destination therapy in 6 (6%) patients. Forty-nine of the patients were discharged home post-implant (45%).

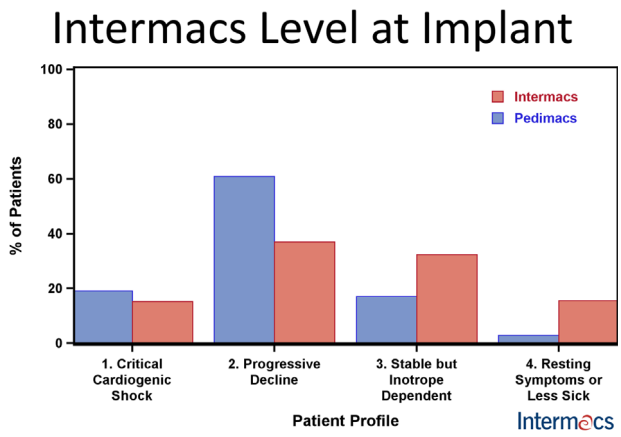


Figure 3 INTERMACS patient profile level at time of implant in pediatric (PediMACS) and adult (INTERMACS) patients (September 2012 to June 2105).

Overall serious adverse event rates were low, including neurologic dysfunction, which occurred in 9 patients (9 events) within 3 months after VAD implantation (early event rate 4.1 per 100 patient-months with 2 late events) (Table 3). The most frequent early adverse events were bleeding, rehospitalizations, infection and cardiac arrhythmia. These events rates were similar to the rates observed in the adult cohort. The frequency of these events decreased after the first month after VAD implantation, but remained high for rehospitalizations (late event rate 16.5 per 100 patient-months). Thirty of the 49 patients (61%) patients discharged home were rehospitalized at least once. Several adverse events were observed at increased rates in pediatric patients and included early psychiatric episodes, early pericardial drainage and late device malfunction.

Overall survival in the PediMACS cohort was excellent with only 9 deaths, and compared favorably with the adult cohort from INTERMACS (Figure 4). Competing outcomes analysis at 6 months post-implant demonstrated a favorable outcome in 92% of patients with 61% transplanted, 31% alive with the device in place, and 8% with death before transplant. These outcomes compared favorably with those of adults supported with CF VADs as a bridge to transplant or bridge to candidacy (Figure 5).

Discussion

There are several important findings of this study. This is the largest study to date on CF VADs in pediatric patients and included 35 implanting centers throughout the USA. CF VADs currently comprise the majority of VADs placed in adolescents, with pulsatile pumps being utilized scarcely.[6] Over 40% of centers implanted only 1 device during the study period, and this highlights the importance of collaborative registries like PediMACS for providing broad and comprehensive understanding of pediatric advanced heart failure patients. Indeed, a similar study would be challenging, if not impossible, to conduct outside of PediMACS.

The overall outcome of pediatric patients supported on these devices is excellent, with only 9 (8%) deaths. The 92% favorable outcome at 6 months is similar to that for adults on CF VADs and superior to pediatric patients on pulsatile VADs.[3-6] This occurred even with the relatively large number of implants among those in critical cardiogenic shock (INTERMACS Level 1) or progressive decline (INTERMACS Level 2), groups associated with worse survival in adults.[11] The adult cohort in our study also fared well with a "favorable" outcome in 89%, with 77% alive on device support and 12% transplanted. In the prospective trial for the Berlin Heart EXCOR VAD, 8.3% of patients died while on VAD support, with 87.5% being successfully bridged to transplantation by 6 months post-implantation.[3] During the period of the trial, patients could be implanted on the VAD outside of the trial and, when all patients supported on the device were included in an analysis, by 12 months post-implantation, 55% had been transplanted and 36% died.[5] It is important to note that this experience with the Berlin Heart EXCOR VAD contained more patients who were younger, smaller, supported with pre-implant ECMO, had congenital heart disease, and were at INTERMACS Level 1 at the time of implant. All these likely contributed substantially to the observed outcome differences. In addition, for infants and small children, there is no available CF VAD, and this group is known to have a high mortality and complication rate.[12,13]

The adverse event rate, especially for neurologic dysfunction, including stroke, was relatively low at 10%, with most of the events occurring in the first 3 months after implantation. This also compares favorably with adults on CF devices and pediatric patients on pulsatile pumps, who have an overall stroke rate of nearly 30%.[3,5,11] Other adverse events, such as infection and bleeding, occurred with increased frequency, especially in the early period after VAD implantation, with rates of 12.9 and 14.2 events per 100 patient-months, respectively; these rates are, however, similar to what was observed in adults. These adverse events decreased after 3 months, down to 4.5 and 2.2 per 100 patient-months, respectively.

It is of interest to note that some adverse events, including early psychiatric issues, occurred at an increased frequency in pediatric patients. Although it is well known that mental health issues are common in adolescents with chronic disease, there is a paucity of data on psychosocial functioning in the pediatric advanced heart failure population.[14-17] This clearly deserves further study so we may determine how these issues affect long-term post-transplant survival, as it is well described that

Table 2 Device Strategy and Device Type

Device strategy and device type	PediMACS (n = 109)
Pre-implant device strategy	
1. Bridge to transplant—listed	59 (54.1)
2. Bridge to candidacy	44 (40.4)
3. Destination	6 (5.5)
Pre-implant device type	
1. LVAD	102 (93.6)
2. RVAD	1 (0.9)
3. BiVAD	6 (5.5)

BiVAD, biventricular assist device LVAD, left ventricular assist device; RVAD, right ventricular assist device.

Table 3 Adverse Events in Pediatric Patients (PediMACS) and Adult Bridge-to-Transplant Patients (INTERMACS) Receiving Durable Continuous-flow Ventricular Assist Devices (September 2012 to June 2015)

	PediMACS ($n = 109$)				INTERMACS ($n = 3,894$)			
Adverse event type	Early events	Early event rate	Late events	Late event rate	Early events	Early event rate	Late events	Late event rate
Arterial non-CNS thromboembolism	2	0.9	0	0.0	45	0.4	9	0.03
Bleeding	31	14.2	6	2.2	1,342	12.8	884	2.7
Cardiac arrhythmia	15	6.9	2	0.8	1,031	9.8	370	1.1
Device malfunction	6	2.8	10[a]	3.7[a]	261	2.5	390[a]	1.1[a]
Hepatic dysfunction	4	1.8	0	0.0	110	1.0	49	0.2
Infection	28	12.9	12	4.5	1,319	12.5	1,267	3.9
Myocardial infarction	0	0.0	0	0.0	4	0.04	9	0.03
Neurologic dysfunction	9	4.1	2	0.8	433	4.1	425	1.3
Other serious adverse event	15[a]	6.9[a]	3	1.1	1,322[a]	12.6[a]	612	1.9
Pericardial drainage	9[a]	4.1[a]	0	0.0	148[a]	1.4[a]	7	0.02
Psychiatric episode	9[a]	4.1[a]	0	0.0	192[a]	1.8[a]	81	0.2
Rehospitalization	30	13.8	44	16.5	2,077	19.7	5,281	16.2
Renal dysfunction	6	2.8	1	0.4	353	3.4	115	0.3
Respiratory failure	14	6.4	0	0.0	633	6.0	173	0.5
Venous thromboembolism	1	0.5	0	0.0	114	1.1	12	0.04
Wound dehiscence	0	0.0	1	0.4	38	0.4	13	0.04

Early events occurred within 3 months of durable device implantation and late event occurred more than 3 months after durable device implantation. Rates are displayed per 100 patient-months. CNS, central nervous system

[a]Difference between INTERMACS and PediMACS statistically significant ($p < 0.05$).

adolescents are at high risk for early graft failure.[18,19] Other adverse events that occurred with greater frequency in the pediatric cohort included late device malfunction and the need for early pericardial drainage. It is not clear why these adverse events would occur at greater rates in children as compared with adults with CF VADs, although it may relate to the early experience, including outpatient management, with these devices in pediatric centers. Data from adult patients in INTERMACS suggest a decrease in adverse events observed over time.[6] Future studies from PediMACS may help to determine whether the same trend is observed as more experience with the devices in pediatric patients is obtained.

The excellent survival of pediatric patients is likely in part due to the relatively short duration of support compared with adult patients on the same devices. By 6 months post-implantation, 61% of pediatric patients underwent heart transplantation compared with only 12% of adults on CF devices. This may lead to questions regarding the appropriateness of continuing to have these patients listed as Status 1A.[20] In the current and proposed changes to the United Network of Organ Sharing (UNOS) policies on listing status, pediatric patients on a CF VAD may remain as Status 1A. This is different from adult patients on VADs, where the Status 1A time is limited to 30 days in the absence of complications.[20] As such, many more pediatric patients on CF VADs were transplanted by 6 months post-implantation compared with adults on CF VADs. Whether criteria similar to those for adults should be utilized in the future for a subset of pediatric patients on CF VADs, such as adolescents with dilated cardiomyopathy and no VAD complications, is an important area and needs to be fully addressed by the transplant community.

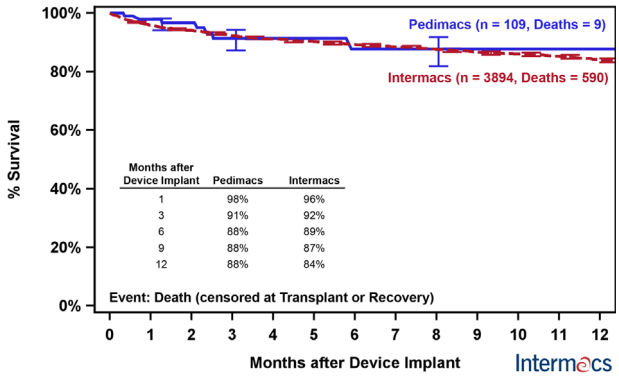


Figure 4 Kaplan-Meier survival analysis of pediatric (PediMACS) and adult (INTERMACS) patients supported with continuous-flow ventricular assist devices (September 2012 to June 2015).

An advantage of the CF devices, as opposed to many of the pulsatile devices used in pediatric patients, is that life outside of the hospital is possible. In this study, just under half of the patients were discharged home, likely improving their quality of life. However, the potential benefit of discharge home from the hospital must be weighed against adverse events and hospital readmissions. In our study, hospital readmissions were very common, occurring at least once in 61% of patients discharged home, with early and late rates of 13.8 and 16.5 readmissions per 100 patient-months, respectively. Further study is needed in the etiologies and prevention of hospital readmissions. In addition, quality of life data are being collected in PediMACS and we will need to understand how quality of life is affected with hospital discharge and hospital readmissions.

In conclusion, CF VADs are commonly utilized in older children and adolescents. The use of CF VADs is associated

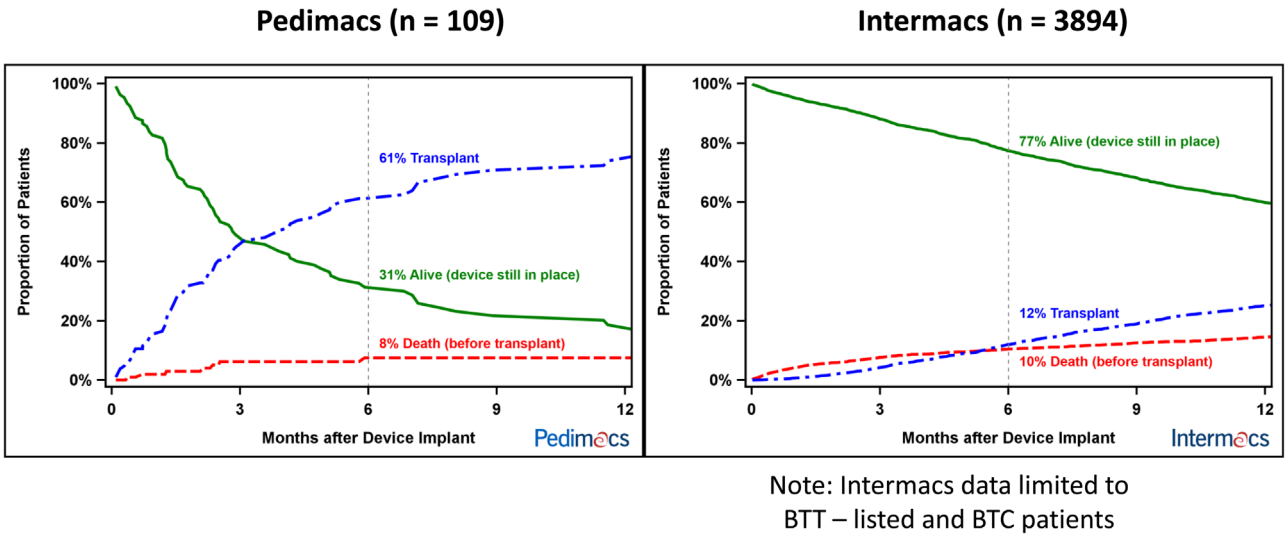


Figure 5 Competing outcome analysis of pediatric patients (PediMACS) and adult patients (INTERMACS) supported with continuous-flow ventricular assist devices (September 2012 to June 2015).

with excellent survival. Further study is needed to understand the impact of patient and device characteristics on outcomes in pediatric patients.

Disclosure statement

Ryan S. Cantor is on the Sunshine Heart Data and Safety Monitoring Board. The authors have no conflicts of interest to disclose.

Supplementary material

Supplementary materials associated with this article can be found in the online version at www.jhltonline.org/.

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