The HeartWare HVAD System for the Treatment of Advanced Heart Failure Patients with Biventricular Support

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Background

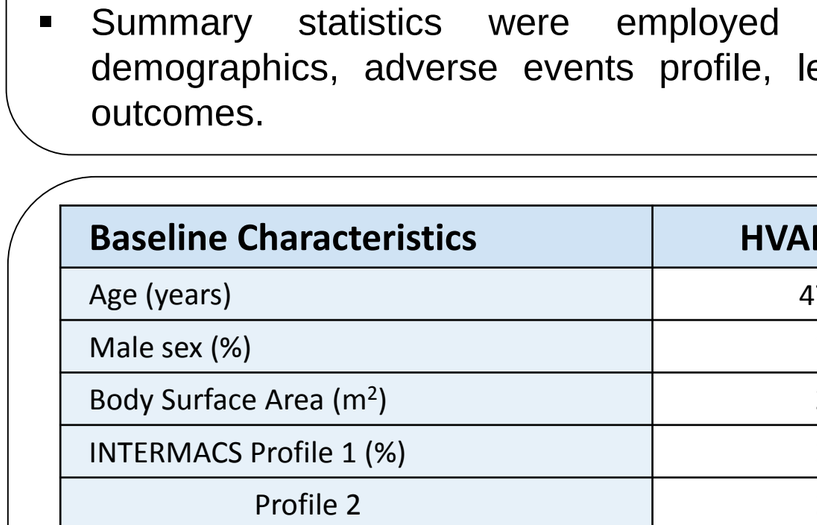
Approximately 10-20% of patients with advanced heart failure cannot be treated with a left ventricular assist device (LVAD) alone. Patients presenting with biventricular heart failure are generally sicker than those with left ventricular heart failure, and they have few options outside of cardiac transplantation. The small size of the HVAD Ventricular Assist System has led many surgeons to implant two HVAD pumps in a biventricular assist device (BiVAD) configuration. However, the HVAD was designed to be used as a left ventricular assist system (LVAD). Various adaptations have been described when the HVAD has been implanted for right ventricular support. We present here a retrospective analysis of aggregate data from BiVAD implants at various centers in Europe and Australia.

Methods

- This retrospective study identified 93 patients implanted with HVADs as a BiVAD at 12 international centers between 2009 and 2017.
- Comparison of the right atrial (n=32) versus right ventricular (n=56) implants were made, as well as Kaplan-Meier estimated survival through 2 years with various implant approaches.
- Secondary endpoints included adverse event profiles, and survival to heart transplantation.
- Summary statistics were employed to describe patient demographics, adverse events profile, length of support, and outcomes.

Baseline Characteristics	HVAD BiVADs (N=93)
Age (years)	47.4 ± 12.93 (91)
Male sex (%)	75.3% (70/93)
Body Surface Area (m^2)	2.0 ± 0.27 (90)
INTERMACS Profile 1 (%)	34.5% (30/87)
Profile 2	26.4% (23/87)
Profile 3	8.0% (7/87)
Profile 4	5.7% (5/87)
Unknown	25.3% (22/87)
Etiology of HF: Ischemic	14.5% (10/69)
Myocarditis	15.9% (11/69)
Idiopathic	47.8% (33/69)
Current Mechanical Support: ECMO	34.1% (30/88)
Bridge to Transplant	47.3% (44/93)

Comparison of Implant Approaches



Implanting the pumps either at the same time (or within 24 hours) has a similar survival profile as implants in a staged approach.

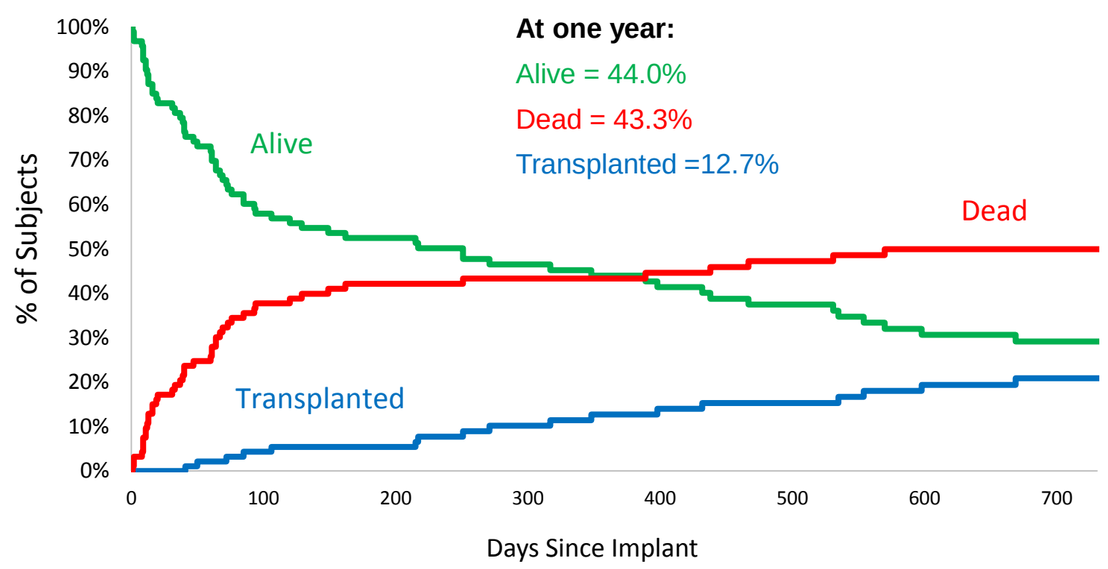
Implants in the RA versus RV also show similar survival profiles.

Adverse Events

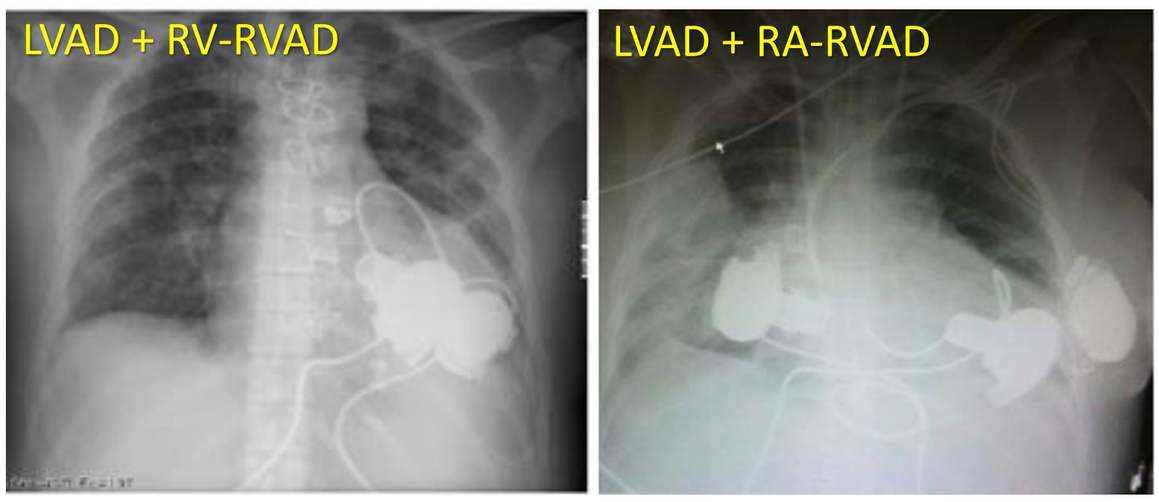
	Overall BiVAD N=93, %	BiVAD: RA N=32, %	BiVAD: RV N=56,%
Bleeding	25.8%	28.1%	25.0%
Cardiac Arrhythmia	4.3%	12.5%	0%*
Hemolysis	4.3%	6.3%	3.6%
Device Malfunction	9.7%	18.8%	5.4%
LVAD Thrombosis	1.1%	3.1%	0%
RVAD Thrombosis	11.8%	15.6%	10.7%
Neurological Dysfunction	15.1%	9.4%	17.9%
Infection	29.0%	37.5%	26.8%
Respiratory Failure	18.3%	25.0%	16.1%
Renal Dysfunction	16.1%	18.8%	16.1%
Right Heart Failure	8.6%	3.1%	12.5%

Abbreviations: RA = right atrial; RV = right ventricular
Neurological Dysfunction includes TIA, confusion/psychiatric episodes, strokes, and neuropathy.
RVAD thrombus was not captured as a device malfunction, but as an "other" serious AE.
* Statistically significant difference, $p<0.05$.

Competing Outcomes on HVAD Biventricular Support



Mean time on support of 93 patients receiving an HVAD as a BiVAD = 427.8 days (median = 161 days, range 1 – 2,526 days).



Conclusions

This analysis represents the largest retrospective review of the use of the HVAD System in biventricular support. Overall survival is similar to that reported by Intermacs for survival on continuous flow BiVADs (~50% at one year; JHLT 2015;34:1495–1504). Survival through 2 years is similar regardless of timing of right sided VAD or implant location. Nonetheless, the retrospective design limits broad data generalizations.

Disclosures:

S. Marasco: None; C. Hayward: Consultant: Medtronic; R. Scramm: None; D. Zimpfer: Consultant: Abbott, Medtronic; M. Ozbaran: None; C. Engin: None; J. Garbade: Consultant: Abbott, Medtronic; A.R. Simon: Consultant: Medtronic, Transmedics, Reliant Heart, 3D matrix; S. Tsui: Consultant: Medtronic, Edwards Lifesciences; F. Wagne : None; A.E. Fiane: None; M. Pac: None. U. Kervan: None; J.D. Schmitto: Consultant: Abbott.

Biventricular Use of the HVAD System is an off-label use of the device. Please refer to the Instructions for Use for labeled indications.