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SPECIAL ARTICLE

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Impact of durable ventricular assist devices on post-transplant outcomes in adults with congenital heart disease

Ari Cedars MD[1] | Luke Burchill MD, PhD[2] | S. Lucy Roche MB, ChB[3] | Jonathan Menachem MD[4] | Kelly Axsom MD[5] | Kristen Tecson PhD[6] | for the ACTION Learning Network, Adult Congenital Heart Disease Sub-Committee

[1]University of Texas Southwestern Medical School, Dallas, Texas, USA

[2]University of Melbourne, Melbourne, Australia

[3]University of Toronto, Toronto, Ontario, Canada

[4]Vanderbilt University, Nashville, Tennessee, USA

[5]Columbia University, New York, New York, USA

[6]Baylor University Medical Center, Dallas, Texas, USA

Correspondence
Ari Cedars, The University of Texas Southwestern Medical Center, 2001 Inwood Rd. Suite WC05.852, Dallas, TX 75390, USA.
Email: Ari.cedars@utsouthwestern.edu

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Abstract

Background: There are no published data on post-transplant outcomes in durable ventricular assist device (VAD)-supported adult congenital heart disease (ACHD) patients.
Methods: We compared post-transplant outcomes in VAD-supported vs non-VAD-supported ACHD patients using the Scientific Registry of Transplant Recipients.
Results: At 1 year, there was no difference in post-transplant mortality between VAD-supported (12 patients) and non-VAD-supported (671 patients) ACHD patients.
Conclusions: In appropriate ACHD patients, VAD use as a bridge to transplant is a reasonable strategy.

KEYWORDS
adult congenital heart disease, heart transplant, ventricular assist device

1 | INTRODUCTION

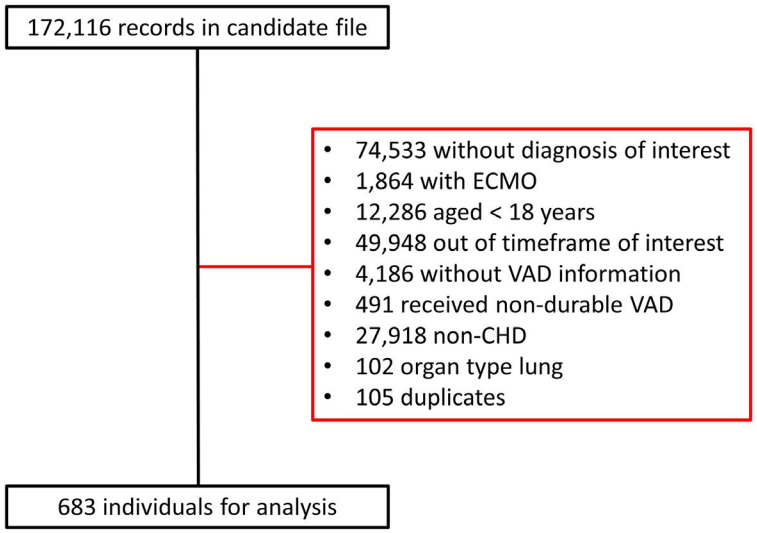
There is a need for more information on outcomes after durable ventricular assist device (VAD) implant in adults with congenital heart disease (ACHD). Heart failure (HF) is currently the leading cause of death in ACHD patients.[1] Although transplantation is a good option for end stage heart failure in ACHD, these patients have increased mortality while listed for transplant compared to their non-ACHD counterparts[2] due to a combination of delayed referral, anatomic complexity, allosensitization, lower listing status, longer wait-list times and increased risk of sudden death.[3] The utility of VAD in clinically deteriorating patients awaiting heart transplant is well established for non-ACHD patients however it is rarely used in ACHD despite generally favorable data on post-VAD outcomes.[4] To further elucidate a role for VAD as a bridge to transplant in ACHD, we investigated post-transplant outcomes in VAD-supported ACHD patients.

2 | METHODS

2.1 | Data

We employed the Scientific Registry of Transplant Recipients (SRTR) database for the present study. The SRTR data system includes data on all donor, wait-listed candidates, and transplant recipients in the United States, submitted by the members of the Organ Procurement and Transplantation Network (OPTN). The Health Resources and Services Administration, U.S. Department of Health and Human Services provides oversight to the activities

FIGURE 1 Inclusion diagram



for the OPTN and SRTR contractors. The analysis was approved by the University of Texas Southwestern Medical Center Institutional Review Board.

2.2 | Primary outcome

One-year post-transplant mortality.

2.3 | Subjects

We compared adults (>18 years of age) with HF secondary to congenital heart disease who were bridged to transplant with durable VAD to ACHD patients wait-listed for transplant without VAD. To maximize relevance for the current era and to allow for one full year of follow-up, we limited the timeframe to that from 1999 to 2017. We excluded patients patients listed for multi-organ transplant, those on extracorporeal membrane oxygenation support and those with a non-durable mechanical circulatory support. The durable VAD group included only patients with information on type of VAD implanted who had one of the following types: Heartmate VE, XVE, II, Jarvik 2000, Micromed Debakey adult and child, Heartware HVAD and Ventracore ventrassist.

2.4 | Statistical analyses

All continuous variables were skewed and are presented as medians (quartile 1, quartile 3). Categorical variables are presented as frequency (percentage). To assess differences in patient characteristics between those with and without VAD, we performed Wilcoxon Rank Sum, Chi-Squared tests, or Fisher's exact tests, as appropriate. We tested for differences in survival rates and curves using Fisher's exact and the Logrank test, respectively. Hypothesis tests assume a two-sided alternative and a type I error rate of 5%. Analyses were performed using SAS 9.4 (Cary, NC).

3 | RESULTS

A total of 683 ACHD patients (Figure 1) who had undergone heart transplant during the investigated period were identified, 12 of whom had VAD as a bridge to transplant, 671 had not. There were few differences between the groups as shown in Table 1.

The median post-transplant follow-up times for this 1-year outcome analysis were 192.5 days (183, 216) and 216 days (182, 365) for VAD and non-VAD patients, respectively. At 30 days, 6 months, and 1 year after transplant, there were no deaths in the VAD group. In the non-VAD group, there were 3 (.45%), 17 (2.53%), and 32 (4.77%). There was no difference in survival at any of the three time points (P = .8166, .5769 and .5193, respectively; Figure 2).

There were 12 VAD transplant recipients with ACHD and 4188 VAD transplant recipients without ACHD. There were no post-transplant deaths among VAD transplant recipients with ACHD; however, 7 (.17%), 93 (2.22%), and 180 (4.3%) VAD transplant recipients without ACHD died within 30 days, 6 months, and 1 year of transplant, respectively. There were no differences in survival rates between ACHD and non-ACHD VAD transplant recipients (P = .8873, .5990 and .4842 at 30 days, 6 months, and 12 months, respectively).

4 | DISCUSSION

In this brief analysis, we investigated post-transplant outcomes in ACHD patients who underwent VAD as a bridge to transplant. We found only 12 (1.8%) mostly male ACHD patients who received VAD as a bridge to transplant. While numbers are limited, use of VAD did not appear to adversely impact post-transplant outcomes and there is no significant difference in outcomes between ACHD and non-ACHD post-VAD transplant recipients up to one year after transplant.

These data along with other recent analyses should encourage broader consideration of VAD in appropriate transplant-listed

TABLE 1 Characteristics of adults with congenital heart disease who received a heart-only transplant

Characteristic	LVAD (n = 12)	No LVAD (n = 671)	*P* value
Age	30.5 [22.5, 40.5]	34 [24, 46]	.4297
Gender (male)	11 (91.67%)	401 (59.85%)	.0336
Body mass index	23.5 [22, 29.5]	23 [20, 27]	.2646
Caucasian	10 (83.33%)	598 (89.12%)	.6312
Education			
High school or less	5 (41.67%)	256 (38.15%)	
Attended college	7 (58.33%)	335 (49.93%)	
Unknown	0 (0%)	80 (11.93%)	
Prior cardiac surgery			.0801
Yes	12 (100%)	466 (69.45%)	
No	0 (0%)	65 (9.69%)	
Unknown	0 (0%)	140 (20.86%)	
Symptomatic cerebrovascular disease*			.1095
Yes	1 (8.33%)	11 (1.64%)	
No	10 (83.33%)	627 (93.44%)	
Unknown	1 (8.33%)	33 (4.92%)	
Diabetes			.1683
Yes	0 (0%)	2 (.3%)	
No	0 (0%)	137 (20.42%)	
Unknown	12 (100%)	532 (79.28%)	
Dialysis			1
Yes	0 (0%)	10 (1.49%)	
No	12 (100%)	660 (98.36%)	
Unknown	0 (0%)	1 (.15%)	
Drug treated hypertension			.1745
Yes	5 (41.67%)	138 (20.57%)	
No	5 (41.67%)	418 (62.3%)	
Unknown	2 (16.67%)	115 (17.14%)	
Functional limitations*			.4838
None	3 (25%)	252 (37.56%)	
Some	3 (25%)	159 (23.7%)	
Severe	6 (50%)	203 (30.25%)	
Unknown	0 (0%)	57 (8.49%)	
Smoking history			.1526
Yes	3 (25%)	102 (15.2%)	
No	9 (75%)	437 (65.13%)	
Unknown	0 (0%)	132 (19.67%)	
Implantable defibrillator			.1833
Yes	6 (50%)	288 (42.92%)	
No	5 (41.67%)	371 (55.29%)	
Unknown	1 (8.33%)	12 (1.79%)	
Pulmonary artery mean pressure			.6951
≥25	5 (41.67%)	257 (38.30%)	
<25	6 (50.00%)	276 (41.13%)	
Unknown	1 (8.33%)	138 (20.57%)	

(Continues)

TABLE 1 (Continued)

Characteristic	LVAD (n = 12)	No LVAD (n = 671)	*P* value
Albumin			1
≥3.2	1 (8.33%)	73 (10.88%)	
<3.2	8 (66.67%)	434 (64.68%)	
Unknown	3 (25%)	164 (24.44%)	
Drug treated COPD			1
Yes	0 (0%)	10 (1.49%)	
No	10 (83.33%)	523 (77.94%)	
Unknown	2 (16.67%)	138 (20.57%)	
IV inotropes			.0785
Yes	0 (0%)	159 (23.70%)	
No	12 (100%)	511 (76.16%)	
Unknown	0 (0%)	1 (.15%)	
Life support*			.0436
Yes	0 (0%)	173 (25.82%)	
No	12 (100.0%)	497 (74.07%)	
Unknown	0 (0%)	1 (.15%)	
Type of LVAD			–
Heartmate II	11 (91.67%)	–	
Heartware HVAD	1 (8.33%)	–	

Note: Variables assessed at the time of heart transplant.
*Based on SRTR definitions.[8]

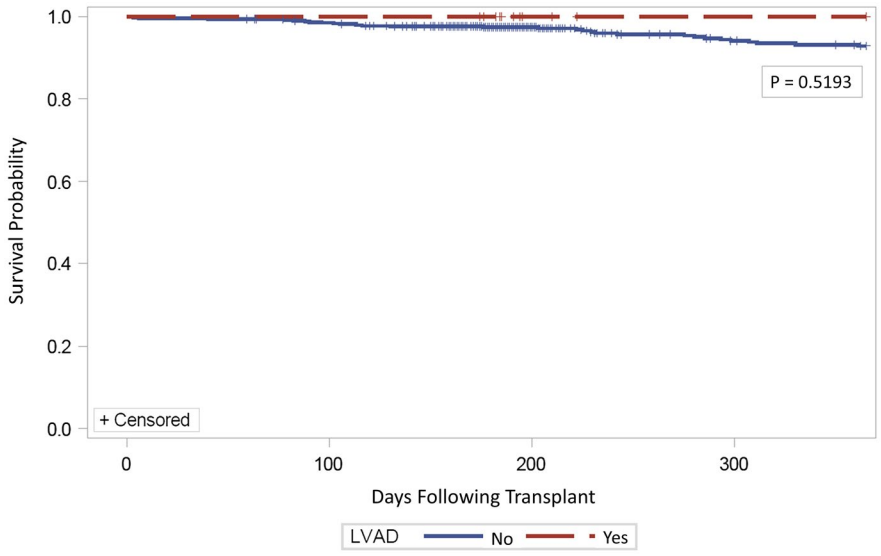


FIGURE 2 Post transplant survival in ACHD patients bridged to transplant with VAD (red) and transplanted without bridge (blue)

ACHD patients. Despite the potential to beneficially impact waiting list outcomes, VAD remains infrequently used in ACHD patients.[4,5] The arguments against VAD use in this population have broadly been two. First, concern that VAD might not be safe and efficacious in anatomy for which it was not designed. Second, that VAD implant might adversely impact post-transplant outcomes due to additional surgical scarring, exposure to blood products with consequent allosensitization and augmented operative difficulty associated with VAD explant at the time of transplant in patients with already complex anatomy. Previous INTERMACS analyses have addressed the first of these questions.[4,6] Maxwell et al addressed the second among ACHD patients supported by all types of mechanical circulatory support in aggregate.[7] The present analysis, although limited, adds to these data by specifically investigating outcomes after durable VAD.

4.1 | Limitations

In addition to all of the limitations inherit to retrospective research using SRTR, the test group in the present analysis is very small. With a

larger sample, we expect that adverse events would be detected in the ACHD VAD group. Nevertheless, anecdotal experience suggests that VAD has been used predominantly in severely deteriorating ACHD patients without other options. Following this logic, these patients are likelt at higher risk of adverse outcomes than the average transplant-listed ACHD patient, and one might therefore anticipate fewer rather than more events with expanded use in lower risk individuals. Nevertheless, given limited patient numbers and follow-up, the impact of VAD on long-term post-transplant outcomes cannot be definitively concluded based on the present analysis.

In conclusion, post-transplant outcomes in VAD-supported ACHD patients are not worse than in non-VAD-supported patients. VAD is a reasonable option in transplant-listed ACHD patients.

5 | DISCLAIMER

The data reported here have been supplied by the Hennepin Health Research Institute (HHRI) as the contractor for the Scientific Registry of Transplant Recipients (SRTR). The interpretation and reporting of these data are the responsibility of the authors and in no way should be seen as an official policy of, or interpretation by the SRTR or the U.S. Government.

CONFLICT OF INTEREST

The authors declare that they have no conflicts of interest with the contents of this article.

AUTHOR CONTRIBUTION

All authors have read and approved the final manuscript.
Drafting manuscript, study design: Cedars
Drafting manuscript, critical reading: Burchill, Roche, Menachem, Axsom
Data analysis, database search: Tecson

ORCID

Ari Cedars https://orcid.org/0000-0002-9975-5301

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