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Outcomes following isolated right ventricular assist device as durable support for primary right heart failure: An INTERMACS analysis

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Outcomes with isolated right ventricular assist devices (iRVAD) using pumps designed for the left ventricle are not well described. This study compares the clinical characteristics and outcomes of iRVAD patients to those patients treated with left ventricular assist device (LVAD) and biventricular assist devices (BiVAD). This study consisted of patients who received iRVAD from the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) registry (2006-2017). The primary outcome was 2-year survival. Of 20,789 patients, 26 (0.13%) received iRVAD, 17 with pulsatile flow and 9 with continuous-flow devices. Device strategy was bridge to recovery/rescue therapy in 9 (35%), bridge to transplant/decision in 14 (52%), and destination therapy in 3 (12%). Twelve (46%) patients were INTERMACS profile 1, 5 patients (19%) required extracorporeal

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membrane oxygenation, and 13 (50%) needed mechanical ventilation. Two-year survival for patients with iRVAD (41.3%) was similar to BiVAD (45.2%) and significantly lower than LVAD (69.0%). In patients with isolated right-sided failure, long-term iRVAD support is feasible.
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Isolated right ventricular (RV) failure requiring mechanical circulatory support (MCS) is uncommon. In cases when severe RV dysfunction does not recover with pharmacologic or temporary MCS, long-term support may be considered.[1,2]

The RV has a dramatically different geometry, chamber thickness, and compliance than the left ventricle, posing challenges for inflow cannulation.[3,4] Understanding clinical characteristics, complications, and outcomes of patients on durable isolated right ventricular assist devices (iRVAD) could inform modifications of the current technologies guiding device innovation to improve outcomes in chronic isolated right heart failure (RHF).

The study cohort, derived from the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS), included all patients treated with durable iRVAD, durable isolated left ventricular assist device (LVAD), and patients treated with durable biventricular assist devices (BiVAD). We excluded patients treated with temporary right ventricular assist devices (RVAD) or the total artificial heart and excluded patients with systemic RV failure due to congenital heart disease (Figure 1).

Data are shown as mean ± standard deviation or median (interquartile range) for continuous variables and total count (N) with proportion (%) for categorical variables. Baseline characteristics were compared with the Student's *t*-test, Wilcoxon rank sum, or chi-square tests as appropriate. A 2-sided p-value < 0.05 was used as the threshold for statistical significance. All analyses were performed using SAS version 9.4 (Cary, NC).

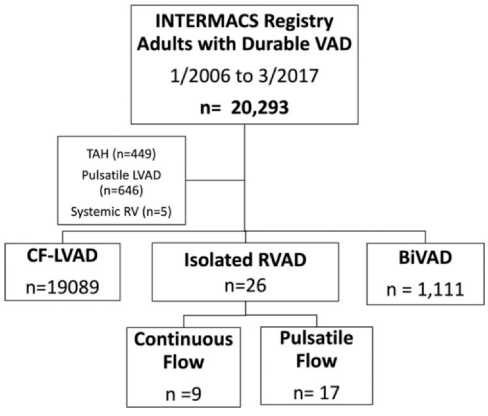

Figure 1 Consort diagram. BiVAD, biventricular assist devices; LVAD, left ventricular assist device; CF-LVAD, continuous flow LVAD; RV, right ventricular; RVAD, right ventricular assist devices; VAD, ventricular assist device.

A total of 20,789 patients were included in this study: 26 (0.13%) patients received iRVAD (65% male, mean age 54.4 ± 13.4 years), 19,152 (92%) patients an isolated LVAD, and 1,122 (5.3%) patients a BiVAD (Figure 1). The baseline characteristics are summarized in Table 1a. Etiology of RHF was valvular disease (31%), nonischemic cardiomyopathy (23%), and ischemic cardiomyopathy (23%). Seventeen patients (65%) were treated with pulsatile flow devices and 9 with centrifugal flow continuous-flow devices. Inflow cannulation was in the RV in 7 patients, right atrial (RA) in 18 patients, and unknown in 1 patient. Patients treated with iRVAD were more critically ill at the time of surgery (Table 1a). A higher proportion of patients treated with iRVAD were mechanically ventilated and supported with renal replacement therapy as compared to patients treated with BiVAD and LVAD. As expected, there were notable differences in the preimplant hemodynamic profiles (Figure 2 and Table 1b) between iRVAD-supported patients and LVAD/BiVAD-supported patients with significantly higher central venous pressure/pulmonary capillary wedge pressure ratio and lower central venous pressure to pulmonary artery pressure step-up.

Within the first year after iRVAD implant, 14 patients (54%) died, 4 patients (15%) were transplanted, and 8 patients (31%) remained alive on support. None of the patients underwent device explant for RV recovery. Importantly, all patients who survived the first year after implant were alive at 2 years. Two-year survival for patients with iRVAD (41.3%) was similar to BiVAD (45.2%) and significantly lower than LVAD (69.0%). At 2 years of follow-up, a favorable outcome, defined as either survival on iRVAD support, transplant, or explant for myocardial recovery, occurred in 11 (42%) patients.

Patients with inflow cannulation of the RA had increased survival compared with patients with RV cannulation (p = 0.04). Survival was similar for those bridged with and without temporary mechanical support before iRVAD implantation. The most common recorded causes of death were RHF (N = 3), multisystem organ failure (N = 3), pulmonary embolism (N = 3), withdrawal of support (N = 2), and major bleeding (N = 1).

Isolated RV failure rarely requires long-term durable RVAD. Our study, the largest series to date evaluating the clinical characteristics and long-term outcomes of patients requiring isolated RV durable MCS, has provided the following insights:

1. Long-term survival after iRVAD (42% overall at 2 years with 31% alive on support at 1 year) is comparable to

Table 1a Preimplant Characteristics

Variable[a]	iRVAD $n = 26$	LVAD $n = 19,089$	BiVAD $n = 1,111$	p[b]
Clinical characteristics				
Age, years	54.5 ± 13.4	56.8 ± 12.9	52.0 ± 13.9	< 0.001
Male gender	17 (65.4)	15,027 (78.7)	814 (73.3)	0.241
BMI, kg/m^2	27.8 ± 6.6	28.7 ± 7.0	28.4 ± 6.7	0.341
BSA, m^2	2.0 ± 0.4	2.1 ± 0.3	2.0 ± 0.3	0.002
Duration of heart failure < 1 year	6 (23.0)	3,055 (16.0)	321 (28.9)	< 0.001
No prior cardiac surgery	5 (19.2)	12,624 (66.1)	656 (59.0)	< 0.001
Device strategy: BTT definite/probable	14 (53.9)	10,381 (54.4)	729 (65.6)	< 0.001
INTERMACS profile 1 or 2	19 (82.6)	9,968 (52.5)	949 (85.8)	< 0.001
Interventions within 48 hours before VAD				
ECMO	5 (19.2)	761 (4.0)	229 (20.6)	< 0.001
Mechanical ventilation	13 (50.0)	1,244 (6.5)	247 (22.2)	< 0.001
Renal replacement therapy	10 (38.5)	434 (2.2)	97 (8.7)	< 0.001
Medical/device therapy at implant				
Temporary MCS	10 (47.6)	4,188 (26.3)	488 (46.4)	< 0.001
Inotropic support	19 (73.1)	15,528 (81.4)	959 (86.3)	< 0.001
Phosphodiesterase type 5 inhibitors	0	1,393 (10.1)	60 (9.8)	0.410
Inhaled nitric oxide	5 (19.2)	293 (1.5)	34 (3.1)	< 0.001
Laboratory measurements				
Creatinine, mg/dl	1.6 ± 0.7	1.4 ± 0.7	1.6 ± 0.9	< 0.001
Total bilirubin, mg/dl	2.1 ± 2.0	1.4 ± 1.8	2.6 ± 4.0	< 0.001
Sodium, mEq/liter	135.6 ± 7.4	134.9 ± 4.8	134.4 ± 6.2	0.002
Hemoglobin, g/dl	10.1 ± 2.4	11.3 ± 2.1	10.4 ± 2.1	< 0.001
Echocardiography				
LVEDD	4.8 ± 0.8	6.8 ± 1.1	6.5 ± 1.3	< 0.001
Moderate to severe TR	12 (46.2)	6,945 (37.9)	446 (42.9)	0.004

Abbreviations: BiVAD, biventricular assist devices; BMI, body mass index; BSA, body surface area; BTT, bridge-to-transplant; ECMO, extracorporeal membrane oxygenation; INTERMACS, Interagency Registry for Mechanically Assisted Circulatory Support; iRVAD, isolated right ventricular assist device; LVEDD, left ventricular end-diastolic dimension; LVAD, left ventricular assist device; MCS, mechanical circulatory support; SD, standard deviation; TR, tricuspid regurgitation; VAD, ventricular assist device.

[a]Data presented as *n* (%) for categorical variables and mean (SD) for continuous variables.

[b]*p*-value for comparison of iRVAD vs LVAD.

BiVAD despite critically ill patients requiring the highest level of support at time of iRVAD.

2. iRVAD patients had a common and distinct hemodynamic profile from LVAD or BiVAD patients of RV contractile failure without evidence of excessive RV afterload and low to normal pulmonary artery pressures.

Our results, consistent with prior studies, also show higher survival rates for patients with RA inflow cannulation compared to RV cannulation. This difference may be due to the unique anatomical features of the RV, with a trabeculated and thin apex that limits cannulation options.[5,6] Cannulation decisions should be individualized, considering both anatomical and physiologic factors. The design of future device technology tailored for long-term RV support will need to balance the benefits of RV unloading with the potential for RV recovery vs the superiority of RA cannulation that has been described and likely due to decreased suction and thrombotic events.

Continuous-flow pumps, designed for systemic circulation with high pressure gradients, may not be ideal for the pulmonary circulation characterized by low hydraulic impedance, potentially increasing the risk of lung injury due to unregulated pulmonary blood flow. Although lung injury from continuous flow is not detailed in the INTERMACS registry, cases of respiratory failure and RVAD highlight the need for pump technologies tailored to the pulmonary circuit to improve outcomes.[7]

A limitation of the study, despite having the largest series in INTERMACS, is the small study cohort. Analyses of the baseline characteristics indicate that the patients implanted were not in end-stage RV failure due to pulmonary vascular disease, so our results are not applicable to an advanced cohort with pulmonary arterial hypertension. A limitation, due to time period bias, is not including currently effective strategies for temporary RV support, including ambulatory dual or single cannula percutaneous RVADs (Protek Duo Cardiac Assist, Inc.; RP Flex, Abiomed Inc.). Finally, missing data limited our ability to analyze the follow-up quality of life and functional capacity among iRVAD patients.

In conclusion, this is the largest cohort evaluating the unique characteristics and outcomes of patients treated with isolated durable RVAD. Durable 1-sided RVAD support may serve as a therapeutic option for patients with

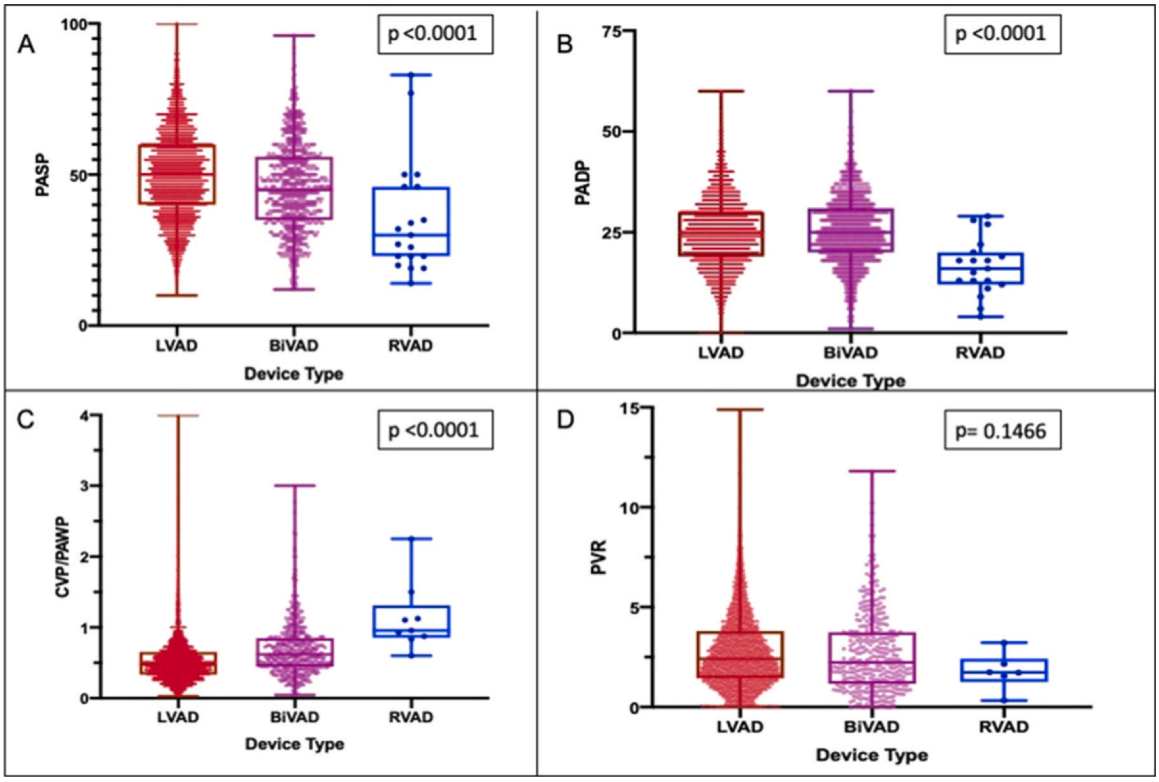

Figure 2 Preimplant hemodynamics among iRVAD, LVAD, and BiVAD patients. BiVAD, biventricular assist devices; iRVAD, isolated right ventricular assist device; LVAD, left ventricular assist device; PADP, pulmonary artery diastolic pressure; PASP, pulmonary artery systolic pressure; PAWP, pulmonary artery wedge pressure; PVR, pulmonary vascular resistance.

refractory RV failure who have a high likelihood of recovery or heart transplantation. Future studies are needed to evaluate how (1) the unique clinical scenarios for durable right ventricular support—RV myopathic failure vs end-stage pulmonary arterial hypertension—can be matched with optimal pump technologies; and (2) outcomes with

Table 1b Preimplant Hemodynamics

Hemodynamic parameter[a,b]	iRVAD *n* = 26	LVAD *n* = 19,089	BiVAD *n* = 1,111	p[c]
Heart rate, bpm	91.3 ± 18.2	88.9 ± 17.6	95.2 ± 20.7	< 0.001
MAP, mm Hg	73.3 ± 10.9	78.0 ± 11.2	74.8 ± 11.9	< 0.001
RAP, mm Hg	14.7 ± 6.7	11.8 ± 6.6	15.1 ± 7.0	< 0.001
PASP, mm Hg	35.6 ± 19.1	50.1 ± 14.7	46.0 ± 14.5	< 0.001
PADP, mm Hg	16.4 ± 6.9	25.0 ± 8.8	25.3 ± 8.6	< 0.001
PAPP, mm Hg	19.3 ± 15.5	25.0 ± 10.2	20.7 ± 10.0	< 0.001
PCWP, mm Hg	14.9 ± 6.7	24.8 ± 9.1	25.8 ± 8.8	< 0.001
CVP/PCWP	1.1 ± 0.5	0.6 ± 0.4	0.7 ± 0.6	< 0.001
Cardiac output, liter/min	5.1 ± 2.1	4.3 ± 1.5	4.0 ± 1.5	< 0.001
PVR, Wood units	1.8 ± 0.9	2.9 ± 2.1	2.8 ± 2.0	0.14
SVR	1,087.4 ± 590.5	1,365.5 ± 609.8	1,314.1 ± 618.4	0.04
TPG, mm Hg	5.9 ± 7.8	9.2 ± 7.6	7.5 ± 7.7	< 0.001
RVSWI, mm Hg × ml/m^2	165.8 ± 151.3	521.4 ± 365.0	389.7 ± 334.9	< 0.001
PAPi	1.5 ± 1.3	3.0 ± 3.1	1.7 ± 1.6	< 0.001

Abbreviations: BiVAD, biventricular assist devices; CVP, central venous pressure; iRVAD, isolated right ventricular assist device; LVAD, left ventricular assist device; MAP, mean arterial pressure; PADP, pulmonary artery diastolic pressure; PAPi, pulmonary artery pulsatility index; PAPP, pulmonary artery pulse pressure; PASP, pulmonary artery systolic pressure; PCWP, pulmonary capillary wedge pressure; PVR, pulmonary vascular resistance; RAP, right atrial pressure; RVSWI, right ventricular stroke work index; SD, standard deviation; SVR, systemic vascular resistance; TPG, transpulmonary gradient.

[a]Data presented as *n* (%) for categorical variables and mean (SD) for continuous variables.

[b]Hemodynamic variables were calculated as follows: PAPP = PASP – PADP; PAPi = PAPP/CVP; PVR = (mPAP – PCWP/CO); TPG = mPAP – PCWP; RVSWI = (mPAP – CVP) × SVI.

[c]*p*-value for comparison of iRVAD vs LVAD.

durable RVAD can be improved with the temporary right ventricular support currently being deployed.

CRediT authorship contribution statement

Edo Y. Birati: Conceptualization, Formal analysis, Writing – original draft. **E. Wilson Grandin:** Writing – original draft, Methodology. **Robert S. Zhang:** Writing – review & editing, Visualization. Matthew Seigerman: Data curation, Writing – review & editing. **Allison Padegimas:** Data curation, Writing – review & editing. **Fausto Cabezas, Keshava Rajagopal, Jeremy A. Mazurek, Michael S. Kiernan, Navin K. Kapur, Pavan Atluri, Guilherme H. Oliveira, Francis D. Pagani, Susan L. Myers, Jeffrey Teuteberg, Robert L. Kormos, James K. Kirklin, Michael A. Acker:** Writing – review & editing. **Jesus Eduardo Rame:** Writing – review & editing, Supervision, Methodology, Conceptualization.

Disclosure statement

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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