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HVAD Flow Waveform Estimates Left Ventricular Filling Pressure

TERUHIKO IMAMURA, MD, PhD^{1,2}, NIKHIL NARANG, MD³, DANIEL RODGERS, BN¹, DAISUKE NITTA, MD, PhD¹, JONATHAN GRINSTEIN, MD⁴, TAKEO FUJINO, MD, PhD¹, GENE KIM, MD¹, ANN NGUYEN, MD¹, VALLUVAN JEEVANANDAM, MD⁵, GABRIEL SAYER, MD⁶, NIR URIEL, MD, MSc⁶

¹Department of Medicine, University of Chicago Medical Center, Chicago, Illinois

²Second Department of Medicine, University of Toyama, Toyama, Japan

³Advocate Heart Institute, Advocate Christ Medical Center, Oak Lawn, Illinois

⁴Division of Cardiology, MedStar Heart and Vascular Institute Advanced Heart Failure and Cardiac Transplantation, NW, Washington, DC

⁵Department of Surgery, University of Chicago Medical Center, Chicago, Illinois

⁶Division of Cardiology, Columbia University Irving Medical Center, New York, New York.

Abstract

Background: HVAD left ventricular assist device flow waveforms provides graphical real-time information linking device performance with invasive hemodynamics. Previous studies have demonstrated a good correlation between the slopes of the ventricular filling phase slope (VFPS) and directly measured pulmonary capillary wedge pressure (PCWP). We aimed to validate the utility of VFPS to estimate PCWP and predict clinical outcomes.

Methods: In this prospective blinded study, screenshots from the HVAD monitor and simultaneous invasive hemodynamic measurements were obtained. Each screenshot was digitized and the VFPS was calculated by 2 independent reviewers who were blinded to the hemodynamic results. The equation $PCWP = 7.053 + 1.365 \times (VFPS)$ was derived from a previously published dataset and the estimated PCWP was correlated to the actually measured PCWP.

Results: One hundred thirty-one sets of simultaneous measurements (VFPS and PCWP) were obtained from 27 HVAD patients (mean age 55 years, 47% male). A previously proposed cutoff of VFPS 5.8 L/min/s predicted PCWP 18 mmHg with 91.5% sensitivity and 95.2% specificity with the area under curve of 0.987. The estimated PCWP significantly correlated with measured PCWP ($R^2 = 0.65$, $P < .001$) and showed acceptable agreement with measured PCWP. Patients with VFPS 5.8 L/min/s experienced significantly higher heart failure readmission rates than those without (0.24 vs 0.05 events/y, $P < .001$).

Reprint requests: Nir Uriel, MD, MSc, Division of Cardiology, Columbia University Irving Medical Center, 622 West 168th Street, PH 4-129, New York, NY 10032. Tel: 1-212-342-3253; Fax: 1-646-317-4681. nu2126@cumc.columbia.edu.

Disclosures

G.S. is a consultant for Medtronic; V.J. is a consultant for Abbott; N.U. and J.G. hold a patent on the VFPS.

Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.cardfail.2020.01.012.

Conclusions: VFPS of the HVAD flow waveform is a novel noninvasive parameter that can estimate PCWP. (*J Cardiac Fail* 2020;00:1-7)

Keywords

Heart failure; ventricular assist device; heartware

Continuous-flow left ventricular assist devices (LVAD) improves survival in patients with advanced heart failure (HF).¹ However, LVAD complications continue to remain common despite advances in pump engineering. Optimizing hemodynamics can be challenging in some LVAD patients.² Failure of hemodynamic optimization is associated with adverse clinical outcomes,³ and therefore identifying LVAD patients with abnormal hemodynamics may be important for preventing readmission. Currently, the gold standard for hemodynamic assessment is right heart catheterization (RHC), though non-negligible procedural-related risks must be considered with invasive assessments. Therefore, an unmet need remains for noninvasive methods to estimate hemodynamics as part of long-term LVAD management.⁴

The HeartWare HVAD (Medtronic, Framingham, MA) is among the widely-used continuous-flow LVADs available for durable mechanical support.^{5,6} The HVAD system uniquely displays instantaneous device flow, which is estimated based on LVAD speed, the electrical current drawn by the pump, and blood viscosity.⁷

Various clinical scenarios can be elucidated by reviewing the HVAD waveform.⁸ We previously showed a significant relationship between the device flow pattern and cardiac filling pressures.⁹ In that study, pulmonary capillary wedge pressure (PCWP) had a linear association with the ventricular filling phase slope (VFPS), which was digitally calculated from the device flow.⁷ This association was based on a hypothesis that the pump flow is dependent on the gradient between the left ventricular pressure (LVP), which changes throughout the cardiac cycle, and aortic pressure. Aortic pressure is assumed to be constant during diastole while under continuous-flow LVAD support (Supplementary Fig. S1).⁸ Based on this hypothesis, elevation in left ventricular diastolic pressures (or PCWP as a surrogate measure) results in increased flow through the LVAD during diastole.

In this prospective study, we assessed whether the VFPS, which was measured by reviewers blinded to the results of hemodynamic measurements, would be useful to estimate PCWP. We also investigated the predictive value of VFPS on HF readmissions.

Methods

Patient Selection

In this prospective study, consecutive patients who underwent HVAD LVAD implantation were prospectively enrolled between April 2016 and October 2018. Patients underwent routine invasive hemodynamic and echocardiographic assessments (ramp test or single RHC) for hemodynamic optimization; simultaneous snapshots of the waveform on the controller monitor screen were also collected. The study cohort differed from the initial derivation cohort previously published.⁹ The study was approved by the institutional review

board at the University of Chicago, and all patients gave informed consent before enrollment.

Hemodynamic and Echocardiographic Assessments

Patients underwent RHC via their right internal jugular vein using a 7-French Swan-Ganz catheter. Standard hemodynamic parameters were measured at end-expiration timing. Mean arterial pressure (MAP) was measured by Doppler method. During the ramp test, patients had HVAD speeds increased by 100 rpm from 2300 to 3200 rpm, with hemodynamics and echocardiographic data measured at each speed setting, after at least 2 minutes to allow for a washout period between each measurement. For isolated RHC, hemodynamic and echocardiographic variables were measured at a fixed HVAD speed.

Waveform Analyses

All waveform analyses were performed by 2 independent investigators (T.I. and D.N.) who were blinded to the results of hemodynamic assessments and clinical outcomes. Screenshots of the flow versus time waveforms of the HVAD system were obtained using a digital camera (iPhone 6, Apple Inc, Cupertino, CA; Supplementary Fig. S2A).

The first 3 flow waveforms were converted into a digital signal using a commercially available wave analyzer (IGOR Pro, WaveMetrics Inc, Oswego, OR; Supplementary Fig. S2B).⁹ Waveforms during instances of premature ventricular contractions were excluded. Flow pulsatility was defined as the difference between the maximum flow and the minimum flow (point A – point B). Point C represented the time of end-diastole. VFPS was calculated as a slope between point B and C. Three sets of VFPS were measured by 2 independent investigators, and a total of 6 VFPS were averaged to obtain a final VFPS.

Follow-Up

All patients were followed clinically after flow waveform measurements and hemodynamic assessments (day 0) by clinicians who were blinded to the VFPS values, while receiving guideline-directed medical therapies.¹⁰ HF readmission incidence, which was determined by the need for intravenous diuretic therapy with in-hospital observation, was the primary clinical endpoint. Death and heart transplantation were censored.

Statistical Analyses

Statistical analyses were performed using SPSS Statistics 22 (SPSS Inc, Armonk, IL). Two-sided *P* values < .05 were considered statistically significant. Continuous variables were expressed as mean and standard deviation or as median and interquartile range considering their distribution. Two-group comparison was performed by Mann – Whitney U test for the continuous variables or by Fisher's exact test for the categorical variables. Multiple group comparison for the continuous variables was performed by the Friedman test.

Intra-rater reliability among 3 VFPS measurements was assessed by using the intraclass correlation coefficient (ICC) class 1, and inter-rater reliability between 2 reviewers was assessed by using ICC class 2. ICC > 0.8 was considered excellent reliability.

The previously proposed cutoff of VFPS ≥ 5.8 L/min/s to estimate PCWP ≥ 18 mmHg⁹ was validated by using the receiver operating characteristics analysis. Linear regression analysis was used on the waveform dataset from the previously published study to create the following equation: estimated PCWP = $7.053 + 1.365 \times (\text{VFPS [L/min/s]})$.⁹ In this derivation cohort, we also created a model in which VFPS was adjusted by LVAD flow and LVAD speed. However, it had a lower C statistic compared with the unadjusted model, and we opted to use an unadjusted model as well. The correlation of estimated PCWP with measured PCWP was validated by using Pearson correlation coefficients and the Bland – Altman test. Further-more, we performed generalized estimating equation to assess the correlation between estimated PCWP and measured PCWP to account for multiple data derived from the same patients.

HF event rates were expressed as event rate per patient-year and compared between the VFPS ≥ 5.8 L/min/s group and the VFPS < 5.8 L/min/s group by using negative binomial regression analyses.

Results

Baseline Characteristics

In total, 131 sets of measurements (waveform and PCWP) were obtained from 19 ramp tests and 8 single RHCs in 27 patients (53 ± 17 years, 15 males) at 5 (2, 15) months following HVAD implantation. The indication for HVAD implantation was destination therapy for the majority of patients included (56%; Table 1).

Measurement of VFPS

VFPSs were measured in each screenshot. Example screenshots (low VFPS and high VFPS cases) are shown in Supplementary Figs. S3A and S3B, respectively.

The intra-rater reliability of the 3 VFPS measurements was ICC (1, 1) = 0.811 and ICC (1, 3) = 0.928 for reviewer 1 (T.I.), and ICC (1, 1) = 0.912 and ICC (1, 3) = 0.969 for reviewer 2 (D.N.) ($P < .001$ for all). The inter-rater reliability between the 2 reviewers was ICC (2, 1) = 0.945 and ICC (2, 2) = 0.972 ($P < .001$ for both). In the setting of atrial fibrillation (10 patients), intra-rater reliability remained high for both reviewers (0.931 and 0.966).

Distributions of VFPS are shown in Fig. 1 (median 3.9 [2.0, 5.8]). Thirty-four cases (26%) had VFPS ≥ 5.8 L/min/s. A comparison of baseline characteristics between these 2 groups (ie, high and low VFPSs) is shown in Supplementary Table S1. Intracardiac filling pressures were higher in the group with VFPS ≥ 5.8 L/min/s, whereas cardiac index was lower ($P < .05$ for all).

VFPS and Measured PCWP

Average measured PCWP was 13.0 ± 5.2 mmHg. VFPS had a strong positive correlation with measured PCWP ($R^2 = 0.65$, $P < .001$, standard error of estimate = 3.05, and β 1.8 [95% confidence interval 1.5 – 2.0]). As shown in Supplementary Fig. S4, there was also a significant correlation between the change in VFPS and the change in PCWP during

incremental LVAD speed (from lowest to highest) in the 17 patients who underwent a hemodynamic ramp test ($R^2 = 0.68$).

The previously proposed cutoff of VFPS ≥ 5.8 L/min/s predicted PCWP ≥ 18 mmHg with an area under the curve of 0.987, and had 92.9% sensitivity, 92.2% specificity, 76.5% positive predictive value, and 97.9% negative predictive value (Fig. 2A). Median measured PCWP in the VFPS ≥ 5.8 L/min/s group ($N = 34$) was 19 (18, 22) mmHg compared with 10 (8, 15) mmHg among those in the VFPS < 5.8 L/min/s group ($N = 97$; $P < .001$ and β 6.4 [95% confidence interval 5.3–7.5]; Fig. 2B).

Among 34 cases with VFPS ≥ 5.8 L/min/s, 8 (26%) had PCWP < 18 mmHg. There were no significant differences in clinical parameters between true- and false-positive cases, except for relatively lower central venous pressure in the false-positive group ($P = .082$).

Estimation of PCWP Using VFPS

Linear regression analysis was used to derive the equation to estimate PCWP: $7.053 + 1.365 \times (\text{VFPS})$ from our prior study.⁹ PCWP estimated by this equation had a strong correlation ($R^2 = 0.65$, $P < .001$, and β 1.3 [95% confidence interval 1.1–1.5]; Fig. 3A) and good agreement (Fig. 3B) with measured PCWP in nearly all plots within ± 2 standard deviations.

To determine whether the predictive value was adversely affected by heart rate, we adjusted the equation for heart rate and derived the following equation: $\text{PCWP} = 1.61 \times (\text{VFPS}) - 0.02 \times (\text{heart rate}) + 7.659$. However, the addition of heart rate did not weaken the β -coefficient for VFPS and did not improve the overall predictive value of the model ($R^2 = 0.65$).

To assess the performance of the equation under different clinical conditions, we stratified the observations by MAP, central venous pressure, left ventricular size, mitral regurgitant severity, and aortic valve opening, and evaluated the correlation between estimated and measured PCWP in each group (Supplementary Table S2). Overall, correlation coefficients remained statistically significant across all groups ($P < .001$ for all).

Prediction of Clinical Outcome Using VFPS

Among 27 patients, 6 patients had VFPS ≥ 5.8 L/min/s at their set LVAD speeds. There was a strong correlation between VFPS and actually measured PCWP ($R^2 = 0.77$) among them (Fig. 4A). There were no statistically significant differences in the baseline demographic characteristics between these 2 groups ($P > .05$ for all; Supplementary Table S1). Patients with VFPS ≥ 5.8 L/min/s had worse HF symptomology and higher N-terminal pro-B-type natriuretic peptide ($P < .05$ for both; Supplementary Table S3). More patients with VFPS ≥ 5.8 L/min/s received diuretics compared with those with VFPS < 5.8 L/min/s (83% vs 38%, $P = .050$).

During 12 (6, 23) months of follow-up, patients in the higher VFPS group had approximately 10-fold increase in the HF readmission rate compared with the lower group following enrollment (0.400 vs 0.044 events/patient-year, $P < .001$, incidence rate ratio 9.26, 95% confidence interval 8.33–10.41; Fig. 4B).

Discussion

In this prospective single-center study, we assessed the correlation and prognostic ability of VFPS in HVAD patients. Our main findings are as follows: 1) VFPS ≥ 5.8 L/min/s had high sensitivity and specificity in predicting PCWP ≥ 18 mmHg. 2) The equation calculated from VFPS to predict PCWP was highly accurate. 3) High VFPS was strongly associated with increased rates of HF readmissions during HVAD support.

Implication of Noninvasive Estimation of Left-Sided Filling Pressure

The implications of adverse hemodynamics have been reported in HF patients¹¹ and in those supported by LVADs. We recently showed that abnormal hemodynamics was associated with adverse clinical outcomes,³ and optimization of hemodynamics resulted in a reduction in readmission rates in LVAD patients.¹² However, repeated invasive hemodynamic assessment is time-consuming, expensive, and carries procedural risks. The CardioMEMS (Abbott, Abbott Park, IL) implantable pulmonary artery sensor may be a suitable noninvasive alternative to monitor hemodynamics¹³; however, some LVAD patients may experience decoupling between the diastolic pulmonary artery pressure and PCWP,¹⁴ rendering the CardioMEMS less accurate to estimate LVP.

Other devices have been developed to directly measure left atrial pressure or LVP. The LAPTOP-HF study, which tested a left atrial pressure sensor implanted via the venous system and positioned in the left atrium via the atrial septum,¹⁵ was stopped prematurely because of futility. Direct implantation of pressure sensors in the left heart during LVAD implantation might represent another option for hemodynamic monitoring in the future, although the safety of such devices in patients with LVADs has not been evaluated.

Novel Equation Using VFPS

Previously, we reported that VFPS estimated PCWP and that VFPS ≥ 5.8 L/min/s indicated elevated PCWP.⁹ Hereby, we validated those results in this reviewer-blinded prospective study. Considering that the intrarater reliability increased from ICC (1, 1) to ICC (1, 3) in both reviewers, multiple readings increase reliability. The inter-rater reliability remained unchanged from ICC (2, 1) to ICC (2, 2), thus a single review could be sufficient to obtain reliable measurements.

The interpretation of the HVAD flow waveform is highly useful in clinical LVAD management. Currently, its use is mostly in the realm of detecting conditions associated with low flow and low pulsatility (tamponade, hypovolemia, and right ventricular failure), device thrombosis, or even arrhythmia⁸; however, it is evident that more information can be extrapolated from the waveform. In the current study, the high sensitivity and specificity of the VFPS to detect elevated PCWP underscores the clinical value of this tool in optimizing left ventricular unloading and potentially preventing HF readmissions.

Currently, we recommend measuring VFPS during LVAD clinic visits. The high sensitivity can reassure the clinician that the presence of a low VFPS may not require further intervention. When the VFPS is high, it can aid in the decision of any interventions, especially if other factors suggest the presence of clinical congestion. Of note, not all

patients can achieve hemodynamic optimization by device speed adjustment alone. As shown in prior studies,^{12,16} adjustment of medical therapies considering VFPS should also be considered to achieve hemodynamic optimization and successful VFPS-guided management. Furthermore, any other LVAD-related comorbidity that increases PCWP might be detected in the setting of elevated VFPS.

Recently, Doppler echocardiographic measurements were proposed to estimate left atrial pressure.¹⁷ Although the accuracy of echocardiographic measurements might be comparable to VFPS assessment, we believe there are several advantages of VFPS worth considering. VFPS can be measured using free software within a couple of minutes without the need for expert review, whereas considerable time, expertise, and skill are needed to accurately obtain echocardiographic Doppler measurements in patients with LVAD. Furthermore, if the HVAD device is updated in the future to automatically measure VFPS, it can be measured remotely and therefore be of use in routine clinical care.

Limitations

This is a single-center study with moderate size. Although the patient cohort in this validation study differed from the previous derivation cohort, both studies were conducted in the same institute. Application of VFPS should be validated in a multicenter setting. We performed generalized estimating equation analyses to account for the data derived from the same patients, but we cannot completely exclude selection bias. Longitudinal evaluations of VFPS over time were not reported. Data regarding changes in PCWP and VFPS from alterations in loading conditions other than LVAD speed changes, including fluid loading, diuretic use, and exercise were also not reported.¹⁸

We assumed arterial pressure to be constant during diastole, but this may not be true in all cases. We enrolled only HVAD patients, but this concept may be expanded to other devices if accurate waveform data are made available. We did not measure the VFPS with the Lavare cycle turned on in any of our patients, and cannot comment on its performance during Lavare cycle operation. Our findings were applicable in patients with atrial fibrillation, which was consistent with another previous study demonstrated by Lai et al.¹⁹

A relatively wide scatter of measured PCWPs was observed at lower estimated PCWP. Agreements between the estimated and measured PCWP was relatively less at lower PCWP measurements, making the regression equation less suitable to detect hypovolemia accurately. This may be better ascertained from other HVAD waveform features including low flow alarms and low pulsatility.⁸ Nevertheless, we believe that the utility of this model is still useful because the equation is intended to detect congestive heart failure instead of hypovolemia.

Conclusion

VFPS of the HVAD flow waveform is a novel noninvasive parameter that can estimate PCWP and may aid in the clinical management of HVAD patients.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Fig. 1.
Distribution of VFPS.

Fig. 2.

(**A**) Receiver operating characteristics curve for VFPS ≥ 5.8 L/min/s and (**B**) stratification of PCWP by using the cutoff of VFPS: 5.8 L/min/s. The red circle indicates the cutoff of VFPS: 5.8 L/min/s. * $P < .05$ by Mann Whitney U test. $^\dagger P < .05$ by generalized estimating equation analysis.

Fig. 3.
(A) Correlation plot PCWP and **(B)** Bland – Altman analysis of agreement between estimated and measured PCWP. $*P < .05$ by Pearson's correlation coefficient. $^\dagger P < .05$ by generalized estimating equation analysis. SEE, standard error of the estimate; CI, confidence interval.

Fig. 4. HF readmission rates stratified by VFPS ≤ 5.8 L/min/s. IRR, incidence rate ratio. $*P < .05$ by negative binomial regression analyses.

Table 1.**Baseline Characteristics**

Patients Demographics (N = 27)	
Age, y	53 ± 17
Male gender	15 (56%)
Race	
White	14 (52%)
Black	12 (44%)
Asian	1 (4%)
Body surface area, m ²	1.88 ± 0.23
Ischemic etiology	8 (30%)
Destination therapy	15 (56%)
Prior LVAD duration, mo	5 (2, 15)
Diabetes mellitus	6 (22%)
History of stroke	3 (11%)
Atrial fibrillation	10 (37%)
History of ventricular tachyarrhythmia	4 (15%)
Device parameters and hemodynamics (N = 131)	
Device speed, rpm	2594 ± 276
Estimated device flow, L/min	4.0 ± 1.1
Device power, Watt	3.7 ± 1.1
Left ventricular diastolic diameter, cm	5.5 ± 0.7
Aortic valve opening	50 (38%)
Mild or greater aortic insufficiency	18 (14%)
Mitral regurgitation	
None or trace	116 (88%)
Mild	15 (12%)
Heart rate, bpm	87 ± 7
Central venous pressure, mmHg	7.6 ± 3.8
Mean pulmonary artery pressure, mmHg	24.1 ± 7.2
Pulmonary capillary wedge pressure, mmHg	13.0 ± 5.2
Cardiac index, L/min/m ²	2.65 ± 0.41
Mean arterial pressure, mmHg	91.2 ± 11.1
Pulmonary artery pulsatility index	2.79 ± 1.70