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Impact of HeartWare ventricular assist device discontinuation on the pediatric population: An Advanced Cardiac Therapies Improving Outcomes Network (ACTION) registry analysis

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BACKGROUND: The HeartWare ventricular assist device (HVAD) was discontinued in July 2021. The study aims to describe the impact the discontinuation the HVAD had on pediatric ventricular assist device (VAD) utilization and outcomes.
METHODS: The Advanced Cardiac Therapies Improving Outcomes Network (ACTION) registry was queried for type of VAD utilization and outcomes/adverse event rates in patients with a body surface area of 0.7 to 1.4 m^2. Results were compared from before and after July 2021. All patients in the registry implanted with an HVAD were reported to determine overall outcomes of these patients and define who remains on the device.
RESULTS: The HeartMate 3 (HM3) primarily replaced the HVAD in pediatric patients increasing from 29 of 258 (11%) of implants before July 2021 to 31 of 109 (29%) of implants after. A small increase in the use of the Berlin Heart EXCOR (40 of 258, 16% before to 20 of 109, 18% after) and paracorporeal continuous flow devices (116 of 258, 45% before to 58 of 109, 53% after) was also observed. The rate of ischemic stroke increased in the overall population and a decrease in bleeding complications in the EXCOR group was observed. Of the 187 pediatric patients implanted with an HVAD in the registry, 7 patients remain supported, 1 patient transitioned from the HVAD to an HM3, and 6 patients were lost to follow-up.
CONCLUSIONS: The HM3 has been the primary replacement for the HVAD in the medium-sized pediatric population. The rate of ischemic stroke was higher after July 2021.
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Background

The HeartWare ventricular assist device (HVAD; Medtronic, Minneapolis, MN) was abruptly removed from the market in July 2021 due to concerning outcomes in the adult population. The relative size of the HVAD made it desirable in the pediatric population with excellent results.[1-3] It is unclear what impact the removal of this device has had on the pediatric population given the limited number of devices approved for use in children and the anatomical and size constraints present in the pediatric population. It is also unclear what happened to pediatric patients who were actively supported with an HVAD at the time it was discontinued.

The aims of this study are to describe the devices that replaced the HVAD in the pediatric population and assess if this shift in devices has had any impact on the outcomes of children requiring a durable ventricular assist device (VAD). We also aimed to report the outcomes of pediatric patients actively supported with an HVAD and especially those who continue to be supported following the discontinuation.

Material and methods

The ACTION (Advanced Cardiac Therapies Improving Outcomes Network) learning network was established in 2017 with a mission to improve clinical outcomes and the patient/family experience for children with heart failure.[4] Data for all patients supported on a VAD at a participating institution are collected in the ACTION Outcome Registry (Simplified Clinical Data Systems). As of 2023, the network includes 62 centers across the United States and Canada which encompasses most pediatric cardiovascular centers in North America implanting durable VADs in the pediatric population. A single Institutional Review Board (IRB) model is used for the network with local IRB reliance from all member institutions. All patients/patient families in the prospective collected database are consented for inclusion and data collection. The initial quality improvement project of this network aimed at decreasing the rates of strokes seen in pediatric patients supported on a VAD. The project focused on three interventions: (1) anticoagulation management, (2)

standardized blood pressure measurement and goals for patients on continuous flow devices, and (3) improved communication between providers managing patients.[5]

To determine the effect of the HVAD discontinuation on the pediatric population, we queried the ACTION Outcome Registry for patients with implant dates from the start of the registry (April 2018) through January 1, 2023. Data for follow-up through April 1, 2023, were included to allow for at least 3 months of follow-up of all patients included in the analysis. For the first objective, we focused on patients with a body surface area (BSA) of 0.7 to 1.4 m^2. Few patients smaller than 0.7 m^2 (about 5 years of age) received the HVAD, and patients over 1.4 m^2 (about 12 years of age) are typically large enough for implantation with the other intracorporeal continuous (IC) flow device available on the market (HeartMate 3; Abbott Cardiovascular, Plymouth, MN). Patients were separated into 2 groups based on the day of implantation occurring before or after July 1, 2021.

The distribution of initial device implants was compared between the groups before and after July 2021. These data were used to determine what device was used to replace the HVAD after discontinuation and to investigate if the discontinuation had any effect on the distribution of choice of device. To compare mortality and the incidence/rate of adverse events (major bleeding, infection, neurological dysfunction, and ischemic stroke), we excluded those patients placed on a paracorporeal continuous flow device as they likely represent a different preoperative risk factor given the general temporary/emergent intention in the use of those devices. Mortality was defined as death on the device before transplant or recovery. The adverse events were defined as per the registry definitions and are available within Supplemental Appendix A. To directly compare the outcomes and adverse event incidences/rates in patients with the 2 available intracorporeal devices, the HVAD population was compared to the HeartMate 3 (HM3) population over the entire study period.

The outcomes and selected adverse event incidences of all patients (regardless of size) reported in the registry supported on the HVAD are included. To focus on the patients most impacted by the discontinuation of the HVAD, we report the current (April 2023) known status of all remaining patients on the HVAD in the registry and searched the registry for any patients who were transitioned from the HVAD to another device.

Statistical analysis was limited given the descriptive nature of this study. Summary statistics were generated using frequencies and percentages for categorical variables and medians and interquartile ranges for continuous variables. To compare different groups, the chi-square or Fisher's exact test was used for categorical variables, and the Mann-Whitney test was used for continuous variables.

Results

A total of 367 patients with a BSA 0.7 to 1.4 m^2 were identified in the registry of which 258 were implanted before and 109 were implanted after July 2021. The HVAD was implanted in 73 of the 258 (28%) of the population prior to July 2021. After July 2021, the utilization of the HM3 increased from 29 of 258 (11%) to 31 of 109 (29%). Smaller increases in the utilization of paracorporeal continuous flow devices and the Berlin Heart EXCOR (EXCOR, Berlin Heart of North America, Woodlands, TX) were also observed (Figure 1).

Age, sex, BSA, weight, and diagnosis for all patients (including before and after 2021) implanted with an HVAD, HM3, or EXCOR are shown in Table 1. Patients implanted with an EXCOR were smaller than the other 2 devices. The smallest patient implanted with an HM3 in the registry was 17.7 kg, 0.73 m^2. These demographic factors did not differ before or after July 2021 in patients implanted with an EXCOR or HM3 (Table 2). Mortality, incidence, and rate of adverse events for the entire population, and specifically the EXCOR and HM3 compared before and after July 2021 are shown in Table 3. The rate of ischemic stroke increased in the time after July 2021. Outcomes and adverse event incidence/rates were similar within the device populations other than a decrease in the rate of major infection in the HM3 group and incidence of major bleeding in patients implanted with an EXCOR after July 2021. The rates of major bleeding and major infection were higher in the HM3 group compared to the HVAD group while neurologic dysfunction, stroke, and mortality were similar (Table 4).

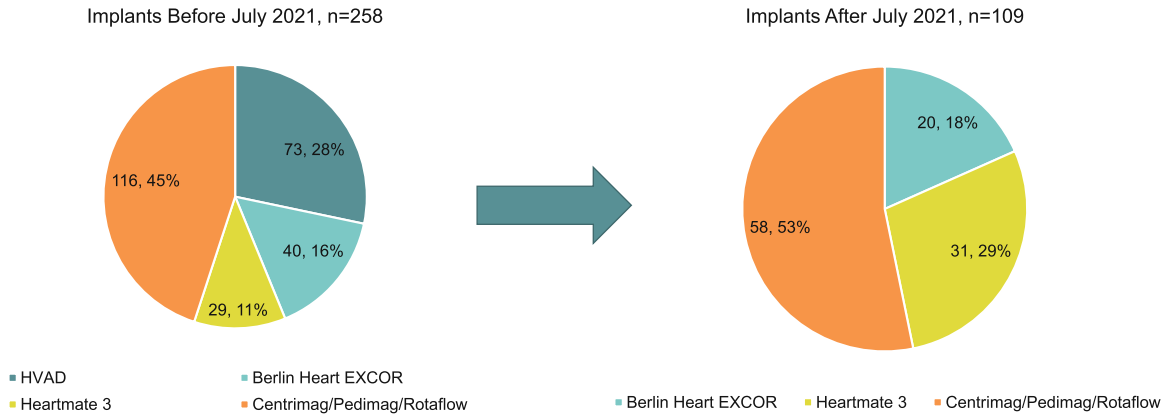

Figure 1 Distribution of device use in pediatric patients with body surface area 0.7 to 1.4 m^2 before and after the discontinuation of the HeartWare ventricular assist device. HVAD, HeartWare ventricular assist device.

Table 1 Demographics of Patients With BSA 0.7 to 1.4 m^2 in the ACTION Outcome Registry by Device

Characteristic	HVAD ($n = 73$)	HM3 ($n = 60$)	EXCOR ($n = 60$)	p-value
Age (years)	9.9 (6.9, 11.4)	12.2 (10.2, 14.7)	7.9 (5.6, 11.06)	< 0.001
Male (%)	37 (51%)	33 (55%)	34 (57%)	0.772
BSA (m^2)	0.99 (0.83, 1.2)	1.18 (1.05, 1.29)	0.87 (0.76, 1.07)	< 0.001
Weight (kg)	27 (21, 36)	34.8 (29.6, 40.2)	22.4 (19.2, 30.9)	< 0.001
Diagnosis				
Congenital heart disease	24 (33%)	15 (25%)	18 (30%)	0.609
Dilated cardiomyopathy	40 (55%)	41 (68%)	26 (43%)	0.02
Other	9 (12%)	4 (7%)	16 (27%)	0.006

Abbreviations: ACTION, Advanced Cardiac Therapies Improving Outcomes Network; BSA, body surface area; EXCOR, Berlin Heart EXCOR; HM3, HeartMate 3; HVAD, HeartWare ventricular assist device.
Data reported as median (interquartile range) or n (%)

Table 2 Demographics of Patients With BSA 0.7 to 1.4 m^2 Implanted With a HeartMate 3 or Berlin Heart EXCOR Compared Before and After July 2021

Characteristic	Before July 2021	After July 2021	p-value
HeartMate 3	N = 29	N = 31	
Age (years)	11.7 (9.7, 14.7)	12.8 (10.6, 14.8)	0.439
Male (%)	13 (45%)	20 (65%)	0.125
BSA (m^2)	1.16 (1.02, 1.31)	1.19 (1.05, 1.28)	0.513
Weight (kg)	33.8 (28.1, 40.4)	36.7 (29.8, 39.9)	0.430
Diagnosis			
Congenital heart disease	8 (28%)	7 (23%)	0.654
Dilated cardiomyopathy/myocarditis	21 (72%)	20 (65%)	
Other	0 (0%)	4 (13%)	
Berlin Heart EXCOR	N = 40	N = 20	
Age (years)	7.9 (5.7, 9.7)	7.8 (5.1, 11.6)	0.403
Male (%)	20 (50%)	14 (70%)	0.14
BSA (m^2)	0.88 (0.77, 1.07)	0.85 (0.75, 1.07)	0.485
Weight (kg)	23.5 (19.5, 31.5)	21.4 (18.6, 29.5)	0.352
Diagnosis			
Congenital heart disease	10 (25%)	8 (40%)	0.10
Dilated cardiomyopathy	16 (40%)	10 (50%)	
Other	14 (35%)	2 (10%)	

Abbreviations: BSA, body surface area; EXCOR, Berlin Heart EXCOR; HM3, HeartMate 3; HVAD, HeartWare ventricular assist device.

A total of 187 patients were implanted with an HVAD in the registry. The smallest patient implanted with an HVAD was 10.1 kg and 0.45 m^2. The majority (138/187, 74%) of patients have been explanted at the time of transplant with a mortality rate of 17% (31/187). As of April 2023, 7 patients remained on the HVAD in the registry, 1 patient transitioned to an HM3, and 6 patients had an unknown or unrecorded outcome.

Discussion

Pediatric providers caring for children requiring VAD support were disappointed when the HVAD was abruptly discontinued from the market. This report highlights these concerns demonstrating the increase in utilization of less ideal devices for medium-sized patients. The larger HM3 saw the greatest increase in use. Inferior outcomes with this device have been demonstrated in a comparable population of patients with BSA 0.7 to 1.4 m^2 compared to larger patients.[6] There was a small increase in the use of older paracorporeal pulsatile (EXCOR) or traditionally temporary paracorporeal continuous flow devices that are associated with higher rates of adverse neurologic events.[7,8] The rate of ischemic stroke increased in the population after discontinuation of the HVAD in this report but thankfully no other significant impact on outcomes was demonstrated.

With the loss of the HVAD, fewer pediatric patients can be supported by the latest generation of IC pumps. IC technology has consistently demonstrated improved outcomes with fewer adverse events in adult[9] and pediatric populations.[7,8] In addition to better outcomes, the quality of life on support with IC devices is improved with an ability to discharge the patient home. Discharge is not possible with the current pediatric paracorporeal devices (EXCOR or paracorporeal continuous flow). Development of a pediatric-specific device was hoped for over a decade ago with the Pumps for Kids, Infants and Neonates trial.[10] A

Table 3 Mortality and Adverse Event Incidence in Patients With BSA 0.7 to 1.4 m^2 Implanted With a HeartMate 3 or Berlin Heart EXCOR Compared Before and After July 2021

Outcome	Before July 2021	After July 2021	*p*-value
All devices	N = 168	N = 85	
Major bleeding	31 (18.4%)[a]	15 (17.6%)[a]	0.87
	42 (0.12)[b]	17 (0.16)[b]	0.35
Major infection	44 (26.2%)[a]	21 (24.7%)[a]	0.79
	70 (0.20)[b]	17 (0.16)[b]	0.37
Neurologic dysfunction	30 (17.8%)[a]	12 (14.1%)[a]	0.45
	37 (0.10)[b]	15 (0.14)[b]	0.38
Ischemic stroke	11 (6.5%)[a]	7 (8.2%)[a]	0.62
	13 (0.03)[b]	7 (0.065)[b]	< 0.0001
Mortality	13 (7.7%)[a]	8 (9.4%)[a]	0.64
HeartMate 3	N = 29	N = 31	
Major bleeding	8 (28%)[a]	7 (23%)[a]	0.65
	12 (7.9)[b]	9 (4.3)[b]	0.17
Major infection	14 (48%)[a]	8 (26%)[a]	0.07
	24 (15.8)[b]	11 (5.27)[b]	0.001
Neurologic dysfunction	5 (17%)[a]	4 (13%)[a]	0.63
	5 (3.3)[b]	4 (1.9)[b]	0.41
Ischemic stroke	2 (6.9%)[a]	3 (10%)[a]	0.61
	2 (1.31)[b]	3 (1.43)[b]	0.91
Mortality	3 (10%)[a]	3 (10%)[a]	0.93
Berlin Heart EXCOR	N = 40	N = 20	
Major bleeding	7 (18%)[a]	0 (0%)[a]	0.04
	8 (5.43)[b]	0 (0)[b]	0.06
Major infection	12 (30%)[a]	2 (10%)[a]	0.08
	14 (9.5)[b]	4 (6.3)[b]	0.50
Neurologic dysfunction	6 (13%)[a]	1 (5%)[a]	0.36
	6 (4)[b]	1 (1.5)[b]	0.41
Ischemic stroke	3 (7.5%)[a]	0 (0%)[a]	0.54
	3 (2)[b]	0 (0)[b]	0.25
Mortality	5 (12.5%)[a]	1 (5%)[a]	0.36

Abbreviations: BSA, body surface area; EXCOR, Berlin Heart EXCOR.
[a]Adverse event incidence expressed as number of patients experiencing atleast 1 event (% of patients).
[b]Adverse event rate expressed as total number of events (rate per 100 patient months).

Table 4 Mortality and Adverse Event Incidence/Rate in Patients With BSA 0.7 to 1.4 m^2 Implanted With HeartWare Ventricular Assist Device Compared to HeartMate 3

Outcome	HeartWare (N = 73)	HeartMate 3 (N = 60)	*p*-value
Major bleeding	12(16.4%)[a]	15 (25%)[a]	0.22
	17 (3.13)[b]	21 (5.8)[b]	0.05
Major infection	16 (21.9%)[a]	22 (36.7%)[a]	0.06
	27 (4.9)[b]	35 (9.7)[b]	0.009
Neurologic dysfunction	18 (24.6%)[a]	9 (15%)[a]	0.16
	23 (4.2)[b]	9 (2.5)[b]	0.17
Ischemic stroke	5 (6.8%)[a]	5 (8.3%)[a]	0.74
	5 (1.1)[b]	5 (1.3)[b]	0.7
Mortality	6 (8.2%)[a]	6 (10%)[a]	0.72

Abbreviations: BSA, body surface area.
[a]Adverse event incidence expressed as number of patients experiencing at least 1 event (% of patients).
[b]Adverse event rate expressed as total number of events (rate per 100 patient months).

suitable pediatric device was not realized, and the pediatric community still relies on adapting adult technology to smaller patients or continued use of older technology that has been shown to be inferior in adult populations.

Despite this reliance on older technology, this report highlights the ability to continually improve outcomes with the EXCOR. The outcomes with the EXCOR were stagnant with a rate of neurologic complications around 30% from the initial trial through the first years of multicenter reporting.[11-13] This current report continues to show a sustained decrease in the rate of neurological complications as demonstrated by the ACTION network[5] and other multicenter reports.[7] Until a new pump is available that is suitable for pediatric use, there will be a continued need to improve outcomes with the existing technology, and multicenter collaboration has proven to be key in that effort.

This report is limited due to the small number of patients contained. Statistical differences in outcomes are difficult to achieve with a limited patient population. Adverse event incidences and rates may also be significantly impacted by differential risks within the patient population. For example, blood pressure control has been shown within the adult population to impact the rates of adverse events including stroke.[14] While the ACTION learning network included recommendations for standardized measurement and goals of blood pressure management for member organizations, we are unable to evaluate the application or effectiveness of these recommendations. Given this limitation, we are unable to draw definitive conclusions of causality in the few differences we did observe and can merely report them as associations.

Use of registry data also does not allow us any insight into how the loss of the HVAD affected the decision making at individual institutions or the larger impact on the pediatric heart transplant population in general. The ACTION Outcome Registry data only reports on patients who were implanted with a VAD at participating institutions. It is possible that some individuals who may have benefitted from a VAD were listed for transplant primarily. Given the limitations of the registry we are unable to comment on the impact the removal of the HVAD had on the decision to implant a VAD. However, pediatric organ allocation does not differentiate from forms of mechanical circulatory support as all pediatric patients on circulatory support are given the highest allocation priority. Any pediatric patient not on mechanical circulatory support would have to meet other criteria (mechanical ventilation, intraaortic balloon pump, ductal dependent congenital heart disease with ductal patency maintained by stent or prostaglandin infusion, or congenital heart disease patients requiring multiple or high dose inotropic infusions) to achieve the most prioritized status if circulatory support was not

employed. The ACTION Outcome Registry is unable to determine if the loss of the HVAD had any bearing on clinicians' choices to employ therapies other than a VAD to manage patients with decompensated heart failure.

Conclusions

In conclusion, the HM3 has primarily replaced the HVAD in the moderate-sized (0.7-1.4 m^2) pediatric population with a modest increase in the utilization of the EXCOR and paracorporeal continuous flow devices. The overall population showed an increase in the rate of ischemic stroke with sustained good outcomes with the EXCOR device. Few pediatric patients remain on the HVAD with only 1 patient in the registry transitioning from the HVAD to HM3. Continued development of pediatric-specific devices is necessary to expand access of the most current technology to this vulnerable population while continued ongoing multicenter collaborative efforts aim to improve outcomes with currently available devices.

Declaration of Generative AI and AI-assisted technologies in the writing process

Generative AI or AI-assisted technologies were not used in the writing of this manuscript.

Disclosure statement

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Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.jhlto.2024.100064.

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