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ORIGINAL RESEARCH ARTICLE

Accuracy of Doppler blood pressure measurement in HeartMate 3 ventricular assist device patients

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Abstract

Aims Optimal blood pressure (BP) control is imperative to reduce complications, especially strokes, in continuous flow ventricular assist device (VAD) patients. Doppler BP has been shown to be an accurate and reliable non-invasive BP measurement method in HeartMate II and HVAD patients. We examined whether Doppler BP is also accurate in patients with the HeartMate 3 VAD.

Methods and results In a prospective, longitudinal cohort of HeartMate 3 patients, arterial line BP and simultaneously measured Doppler opening pressure were obtained. Correlation and agreement between Doppler opening pressure and arterial line mean arterial pressure (MAP) versus systolic blood pressure (SBP) were analysed, as well as the effect of pulse pressure on the accuracy of Doppler opening pressure.

A total of 589 pairs of simultaneous Doppler opening pressure and arterial line pressure readings were obtained in 43 patients. Doppler opening pressure had good correlation with intra-arterial MAP (r = 0.754) and more closely approximated MAP than SBP (mean error 2.0 vs. −8.6 mmHg). Pulse pressure did not have a clinically significant impact on the accuracy of the Doppler BP method. These results in HeartMate 3 patients are very similar to previous results in HeartMate II and HVAD patients.

Conclusions Doppler BP method should be the default non-invasive BP measurement method in continuous flow VAD patients including patients implanted with the HeartMate 3.

Keywords Heart failure; Ventricular assist device; Blood pressure

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Introduction

Heart failure (HF) is a prevalent medical condition worldwide with significant mortality and morbidity.[1] Among HF patients, an estimated 150 000 to 200 000 have end-stage HF refractory to medical therapy and would benefit from heart transplantation or mechanical circulatory support (MCS) to sustain life.[2] As heart transplantation remains limited by scarce donor availability, ventricular assist devices (VAD), a durable form of MCS, have been increasingly utilized as either bridge to transplant or destination therapy.[3] Currently, an estimated 2500 continuous flow VADs are implanted annually in North America.[4]

While VAD therapy significantly improves survival and quality of life in end-stage heart failure patients, it is associated with a relatively high burden of complications. Stroke, bleeding, and right ventricular failure remain some of the most serious complications.[4] Thus, reducing complications, via advances in VAD design, surgical technique, and medical management, has been an important focus of research. Studies have shown that blood pressure (BP) is associated with a number of adverse events in VAD patients, especially strokes.[5–7] The ENDURANCE Supplemental Trial highlighted the importance of BP control in VAD patients by showing that an intensive BP control strategy targeting a mean arterial pressure (MAP) of ≤85 mmHg significantly reduced stroke risk.[8] The current International Society for Heart and Lung Transplantation (ISHLT) guidelines for VAD patients also recommend BP control with a goal MAP <80 mmHg to reduce complication rates.[9]

One unique challenge of BP control in continuous flow VAD patients is the absence of a readily palpable peripheral arterial pulse due to a reduced pulse pressure. As a result, traditional non-invasive BP measurement methods such as auscultation of Korotkoff sounds and the automated oscillometric method cannot reliably obtain a BP reading, and their accuracy is further jeopardized by a decreased signal-to-noise ratio.[10,11] Arterial line BP measurement is the gold standard in VAD patients but is limited in practice due to its invasiveness. Doppler BP has been increasingly adopted as the preferred non-invasive BP measurement method in VAD patients. To obtain Doppler BP, a Doppler ultrasound probe is placed on the brachial artery, a standard BP cuff is inflated proximally on the ipsilateral arm, and the opening pressure is recorded when a flow signal is first detected as the cuff is deflated. Doppler BP can be obtained not only by clinicians but also by trained patients and caregivers at home. However, the accuracy of Doppler BP was previously untested, and it was not known whether the pressure when a flow signal is first detected by Doppler (opening pressure) is closer to systolic BP or MAP. To answer these questions, a previous large, prospective study examined the accuracy of Doppler BP in continuous flow VAD patients implanted with the HeartMate II and the HeartWare HVAD.[12] For these two devices, Doppler BP was very accurate when compared with arterial line MAP as the gold standard and maintained its accuracy over a wide range of pulse pressures.

The HeartMate 3 Left Ventricular Assist System (Abbott Laboratories) was first approved by the Food and Drug Administration in 2017 and, along with the HVAD, is one of the third-generation centrifugal devices. The HeartMate 3 has a pulsatility mode designed to reduce stasis in the impeller housing.[13] This is generated by rapid changes in rotor speed asynchronous to the cardiac cycle. In theory, this rapid increase in rotor speed could theoretically generate a brief high-pressure arterial wave that may inadvertently be detected by Doppler and potentially impact the accuracy of the Doppler BP method. To the best of our knowledge, no published study has examined Doppler BP's accuracy in HeartMate 3 patients. Therefore, in this study, we examined the accuracy of Doppler BP in HeartMate 3 in the context of the pulsatility mode. Specifically, we assessed (i) the correlation and accuracy of the Doppler opening pressure compared with intra-arterial pressure measured by arterial line as the gold standard; (ii) whether Doppler opening pressure more closely approximates MAP or systolic blood pressure (SBP); and (iii) whether the accuracy of Doppler BP is affected by arterial pulse pressure.

Methods

Sample

A longitudinal cohort of 43 patients who were implanted with a HeartMate 3 from July 2015 to December 2019 at the University of Washington Medical Center were studied. For consistency, this study was carried out, and data were analysed in a similar fashion to our previously published study on Doppler BP in HeartMate II and HVAD patients.[12] During the study period, non-invasive BP measurements in VAD patients were prospectively obtained by Doppler opening pressure per institutional protocol. When study patients had an arterial line placed for intra-arterial BP monitoring for any clinical indication, both arterial line pressures and Doppler opening pressure were taken and recorded. All study patients had an arterial line at some point after VAD implantation, whether immediately post implantation or during a subsequent hospitalization. All pairs of Doppler opening pressures and arterial line BPs that were measured on the same patient within 1 min of each other were included for analysis. Only BP measurements obtained during VAD support were included. Extreme outliers of Doppler opening pressure and arterial line BP (MAP <30 mmHg, MAP >150 mmHg, or arterial line pulse pressure <0 mmHg) were adjudicated as charting errors (<1% of sample) and excluded. The study conformed to the principles outlined in the Declaration of Helsinki and was approved by the University of Washington institutional review board.

Statistical analysis

To assess the overall correlation of Doppler opening pressure and arterial line MAP, we fitted a linear regression model to paired observations using generalized estimating equations with independent working covariance and robust standard errors (SE). This method is statistically more accurate than a simple linear regression model because the generalized estimating equations model accounts for the hierarchical nature of the observations grouped by patient.

To determine whether Doppler opening pressure more closely approximates arterial line MAP or SBP, we compared the mean differences between Doppler opening pressure and arterial line MAP and between Doppler opening pressure and arterial line SBP. In addition, to determine the effect of arterial pulse pressure on the accuracy of Doppler opening pressure, we calculated the mean error of Doppler opening pressure relative to MAP stratified by arterial line pulse pressure.

Results

Sample size

Our sample included 43 patients who underwent primary HeartMate 3 implantation (no device exchange). A total of 589 pairs of simultaneous Doppler and arterial line BP measurements within 1 min of each other were included for analysis. There was a median of nine paired measurements (Interquartile range [IQR] 5–22) per patient. Patient baseline characteristics are summarized in *Table 1*.

Correlation and accuracy of Doppler opening pressure

Doppler opening pressure had a highly statistically significant linear correlation with paired arterial line MAP (P-value <0.0001) (*Figure 1*). The regression equation was arterial line MAP = 28.31 (SE 4.18) + 0.58 (SE 0.06) * Doppler opening pressure. The correlation coefficient r was 0.754.

Paired Doppler opening pressures and arterial line MAPs had a mean difference (Doppler minus arterial line MAP) of 2.0 mmHg (SD 7.3 mmHg). Seventy-five per cent of the paired observations had a difference within ±5 mmHg and 86% were within ±10 mmHg (*Figure 2*).

Paired Doppler opening pressures and arterial line SBPs had a mean difference (Doppler minus arterial line SBP) of −8.6 mmHg (SD 8.4 mmHg). Thirty-five per cent of the paired observations had a difference within ±5 mmHg and 65% were within ±10 mmHg (*Figure 3*).

The correlation and accuracy of Doppler opening pressure compared with arterial MAP versus SBP are summarized in *Table 2*.

Effect of pulse pressure on the accuracy of Doppler opening pressure

The accuracy of Doppler opening pressure as compared with arterial MAP was assessed over different pulse pressure ranges (0–10, 11–20, 21–30, and >30 mmHg). The percentages of observations in the aforementioned pulse pressure ranges were 25%, 43%, 18%, and 13%, respectively. The error of Doppler opening pressure (Doppler minus arterial line MAP) showed a statistically significant increasing trend with increasing pulse pressure (*Figure 4*). For patients with minimal pulsatility (pulse pressure 0–20 mmHg), the mean error of Doppler opening pressure was <1 mmHg. The mean error remained <5 mmHg for pulse pressure up to 30 mmHg.

Table 1 Baseline characteristics

Characteristics	Patients (n = 43)
Age at VAD implantation (years)	52.4 ± 14.9
Gender (% female)	11.6
Race (% white)	83.7
Device	
HeartMate 3	43 (100%)
Arterial line MAP (mmHg)	69.8 ± 8.5 (n = 589)
Arterial line pulse pressure (mmHg)	15 [10, 24] (n = 589)
Doppler opening pressure (mmHg)	71.8 ± 11.1 (n = 589)

Values are mean ± SD, median [interquartile range], or %. MAP, mean arterial pressure.

Discussion

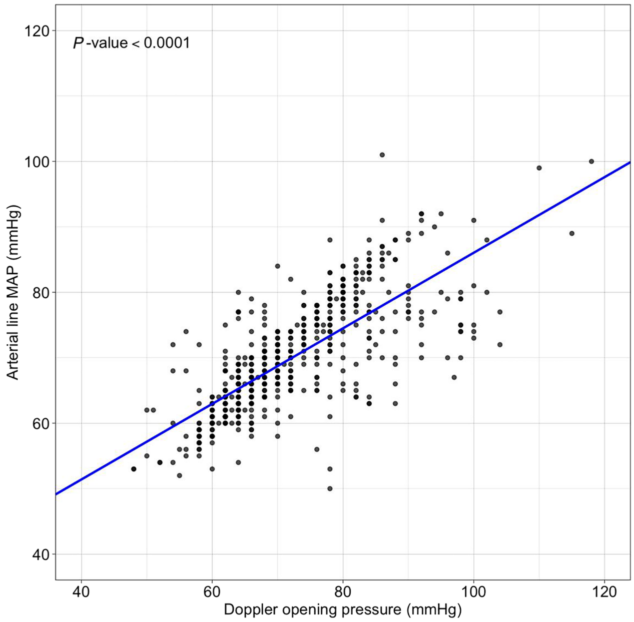
Significance

This study found that in most patients implanted with HeartMate 3, Doppler opening BP measured in a real-world clinical context is a highly accurate approximation of MAP. One previous study also showed that Doppler BP is much closer to MAP than SBP while another study showed the opposite.[10,14] The study that showed Doppler BP to be closer to SBP exclusively analysed BP measurements immediately after VAD implantation when patients were likely in intensive care with multiple vasoactive infusions, thus limiting the generalizability of its results. We also systemically analysed the effect of pulse pressure on the accuracy of Doppler BP method and showed that while the mean difference between Doppler BP and MAP was greater with a larger pulse pressure, it remained <5 mmHg for pulse pressures up to 30 mmHg, a range encompassing the vast majority of VAD patients in clinical practice.

Compared with a previous study in patients implanted with HeartMate II or the HVAD, Doppler BP method had similar accuracy in HeartMate 3 patients.[12] For HeartMate II and HVAD patients, Doppler BP versus arterial line MAP had a correlation coefficient of 0.741 and a mean error of 2.4 mmHg, as compared with 0.754 and 2.0 mmHg, respectively, for HeartMate 3 patients. Thus, it appears that the pulsatility mode of the HeartMate 3 does not affect the accuracy of Doppler BP measurements.

This study represents the largest prospective Doppler BP cohort to date in HeartMate 3 patients, consisting of 589 observations. The results further corroborate those of our previous Doppler BP study in HeartMate II and HVAD patients and strongly support the use of Doppler BP as the default non-invasive BP measurement method in all continuous flow VAD patients. Given that optimal BP control significantly reduces complication rates, especially strokes, in VAD patients, universal adoption of the Doppler BP method is key to further improving VAD outcomes. In addition to clinical practice, the results of this study could also inform future research study design, as a standardized BP monitoring protocol using the Doppler BP method should help eliminate inconsistencies in BP control among VAD trials and make results more comparable.

FIGURE 1 Overall correlation of Doppler opening pressure and arterial line MAP. Blue line represents the linear regression line.



Limitations

This study has a large sample size of 589 paired Doppler versus arterial line BP measurements. Nevertheless, it is a single centre study with its inherent limitations. However, we used a real-world cohort of patients at various time points after VAD implantation and admitted for various reasons so the results should be generalizable to most HeartMate 3 patients. While by design all patients had to have an arterial line to be included in this study, the findings are predicated on the physical properties of continuous flow and hydrostatic pressure, so there is little reason to assume that the accuracy of Doppler BP method would be less in ambulatory outpatients.

FIGURE 2 Distribution of differences between Doppler opening pressure and arterial line MAP. All pressure units are in mmHg.

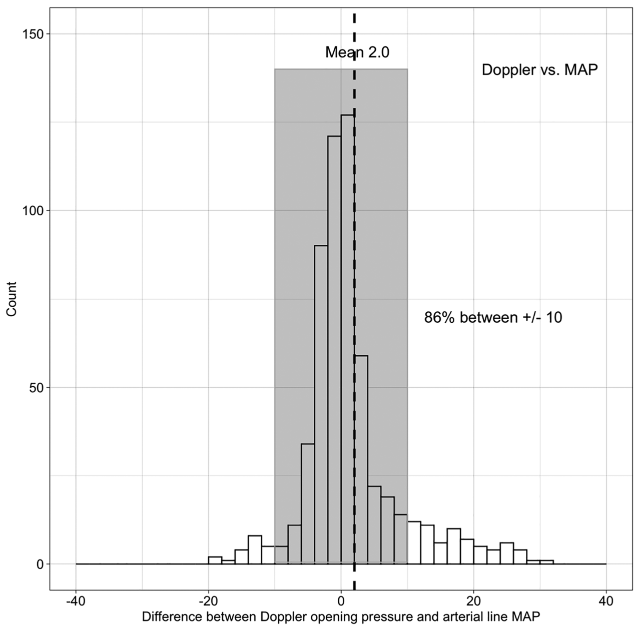


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FIGURE 3 Distribution of differences between Doppler opening pressure and arterial line SBP. All pressure units are in mmHg.

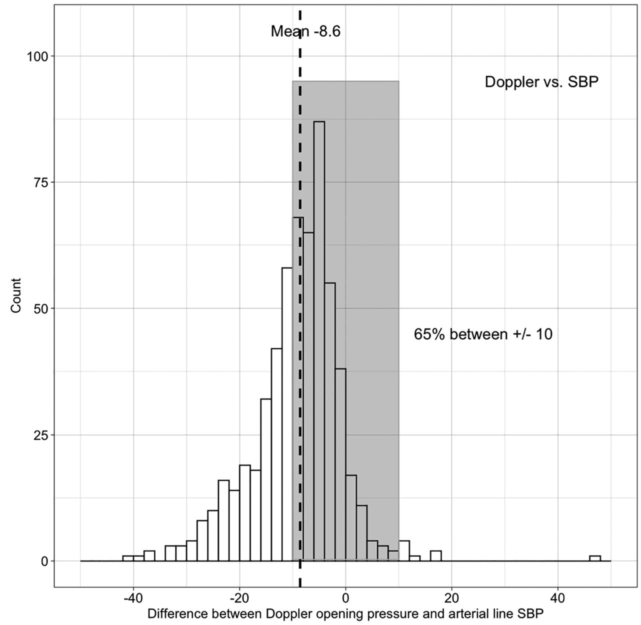
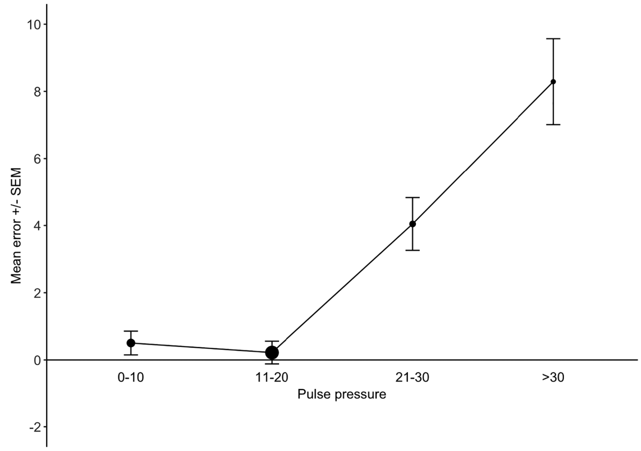


Table 2 Correlation and accuracy of Doppler opening pressure compared with arterial line MAP versus SBP

Comparison	*r*	Mean error	Median error	% within ±5	% within ±10
Doppler - arterial line MAP	0.754	2.0 [7.3]	1 [−2, 3]	75%	86%
Doppler - arterial line SBP	0.780	−8.6 [8.4]	−8 [−13, −4]	35%	65%

All pressure units are in mmHg. *r*, correlation coefficient. Interquartile ranges are reported with median errors, and standard deviations are reported with mean errors.

FIGURE 4 Relationship between mean error of Doppler opening pressure and pulse pressure. All pressure units are in mmHg. The size of the round marker is proportional to the percentage of observations in each pulse pressure range (left-to-right: 25%, 43%, 18%, and 13%).



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Conclusions

In most HeartMate 3 patients, Doppler opening pressure is a very accurate approximation of intra-arterial MAP and correlates much closer to arterial line MAP than SBP. Additionally, Doppler opening pressure has robust accuracy over a wide range of pulse pressures (0–30 mmHg). Despite the pulsatility mode of the HeartMate 3, Doppler BP has very similar accuracy in HeartMate 3 patients compared with HeartMate II and HVAD patients. Therefore, this study lends strong support for using Doppler opening pressure as the default non-invasive BP measurement method in continuous flow VAD patients.

Conflict of interest

C.M. has consulting relationships and is an investigator for Abbott, Medtronic, Abiomed, and Syncardia. J.A.B. has consulting relationships with Abiomed, Abbott, Medtronic, and Syncardia. W.L. is a consultant for Abbott and Medtronic. G. W. is a consultant for Abbott. T.D. has received grant funding from Medtronic. D.Z. is a consultant and investigator for Abbott and Medtronic. The other authors report no conflicts.

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