JACC: HEART FAILURE
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PUBLISHED BY ELSEVIER
VOL. 4, NO. 3, 2016
ISSN 2213-1779/$36.00
http://dx.doi.org/10.1016/j.jchf.2015.10.001

Hemodynamic Ramp Tests in Patients With Left Ventricular Assist Devices

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ABSTRACT

OBJECTIVES This study tested whether combined invasive hemodynamic and echocardiographic ramp tests can help optimize patient management.

BACKGROUND Guidelines for optimizing speed and medications in continuous flow ventricular assist device (cfLVAD) patients are mainly based on expert opinion.

METHODS Thirty-five cfLVAD patients (21 HeartMate II [Thoratec, Pleasanton, California] and 14 HVAD [HeartWare International, Framingham, Massachusetts]) underwent ramp tests with right heart catheterization (including central venous pressure [CVP], pulmonary artery pressure, pulmonary capillary wedge pressure [PCWP], and blood pressure) and echocardiography. Data were recorded at up to 9 speed settings. Speed changes were in steps of 400 revolutions per minute (RPM) for HeartMate II (8,000 to 12,000 RPM) and 100 RPM for HVAD (2,300 to 3,200 RPM) patients.

RESULTS Only 42.9% of patients had normal CVPs and PCWPs at their original RPM settings. Going from lowest to highest speeds, cardiac output improved by 0.16 ± 0.19 l/min/step (total change 1.28 ± 1.41 l/min) and PCWP decreased by 1.23 ± 0.85 mm Hg/step (total change 9.9 ± 6.5 mm Hg). CVP and systolic blood pressure did not change significantly with RPM. RPM were adjusted based on test results to achieve CVPs and PCWPs as close to normal limits as possible, which was feasible in 56% of patients. For the remainder, results indicated which type of medical management should be pursued.

CONCLUSIONS Use of combined hemodynamic and echocardiographic ramp tests in patients provides objective means of optimizing RPM, and has the potential to guide medical management. It remains to be tested whether this strategy has a beneficial impact on quality of life or clinical outcomes. (J Am Coll Cardiol HF 2016;4:208-17)
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Continuous flow left ventricular assist devices (cfLVADs) prolong life in end-stage heart failure (1-3) and are increasingly used as both bridge to transplantation and destination therapy. With increasing duration of cfLVAD support, attention is shifting to enhancing patient quality of life. One important step is optimization of patients' hemodynamic profile, which is dependent on the complex interaction between the individual patient's pathophysiology and pump characteristics. On the patient side, ventricular contractility and volume status, together with pulmonary and systemic vascular properties, are important factors. In contrast, pump characteristics are quantified by speed-dependent pressure-flow relationships. Of the two most widely used cfLVADs, one is a centrifugal flow pump

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Manuscript received August 4, 2015; revised manuscript received October 13, 2015, accepted October 13, 2015.

(HVAD, HeartWare International, Framingham, Massachusetts) and the second one is an axial flow pump (HeartMate II, Thoratec, Pleasanton, California). Multiple investigators have suggested that fundamental differences exist in the pumping characteristics of these 2 devices (4,5).

Optimizing the hemodynamic profile of a cfLVAD patient requires detailed comprehension of ventricular-vascular-cfLVAD interactions (6). The International Society of Heart and Lung Transplantation guidelines predominantly reflect expert opinion, and there is significant physician variability in the assessment and management of cfLVADs (7). (Revolutions per minute (RPM) are recommended to be adjusted to adequately unload the left ventricle (LV) while maintaining midline interventricular septum and minimizing mitral regurgitation (Class of Recommendation: I; Level of Evidence: C). RPM are recommended to be set low enough to allow intermittent aortic valve (AV) opening (Class of Recommendation: IIb; Level of Evidence: B). Diuretics, angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, β-blockers, and mineralocorticoids are considered useful for managing volume status, blood pressure, arrhythmias, and myocardial fibrosis (Class of Recommendation: I; Level of Evidence: C) (8).

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The intent of this study is to develop an evidence-based approach to the management of cfLVAD patients based on the interaction between device function and patient hemodynamics. We applied a standardized hemodynamic ramp protocol in clinically stable cfLVAD patients to assess the impact of acute changes in cfLVAD speed on hemodynamics and LV unloading. We hypothesize that the findings of this study will have important implications for the refinement of management guidelines and establish the role of periodic hemodynamic monitoring in cfLVAD patients.

METHODS

In this prospective study, 35 consecutive cfLVAD patients (14 HVAD and 21 HeartMate II) were enrolled and evaluated with a hemodynamic and echocardiographic ramp test. The test was performed in stable outpatients, ideally between 1 and 3 months following LVAD implantation. Patients implanted prior to the initiation of this protocol were enrolled as they were seen in the outpatient clinic, regardless of time since surgery. This study includes patients undergoing the hemodynamic ramp study for LVAD speed optimization. Patients in whom an LVAD thrombus was suspected were excluded.

RAMP TEST PROTOCOL. In the catheterization laboratory, patients underwent an echocardiographic ramp study using previously reported methods (8,9). Simultaneously, we assessed hemodynamics with right heart catheterization. The complete protocol is described in the Appendix. The hemodynamic parameters recorded included opening Doppler blood pressure (oD-BP) (9); central venous pressure (CVP); systolic, diastolic, and mean pulmonary artery pressures (PAP); and pulmonary capillary wedge pressure (PCWP). Cardiac output (CO) and cardiac index (CI) were calculated by the indirect Fick method. Two-dimensional echocardiographic parameters were collected as detailed previously (10,11). At the conclusion of each test, the attending cardiologist reviewed the data and the device was set at the speed wherein hemodynamic normalization was achieved, that is, PCWP <18 mm Hg and CVP <12 mm Hg, with the secondary goals of intermittent AV opening and minimal mitral regurgitation.

DATA ANALYSIS AND STATISTICAL METHODS. Ramp test parameter recordings at different speeds were entered into a spreadsheet (EXCEL 2010 Microsoft Corporation, Redmond, Washington) and plotted with either EXCEL or Origin (OriginLab Corporation, Northampton, Massachusetts) software. All statistical analyses were performed using SPSS (version 22, IBM, Armonk, New York). Normality was tested with the Shapiro-Wilk test. Normally distributed continuous variables were reported as mean ± SD, and skewed continuous data are reported as median (interquartile range). Categorical variables were summarized using frequencies and percentages. Continuous variables were compared using the Student's *t* test or Mann-Whitney *U* test, as appropriate. Categorical values were compared with the chi-square or Fisher's exact test. A p value of 0.05 was considered statistically significant. Slopes were calculated using linear regression (10), which is described in detail in the Online Appendix. The University of Chicago's Institutional Review Board committee approved this study and all patients signed informed consent.

RESULTS

BASELINE CHARACTERISTICS. Patient characteristics are summarized in Table 1. Patients were

ABBREVIATIONS AND ACRONYMS

AV = aortic valve

cfLVAD = continuous flow left ventricular assist device

CI = cardiac index

CO = cardiac output

CVP = central venous pressure

LV = left ventricle/ventricular

oD-BP = opening Doppler blood pressure

PAP = pulmonary artery pressure

PCWP = pulmonary capillary wedge pressure

RPM = revolutions per minute

RV = right ventricle/ventricular