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Variability in Blood Pressure Assessment in Patients Supported with the HeartMate 3TM

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Variability in Blood Pressure Assessment in Patients Supported with the HeartMate 3™

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Targeted blood pressure (BP) control is a goal of left ventricular assist device medical management, but the interpretation of values obtained from noninvasive instruments is challenging. In the MOMENTUM 3 Continued Access Protocol, paired BP values in HeartMate 3 (HM3) patients were compared from arterial (A)-line and Doppler opening pressure (DOP) (319 readings in 261 patients) and A-line and automated cuff (281 readings in 247 patients). Pearson (R) correlations between A-line mean arterial (MAP) and systolic blood pressures (SBP) were compared with DOP and cuff measures according to the presence (>1 pulse in 5 seconds) or absence of a palpable radial pulse. There were only moderate correlations between A-line and noninvasive measurements of SBP (DOP R = 0.58; cuff R = 0.47) and MAP (DOP R = 0.48; cuff R = 0.37). DOP accuracy for MAP estimation, defined as the % of readings within ± 10 mmHg of A-line MAP, decreased from 80% to 33% for DOP ≤ 90 *vs.* >90 mmHg, and precision also diminished (mean absolute difference [MAD] increased from 6.3 ± 5.6 to 16.1 ± 11.4 mmHg). Across pulse pressures, cuff MAPs were within ±10 mmHg of A-line 62.9%–68.8% of measures and MADs were negligible. The presence of a palpable pulse reduced the accuracy and precision of the DOP-MAP estimation but did not impact cuff-MAP accuracy or precision. In summary, DOP may overestimate MAP in some patients on HM3 support. Simultaneous use of DOP and automated cuff and radial pulse may be needed to guide antihypertensive medication titration in outpatients on HM3 support. *ASAIO Journal* 2021; XX;00–00

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Introduction

An accurate and precise determination of blood pressure (BP) in patients on continuous-flow left ventricular assist device (cf-LVAD) support is important for reducing the risks of hypertension-associated complications. Elevated BP has been correlated with increased frequencies of cerebrovascular events and pump thrombosis and may contribute to progressive aortic insufficiency.[1–4] In addition, all continuous flow devices have some degree of afterload sensitivity such that device flows are reduced during the states of hypertension. There are recent Society of Thoracic Surgeons-Intermacs registry data showing that patients with evidence of chronic hypotension during cf-LVAD support have inferior survival and increased frequencies of serious complications.[4] Thus, close monitoring of BP in outpatients on cf-LVAD support is essential.

However, assessment of BP during cf-LVAD support is challenging. Most automated cuff technologies utilize oscillometric methods to measure BP. Oscillometric methods rely on measuring vibrations emitted from the assessed artery during cuff deflation. These vibrations are transmitted to a transducer within the cuff, and an electrical signal is generated which is then used to calculate the mean arterial pressure (MAP), from which the systolic blood pressure (SBP) and diastolic blood pressure (DBP) are then derived through mathematical formulas.[5] Due to reduced peripheral pulsatility, automatic cuff technologies often fail to register

a reading in patients who have narrow arterial pulse pressures during cf-LVAD support. Even in cf-LVAD patients who have recorded automated cuff BP values, the accuracy and precision of these measures can markedly vary.[6] Thus, many centers utilize Doppler opening pressure (DOP) to measure the SBP, extrapolating this value to represent the MAP during cf-LVAD support. However, the assumption that the DOP closely approximates MAP may not be correct in all patients on cf-LVAD support, especially those with wider arterial pulse pressures.[4] Furthermore, it is unclear if intermittent pulsatility algorithms in cf-LVAD patients, which induce vascular vibration, limit the precision of SBP measured by either the DOP or automated cuff.[6]

The Heartmate 3 (HM3, Abbott Inc, Abbott Parkway, Illinois) is a centrifugal flow cf-LVAD with full magnetic levitation that also employs a pulsatility algorithm during which the pump speeds up and speeds down every 2 seconds by ± 2000 RPMs. The magnetic levitation of the HM3 rotor with centrifugal flow also imparts unique flow responses to preload and afterload (expressed through the pressure-head curve) which may contribute to increased pulse pressure noted in many HM3 patients.[7] The impact of the novel HM3 speed modulation and rotor magnetic levitation on aortic pulse pressure magnitude is highly variable between patients. Given this variability, the optimal modality for measuring BP in patients on the HM3 device remains to be determined. The aims of this analysis were to determine the accuracy and precision of BP assessed using DOP and automatic cuff in patients on HM3 support, using the arterial line measure as the gold standard. We also wanted to determine if pulse pressure or presence of a radial pulse impacts the accuracy and precision of the individual noninvasive BP measurements.

Materials and Methods

The study cohort for this BP analysis was derived from patients undergoing HM3 implant as part of the Multicenter Study of MagLev Technology in Patients Undergoing Mechanical Circulatory Support Therapy with HM3 (MOMENTUM 3) Continued Access Protocol (CAP) (NCT02892955). Patient enrollment occurred between August 2016 and October 2018. Inclusion/exclusion criteria were similar to the MOMENTUM 3 pivotal trial and have been previously published.[8–10]

BPs were recorded in the MOMENTUM 3 study at postoperative days 1 and 7. Per study protocol, sites were required to provide one BP measurement using any modality but had the option of providing more than one measurement using the same or different BP assessment methods. Modalities for BP measurement could include arterial line (A-line), automated cuff, and/or DOP. Fifty-one sites contributed BP data for this analysis. Providers could use the automated BP cuff and Doppler manufacturers and models of their choice. Providers also had the option of documenting if a palpable radial pulse (defined as 1 pulsation felt in 5 seconds or less) was present at the time of BP measurement. Postoperative echocardiograms obtained within the first 7 days were examined for aortic valve opening. Valves were classified as opening each beat, intermittently opening (open less than every cardiac cycle), or closed throughout the duration of testing.

For this post-hoc analysis, all patients were required to have at least one A-line measurement and at least one simultaneous noninvasive BP measurement (cuff or DOP) during days 1–7 postoperative. Values obtained using the same modality were averaged. When MAP was not provided, the patient's MAP was calculated from the automated cuff and/or A-line SBP and DBP according to the formula: (SBP + 2*DBP)/3. Patients were then grouped according to the type of noninvasive measurement used (cuff and/or DOP) to asses BP. Using the A-line measurement for reference, comparisons were made between A-line BP *versus* cuff BP (cuff group), A-line BP *versus* DOP (DOP group), and/or A-line BP *versus* DOP *versus* cuff BP (DOP + cuff group).

Statistical Analyses

Continuous data were analyzed for normality and are presented as mean ± standard deviation or medians (quartile 1 and quartile 3) as appropriate. Comparisons of continuous data were made using a two-sided *t*-test as appropriate. Categorical data are presented as frequencies (count/total) and comparisons of categorical data were made using the Fisher's exact test as appropriate. The strength of the linear relationship between the noninvasive and A-line pressures was assessed using Pearson correlation coefficient. The Pearson correlation (R) coefficient is a number between −1.0 and +1.0 that describes how the A-line and noninvasive BP measurement are linearly correlated (R = 1 or −1.0 implies perfect correlation and R = 0.0 implies poor linear correlation), with directionality expressed by a positive or negative sign. However, R can be close to 1 even when there is considerable bias in a method (for example, if one method gives a measurement that is always 10 mmHg higher than the another, then R = 1 even if the value is 10 mmHg off) and R is sensitive to outliers, especially when sample sizes are small.[11] Thus, the accuracy of the noninvasive measures was assessed by calculating the percent of noninvasive values within ±10 mmHg of the A-line reference by calculating the mean difference between noninvasive and A-line measurements. The mean difference assesses on average the degree to which a noninvasive measure may over- or underestimate the A-line value. Precision was assessed by examining mean absolute differences (MAD), calculated as the average of the absolute differences between the A-line and noninvasive measures.

The impact of patient arterial pulse pressure on noninvasive cuff accuracy was also assessed. The pulse pressure (PP) was calculated (PP = SBP − DBP) for each A-line reading, and paired noninvasive measures were then grouped into one of four PP categories (≤10 mmHg, >10 and ≤20 mmHg, >20 and ≤30 mmHg, and >30 mmHg). The mean differences and MADs of the noninvasive BP measures from paired A-line measures were calculated for each pulse-pressure group. Then, the frequency of noninvasive measures within ±10 mmHg of A-line was tallied. Patients were subsequently grouped by the presence or absence of a pulse and the same calculations were undertaken. Finally, the frequency of aortic valve opening on echocardiography *versus* the presence or absence of a palpable radial pulse was also evaluated.

All patients were required to have BP measures from at least two of the three BP modalities. A sensitivity analysis was conducted, inclusive of only those patients that had triplicate BP data (*i.e.* simultaneous A-line, automated cuff, and DOP) to confirm findings.

All patients provided informed consent with local institutional review board approval as part of the MOMENTUM 3 clinical trial.

Results

Baseline Demographics and Blood Pressure Measurements

Of 1685 eligible patients on HM3 support, 362 (21.5%) patients had paired BP measures. Within this cohort, 261 patients had 319 simultaneous A-line and DOP measurements (DOP group), 247 had 281 simultaneous A-line and automatic cuff pressures (cuff group), and 138 patients had 162 simultaneous BP measures from all three modalities (DOP + cuff group) (Figure 1). The characteristics and demographics of patients comprising each BP group are shown in Table 1. Patients could be part of more than one group. The mean time from HM3 implant to paired BP measure was 2.9 ± 2.8 days. At the time of BP measure, ≥90% of patients were on inotropes and 15.7%–17.8% of patients in each group were on vasopressors. Overall, the use of oral β-blocker, spironolactone, and angiotensin-converting enzyme inhibitor and/or angiotensin receptor blocker was infrequent in this early postoperative cohort.

The mean SBP, DBP, and MAP according to noninvasive BP measurement grouping are presented in Table 1 with BP modality comparisons in Table 2. The reference arterial line SBP and MAP measurements were similar across all groups. In the cuff and DOP + cuff groups, the mean cuff SBP was significantly higher than A-line SBP (cuff: $p < 0.001$ and DOP + cuff: $p < 0.001$). In the DOP group, the mean DOP was significantly lower than A-line SBP ($p < 0.001$) and significantly higher than A-line MAP ($p < 0.001$). Similar findings were noted when DOPs were compared with A-line in the DOP + cuff group (SBP and MAP: $p < 0.001$). A palpable radial pulse was noted in 46.7–52.8% of patients but was most common in the cuff group (52.8%).

Correlation Between Arterial Line Blood Pressure and Noninvasive Measures

Figure 2 displays the scatter plots with associated Pearson correlation coefficient for DOP and automatic cuff compared with the A-line reference measures. For all the modality comparisons, there was a positive correlation between the noninvasive measurement and the A-line reference measure. However, correlations were only modest (R = 0.37–0.58) and scatter was notable, especially when DOP, cuff SBP, and MAP values were >90–100 mmHg.

Doppler assessment of Arterial Line Systolic Versus Mean Arterial Pressure

Estimates of accuracy and precision for DOP in assessing BP in patients on HM3 support are shown in Table 2. In this cohort, DOP values were most accurately reflective of patient MAP. When compared with A-line, 61.8% of DOP values were within ±10 mmHg of the A-line SBP, whereas 72.1% of DOP values were within ±10 mmHg of the A-line MAP. On average, the DOP was 7.9 ± 10.9 mmHg lower than corresponding A-line SBP and 4.0 ± 10.3 mmHg higher than corresponding A-line MAP.

While the correlation was highest between A-line SBP and DOP, mean absolute differences were large in magnitude, suggesting low overall precision of DOP for assessing A-line SBP

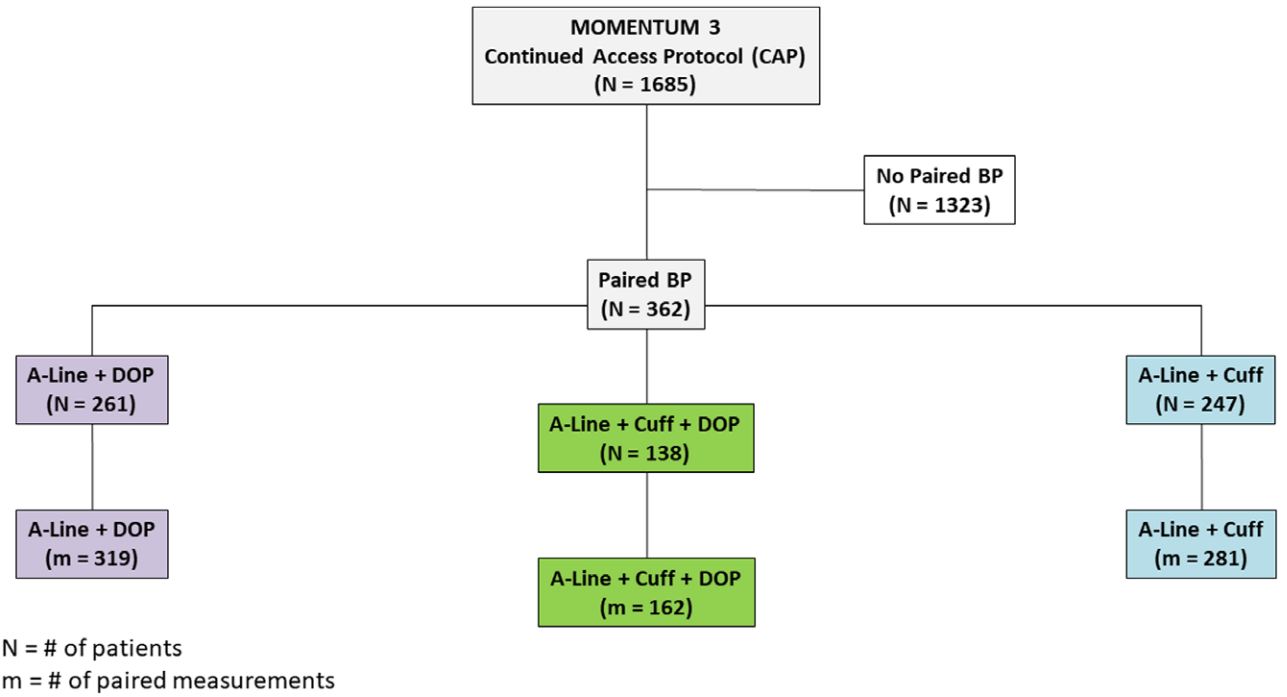

Figure 1. Grouping of patients according to method of non-invasive blood pressure assessment. Arterial line (A-line) blood pressures (BP) were paired with corresponding non-invasive BP measures and paired data were placed into one of three groups: A-line plus Doppler opening pressure (DOP, purple); A-line plus automated cuff (cuff, blue); or A-line with Cuff and DOP (green). N, number of patients; m, number of paired measurements.

Table 1. Preoperative Characteristics According to Paired HeartMate 3 Blood Pressure Grouping and Average Postoperative (Days 1–7) Blood Pressures. Reference for Pairing with Automated Cuff Was Arterial Line Measure.

	DOP Group	Cuff Group	DOP + Cuff Group
	261 Patients	247 Patients	138 Patients
Age, years	61.2 ± 11.3	60.7 ± 12.6	62.2 ± 11.4
Male, % (n/N)	79.7% (208/261)	78.5% (194/247)	79.0% (109/138)
Intermacs profile, %, (n/N)			
Profiles 1–2	35.2% (92/261)	29.9% (73/244)	23.2% (32/138)
Profile 3	54.4% (142/261)	59.4% (145/244)	64.5% (89/138)
Profiles 4–7	10.3% (27/261)	10.7% (26/244)	12.3% (17/138)
Ischemic cardiomyopathy, %, (n/N)	47.9% (125/261)	47.8% (118/247)	52.2% (72/138)
History of hypertension, %, (n/N)	72.8% (190/261)	74.1% (183/247)	70.3% (97/138)
Number of paired BP measures (m)	319	281	162
Days after HM3 implant	3.2 ± 2.8	2.8 ± 2.7	3.3 ± 2.8
Arterial line measurements			
SBP, mmHg	88.8 ± 12.5	89.5 ± 13.3	89.7 ± 12.4
DBP, mmHg	68.3 ± 9.2	67.9 ± 9.5	69.6 ± 9.2
Mean arterial BP, mmHg	76.9 ± 8.6	76.5 ± 8.8	77.7 ± 8.9
Pulse pressure, mmHg	20.6 ± 10.9	21.6 ± 13.2	20.1 ± 10.4
Doppler opening pressure, mmHg	80.9 ± 11.2	NA	83.0 ± 12.3
Non-invasive cuff			
SBP, mmHg	NA	96.2 ± 15.5	94.5 ± 12.9
DBP, mmHg	NA	68.0 ± 11.6	68.1 ± 11.5
Mean arterial BP,mmHg	NA	77.4 ± 11.8	76.6 ± 10.9
Palpable radial pulse, % (m/M)*	48.7% (110/226)	52.8% (86/163)	46.7% (57/122)
Vasoactive medication, % (m/M)			
Inotrope	93.1% (297/319)	92.2% (259/281)	92.0% (149/162)
Vasopressors	15.7% (50/319)	17.8% (50/281)	17.3% (28/162)
Oral medications, % (m/M)			
B-blocker	15.7% (50/319)	14.2% (40/281)	17.9% (29/162) 4.3%
ACEi	4.1% (13/319)	2.8% (8/281)	(7/162)
ARB	0.9% (3/319)	1.4% (4/281)	1.9% (3/162)
Spironolactone	6.0% (19/319)	5.0% (14/281)	8.0% (13/162)
Other vasodilator†	39.5% (126/319)	32.7% (92/281)	32.7% (53/162)
Respiratory failure, % (m/M)‡	6.9% (22/319)	6.4% (18/281)	6.8% (11/162)
RVAD, % (m/M)	2.2% (7/319)	1.8% (5/281)	1.9% (3/162)

Data are shown according to paired blood pressure measurement group. Continuous variables shown as mean ± standard deviation. Categorical variables shown as a percent (counts/total). Patients can contribute data to one group or all groups.

*Palpable radial pulse defined as the presence of ≥ 1 palpated radial pulse in 5 seconds.

†Includes calcium channel blockers, hydralazine, nitrates, clonidine, and α_1 antagonists.

‡Impairment of respiratory function requiring reintubation, tracheostomy or (the inability to discontinue ventilatory support within six days (144 hours) post-VAD implant. This excludes intubation for reoperation or temporary intubation for diagnostic or therapeutic procedures.

A-line, arterial line; ACEi, angiotensin enzyme inhibitor; ARB, angiotensin receptor blocker; BP, blood pressure;DBP, diastolic blood pressure; DOP, doppler; HM3, HeartMate 3; Intermacs (Interagency Registry of Mechanically Assisted Circulatory Support); m, number of measurements; mmHg, millimeters of mercury; n, number of patients; SBP, systolic blood pressure; RVAD, right ventricular assist device.

(Table 2). On inspection of the scatter plots, HM3 patients with a DOP >90 mmHg displayed greater visual scatter from the line of unity with A-line measures, leading to dichotomization of patients at 90 mmHg (Table 2). DOP magnitude had little impact on its accuracy for estimating A-line SBP but a marked impact on its accuracy for estimating A-line MAP. When the DOP was ≤90 mmHg, 61.8% of values were within ±10 mmHg of the A-line SBP compared with 61.5% of values when DOP was >90 mmHg. However, when DOP was ≤90 mmHg *vs.* >90 mmHg, 79.9% *vs.* 32.7% of values were within ±10 mmHg of A-line MAP. In addition, the precision of DOP's estimation of MAP was reduced at high arterial pressures. Although the MADs between DOP and A-line SBP were similar in those with a DOP ≤90 mmHg (10.1 ± 9.0) *vs.* >90 mmHg (9.8 ± 8.9, $p > 0.05$), the MAD from A-line MAP increased from 6.3 ± 5.6 for DOP ≤90 mmHg to 16.1 ± 11.4 mmHg for DOP >90 mmHg. This suggests that DOP is overall less accurate and less precise at estimating arterial MAP at higher arterial pressures, and DOP is more representative of SBP than MAP when values are >90 mmHg in patients on HM3 support.

Impact of Arterial Pulse Pressure on Doppler Opening Pressure Accuracy and Precision during HM3 Support

A representative example of an HM3 patient with *versus* without a widened pulse pressure on A-line is shown in Figure, Supplemental Digital Content 1, *http://links.lww.com/ASAIO/A667*. The impact of arterial pulse pressure on DOP accuracy is shown in Figure 3. When the arterial pulse pressure was ≤10 mmHg, 76.5% of DOP measurements were within ±10 mmHg of A-line SBP and 79.4% of DOP measurements were within ±10 mmHg of A-line MAP. However, when the pulse pressure increased to 20–30 mmHg, only 53.9% and 69.7% of DOP were within ±10 mmHg of A-line SBP and MAP, respectively (Figure 3A). As arterial pulse pressure increased, DOP underestimated A-line SBP (blue line, Figure 3C) and overestimated A-line MAP (orange line, Figure 3C). DOP precision also worsened with increasing arterial pulse pressure (Figure 3E). As pulse pressure increased, the MAD between DOP and A-line SBP and DOP and A-line MAP increased.

Table 2. Assessment of Precision and Accuracy of Each Average Non-Invasive Blood Pressure Measurement *Vs.* Reference Average Arterial Line Measurement.

	A-line SBP *vs*.			A-line MAP *vs*.		
Non-Invasive measurement	Doppler	Cuff SBP	*p*-value	Doppler	Cuff MAP	*p*-value
Number of paired measures	319	281	–	319	281	–
Correlation coefficient, R	0.58	0.47	–	0.48	0.37	–
Accuracy assessment						
% within ±10 mm Hg of A-line (m)	61.8% (197/319)	62.3% (175/281)	0.93	72.1% (230/319)	65.5% (184/281)	0.09
DOP ≤90	61.8% (165/267)	45.7% (80/175)	–	79.8% (213/267)	91.3% (168/184)	–
DOP >90	61.5% (32/52)	54.3% (95/175)	–	32.7% (17/52)	8.7% (16/184)	–
Mean difference ± SD	−7.9 ± 10.9	6.7 ± 14.9	<0.001	4.0 ± 10.3	0.8 ± 11.8	0.001
(median [25th, 75th])	(−6.7 [−13.7, −2.0])	(5.0 [−1.7, 12.0])		(3.0 [−2.0, 9.0])	(0.3 [−5.0, 7.0])	
Precision assessment						
MAD ± SD	10.1 ± 9.0	11.3 ± 11.8	0.15	7.9 ± 7.7	8.8 ± 7.9	0.16
(median [25th, 75th])	(7.3 [3.3, 14.0])	(7.8 [4.0, 14.0])		(6.0 [2.3, 11.0])	(6.3 [3.0, 12.5])	
DOP ≤90	10.1 ± 9.0 (267)	8.8 ± 8.1 (124)	0.16	6.3 ± 5.6 (267)	8.0 ± 7.0 (124)	0.019
DOP >90	9.8 ± 8.9 (52)	11.5 ± 11.8 (38)	0.45	16.1 ± 11.4 (52)	7.3 ± 8.9 (38)	<0.001

Continuous variables shown as mean ± standard deviation or median [25th, 75th] and compared by two-sided *t*-test. Categorical variables shown as a percent (counts/total) and compared by Fisher Exact test. Mean difference and mean absolute difference are from paired A-line values.
A-line, arterial line; DOP, doppler; m, number of measurements; MAD, mean absolute difference; MAP, mean arterial pressure; SBP, systolic blood pressure.

Taken together, these findings suggest that the accuracy and precision of DOP in estimating A-line SBP and MAP are minimally influenced by pulse pressure magnitudes up to 20 mmHg. However, in those with arterial pulse pressures >20 mmHg, the accuracy and precision of DOP in estimating both SBP and MAP is reduced.

Automated Cuff Assessment of Arterial Line Systolic Versus Mean Arterial Pressure

Estimates of accuracy and precision for automated cuff in assessing SBP and MAP in patients on HM3 support are summarized in Table 2. The accuracy of automated cuff for

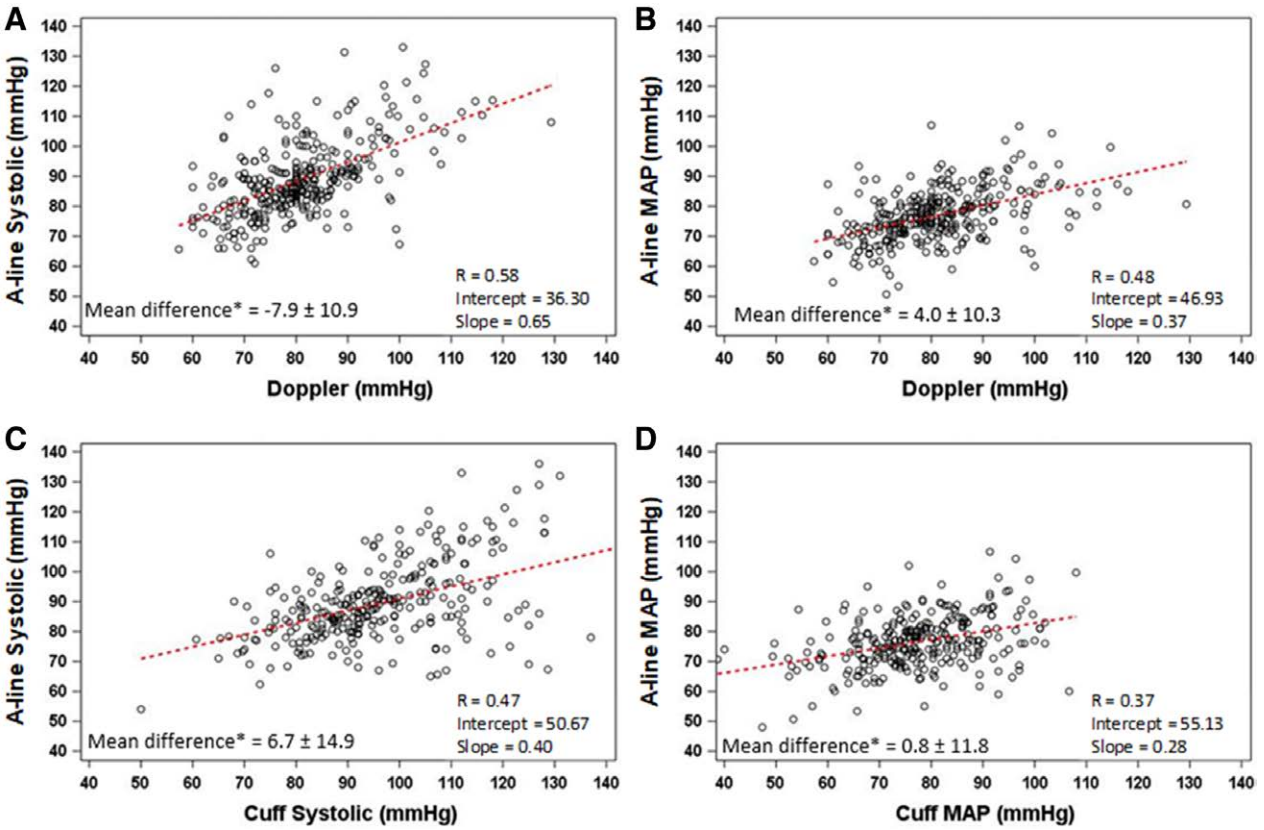

Figure 2. Scatter plots demonstrating correlation and scatter of non-invasive blood pressure measurement *vs*. reference arterial line measure. (A) Doppler *vs*. A-line systolic blood pressure (SBP); (B) Doppler *vs*. A-line mean arterial pressure (MAP); (C) Cuff SBP *vs* A-line SBP; (D) cuff MAP *vs*. A-line MAP; *Mean difference = non-invasive measurement minus A-line measurement.

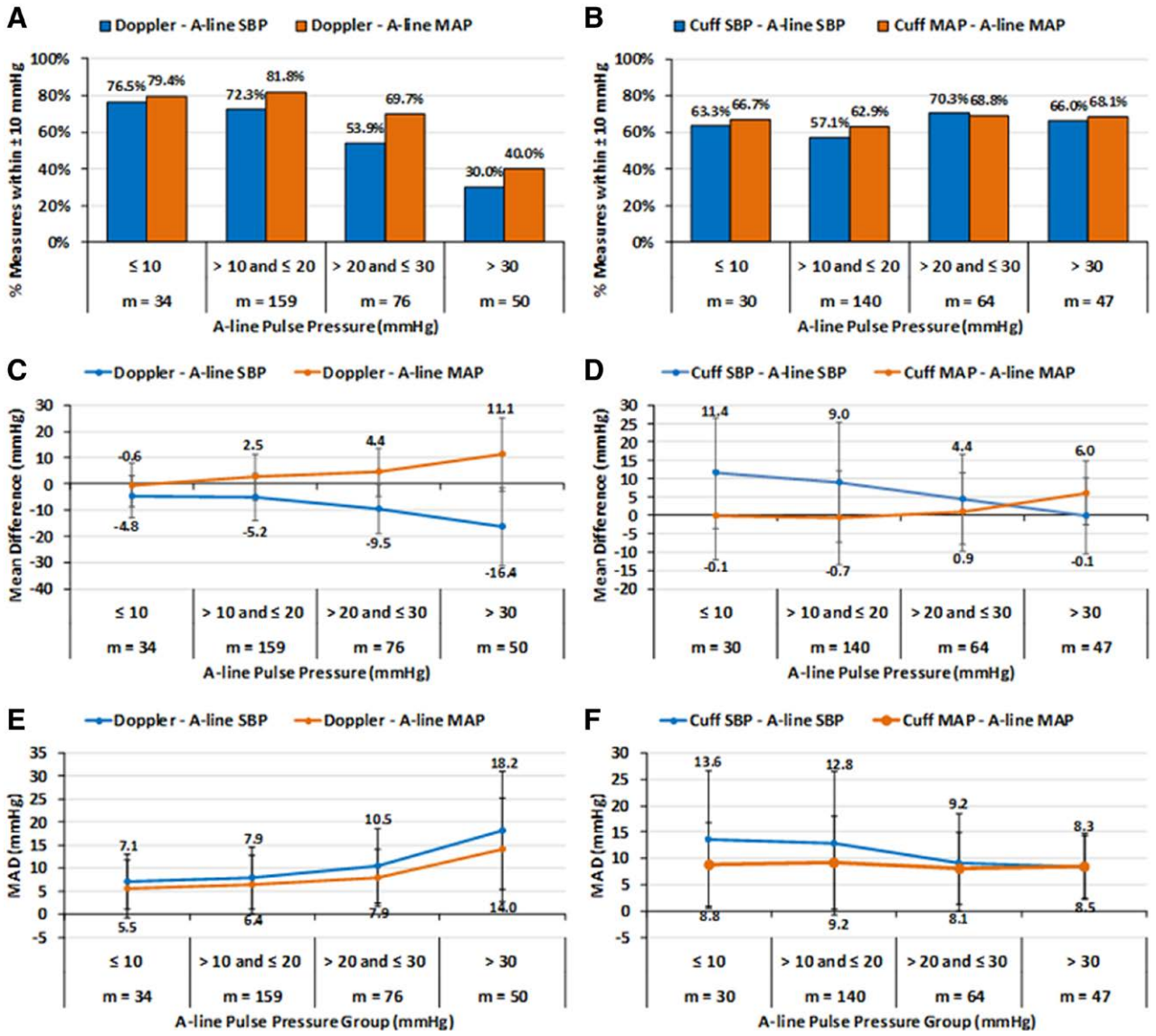

Figure 3. Effect of arterial pulse pressure on non-invasive blood pressure assessment. (A) Frequency of Doppler (DOP) measures within ±10 mmHg of arterial line (A-line) reference measurement. (B) The mean difference between A-line systolic (SBP; orange) or mean arterial (MAP; blue) pressure and DOP. (C) Frequency of cuff measures within ±10 mmHg of A-line reference measurement. (D) The mean difference between A-line SBP or MAP and corresponding cuff measures. (E) The mean absolute difference (MAD) between A-line SBP or MAP and DOP. (F) The mean absolute difference between A-line SBP or MAP and corresponding cuff measurements. Mean difference and mean absolute difference are from paired A-line values. Mean Difference, non-invasive measurement minus A-line measurement. Mean Absolute Difference, non-invasive measure minus A-line measure using absolute values.

assessing SBP and MAP was similar with 62.3% of automated cuff SBPs within ±10 mmHg of the A-line SBP and 65.5% of automated cuff MAPs within ±10 mmHg of the A-line MAP (Table 2). On average, the automated cuff SBP was 6.7 ± 14.9 mmHg higher than A-line SBP and the automated cuff MAP was 0.8 ± 11.8 mmHg higher than A-line MAP. On average, automated cuff precision was better (lower MAD) for estimating A-line MAP than A-line SBP.

The impact of A-line pulse pressure on automated cuff accuracy is shown in Figure 3B and D and precision in Figure 3F. In contrast to DOP, higher arterial pulse pressure lead to increased automated cuff SBP accuracy and precision. When pulse pressures were 20–30 mmHg, 70.3% of cuff SBPs were within ±10 mmHg of A-line SBP compared with 63.3% of cuff SBP measures when pulse pressure was ≤10 mmHg (Figure 3B). At a pulse pressure of 20–30 mmHg, the automated cuff SBP was an average 4.4 mmHg higher than A-line SBP and the MAD was 9.2 mmHg. However, when pulse pressures were ≤10 mmHg, cuff SBPs were an average +11.4 mmHg higher than A-line SBP values (Figure 3D) and MADs were highest (Figure 3F). For MAP estimation, patient pulse pressure had minimal impact on cuff accuracy (Figure 3B,D) or precision (Figure 3F). The cuff MAP was within ±10 mmHg of the A-line MAP 62.9%–68.8% of the time, and mean differences (Figure 3D) and MADs (Figure 3F) were clinically negligible at all pulse pressures.

Overall, these results suggest that BPs in patients with successful automated cuff measures are most valid for estimation

of HM3 patient MAP. The accuracy of automated cuff SBP measures is reduced when arterial pulse pressure is <20 mmHg, but cuff MAP accuracy and precision are largely maintained when cuff readings are successfully obtained.

Doppler Versus Automated Cuff Blood Pressure Assessment

Since MAP is used for BP management in patients on cf-LVAD support, we focused next on comparisons between DOP and cuff estimation of A-line MAP. Doppler opening pressure (72.1%) and automated cuff (65.5%) had similar frequencies of readings within ±10 mmHg of A-line ($p = 0.09$) (Table 2). However, mean differences from A-line MAP were significantly lower for automated cuff MAP (0.8 ± 11.8 mmHg) than DOP (4.0 ± 10.3) ($p = 0.001$). Patients with successful automatic cuff values maintained consistent accuracy (62.9–68.8% within ±10 mmHg A-line) and precision (Figure 3F) over a range of pulse pressures. In contrast, when DOP was >90 mmHg, the precision of DOP for MAP estimation was markedly reduced in comparison with cuff ($p < 0.001$, table 2). When DOPs were ≤ 90 mmHg, the precision of DOP was higher compared to cuff measures.

Correlations between a Palpable Pulse and Blood Pressure Measurements

A palpable pulse was present in 48.7% of those with DOP measures and 52.8% of those with cuff measures (Table 1). Although pulse pressure correlated with the presence of a palpable pulse, only 56.9% of patients with A-line pulse pressures of 21–29 mmHg had a palpable radial pulse (Figure 4).

Table 3 outlines the accuracy and precision of measures based on the presence or absence of a radial pulse. In patients without a palpable pulse, the MAP was most accurately assessed by DOP, with 80.2% of DOP within ±10 mmHg of A-line MAP *vs.* 63.6% by cuff ($p = 0.013$). The precision of DOP and cuff for assessing MAP was similar in those without a palpable pulse (MAD $p = 0.08$).

In those with a palpable pulse, the accuracy of the DOP for estimating A-line MAP was significantly reduced ($p = 0.004$ palpable *versus* nonpalpable). Rather, automated cuff was numerically more accurate in patients with a palpable pulse than DOP (69.8% *vs.* 62.7% of measures were within ±10 mmHg), but results were not statistically significant ($p = 0.36$). A palpable pulse improved the precision (reduced MAD) of the automated cuff but reduced the precision (increased MAD) of DOP (Table 3).

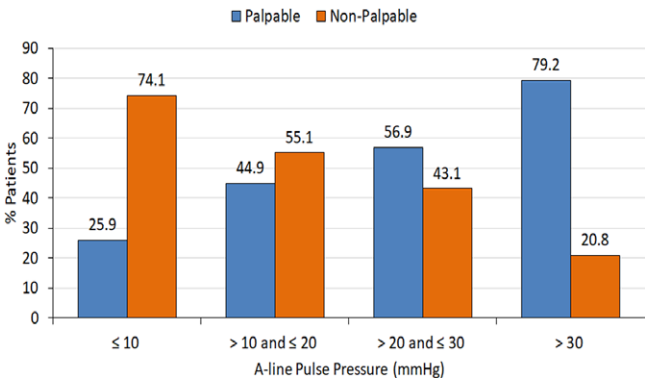

Figure 4. Pulse pressure and the ability to detect a palpable* radial pulse. *A palpable radial pulse is defined as ≥1 pulse in 5 seconds. Pulse pressures, systolic blood pressure – diastolic blood pressure.

Sensitivity Analysis

Correlations were assessed in the subgroup of patients with BP measurements obtained using all three modalities (138 patients with 162 paired readings) to confirm the findings above (Table, Supplemental Digital Content 1, *http://links.lww.com/ASAIO/A667*). Of the BP modalities examined, cuff MAP offered the highest accuracy (71.6% of values within ±10 mmHg of the A-line MAP) and again had the lowest mean differences from A-line measures. As BP increased to over 90 mmHg, the accuracy of DOP was again found to be reduced and the presence of a palpable radial pulse was again associated with reduced DOP precision for MAP estimation.

Aortic Valve Opening

A total of 172 echocardiograms were assessed in 230 patients to determine if aortic valve opening correlated with the presence (measures = 89) or absence (measures = 83) of a palpable pulse (Figure, Supplemental Digital Content 2, *http://links.lww.com/ASAIO/A667*) or pulse pressure (Figure, Supplemental Digital Content 3, *http://links.lww.com/ASAIO/A667*). Overall, the aortic valve opened each beat in 33.1% (57/172), was intermittent in 20.9% (36/172), and fully closed in 45.9% (79/172) of the echocardiograms. The aortic valve opened at least intermittently in 61.8% (55/89) of those with a palpable pulse. Of these, 65.5% (36/55) had aortic valve opening at every beat. In 38% of patients, a palpable radial pulse was felt with no evidence of aortic valve opening. In patients without a palpable radial pulse, aortic valve opening occurred at least intermittently in 45.8% (38/83). Of these, 55.3% (21/38) had regular opening of the valve. Although patients with higher arterial pulse pressures were more likely to have regular opening of the aortic valve on echocardiogram, the absence of aortic valve opening (or presence of opening) was not a reliable indicator of low pulse (or high) pressure. Thus, aortic valve opening cannot be used to infer DOP representation of MAP or SBP.

Discussion

BP management for patients supported with a cf-LVAD is important to help optimize pump flow and reduce hypertension-related complications such as stroke, pump thrombosis, renal dysfunction, aortic insufficiency, and heart failure.[1–4] The key findings of our analysis of HM3 patients enrolled into the MOMENTUM 3 CAP are as follows: (1) there is only a modest linear correlation between noninvasive and A-line assessments of SBP and MAP; (2) DOP approximates both A-line MAP and SBP when pulse pressure is <20 mmHg and overestimates A-line MAP when arterial pulse pressure is >20 mmHg; (3) automated cuff estimation of A-line MAP is accurate in those with successful measures, with little deviation across a range of pulse pressures; (4) roughly half of HM3 patients have a palpable pulse and its presence reduces the accuracy of DOP estimation of MAP by approximately 20%; and (5) the presence

Table 3. Impact of Radial Pulse on the Accuracy and Precision of Noninvasive Measures of Blood Pressure.

	A-line SBP *vs*.			A-line MAP *vs*.		
Noninvasive measurement	Doppler	Cuff SBP	*p*-value	Doppler	Cuff MAP	*p*-value
Accuracy: % measures within ± 10 mmHg of A-line based on palpable pulse						
Nonpalpable	64.7% (75/116)	63.6% (49/77)	1.00	80.2% (93/116)	63.6% (49/77)	0.013
Palpable	59.1% (65/110)	67.4% (58/86)	0.24	62.7% (69/110)	69.8% (60/86)	0.36
p-value (nonpalpable *vs* palpable by same device)	0.39	0.61	–	0.004	0.41	–
Accuracy: mean difference (noninvasive – A-line) based on palpable pulse						
Nonpalpable						
Mean ± SD (N)	–7.5 ± 9.4 (116)	5.4 ± 13.7 (77)	<0.001	2.1 ± 8.9 (116)	–2.3 ± 11.3 (77)	0.005
(Median [25th, 75th])	(–6.7 [–11.8, –2.0])	(4.3 [–1.7, 10.0])		(2.3 [–3.3, 7.0])	(–1.3 [–8.7, 4.0])	
Palpable						
Mean ± SD (N)	–7.7 ± 10.6 (110)	4.4 ± 10.7 (86)	<0.001	5.7 ± 11.0 (110)	1.7 ± 10.2 (86)	0.01
(Median [25th, 75th])	(–6.8 [–13.7, –2.0])	(4.0 [–2.7, 9.8])		(4.0 [–1.3, 12.0])	(1.5 [–4.0, 8.3])	
p-value (nonpalpable *vs* palpable by same device)	0.86	0.61	–	0.008	0.019	–
Precision: mean absolute difference (noninvasive – A-line) from paired A-line based on palpable pulse						
Nonpalpable						
Mean ± SD (N)	9.2 ± 7.7 (116)	10.4 ± 10.4 (77)	0.38	6.7 ± 6.2 (116)	8.5 ± 7.8 (77)	0.08
(Median [25th, 75th])	(7.0 [3.5, 12.8])	(7.3 [4.0, 12.7])		(5.0 [2.5, 8.2])	(5.5 [2.3, 13.0])	
Palpable						
Mean ± SD	10.2 ± 8.2 (110)	9.0 ± 7.1 (86)	0.28	9.1 ± 8.3 (110)	8.0 ± 6.6 (86)	0.29
(Median [25th, 75th])	(8.5 [3.3, 14.3])	(7.2 [4.0, 13.3])		(7.0 [2.3, 13.0])	(6.3 [3.0, 11.7])	
p-value (nonpalpable *vs* palpable by same device)	0.33	0.32	–	0.014	0.62	–

Continuous variables shown as mean ± standard deviation or median (25th, 75th) and compared by two-sided *t*-test. Categorical variables shown as a percent (counts/total) and compared by Fisher Exact test. Mean difference and mean absolute difference are from paired A-line values. Mean Difference, non-invasive measure minus A-line measure. Mean Absolute Difference, non-invasive measure minus A-line measure using absolute values.

A-line, arterial line; DOP, doppler; m, number of measurements; MAP, mean arterial pressure; SBP, systolic blood pressure; SD, standard deviation.

of a palpable pulse is not a reliable predictor of aortic valve opening and is not fully reliable for determining if DOP may be reflective of MAP *versus* SBP alone.

In the present analysis, DOP appeared to more closely approximate A-line MAP than A-line SBP, but pulse pressure had a marked influence on accuracy and precision of DOP. The novel engineering of the HM3 device by means of the artificial pulse and full magnetic levitation of the rotor affords many patients an increased, but highly variable, aortic pulse pressure. Thus, DOP cannot be assumed to always approximate MAP for the purposes of HM3 patient management. On average, DOP overestimated A-line MAP by only 4 mmHg and underestimated A-line SBP by 8 mmHg. When DOP was ≤90 mmHg—the desired MAP specified in the HM3 IFU—80% of DOP were within 10 mm Hg of A-line MAP. However, when DOP was >90 mmHg, only one-third of measurements fell within ±10 mmHg of A-line MAP and this places patients at risk for inappropriate medication titration. Unsurprisingly, the accuracy of DOP to estimate SBP (the first sound heard on cuff deflation) was largely unchanged. The validity of DOP was also dependent on both pulse pressure and the presence of a radial pulse. DOP appears to be most valid and precise in estimating MAP in patients on HM3 support when a palpable pulse was not present and/or the arterial pulse pressure was <20 mmHg. A major limitation of using DOP in the outpatient setting is not having a means of assessing HM3 patient arterial pulse pressure. Based on the data herein, the presence (or absence) of aortic valve opening using clinic-based handheld echocardiography is unlikely to assist in the interpretation of DOP as SBP *versus* MAP.

Automated cuff pressures in this particular study, when successfully obtained, demonstrated reasonable accuracy for estimating patient MAP. As previously mentioned, automated cuffs rely on oscillometric measurements of arterial vibration to generate a MAP, and cuff MAP in the general patient population tends to be more accurate than the associated SBP and DBP values provided by the machine.[5] The utility of using an automated cuff in patients on cf-LVAD support has been limited by the ability of devices to measure BP during states of low pulse pressure.[6,12,13] In patients on HMII support, measurement success has been highly variable and automated cuffs designed specifically for patients on cf-LVAD support are lacking. Although cuff failures were not tallied in our study (which may introduce bias), the cuff MAP in those with successful cuff readings appeared to provide a more valid representation of MAP than DOP at a similar level of precision. At all pulse pressures, the mean differences between automated cuff and A-line MAP were small (−0.1 to 6.0 mmHg), clinically negligible, and not impacted by the presence or absence of a radial pulse. Thus, our findings support the ability to use automated cuff technologies for assessment of MAP in patients on HM3 support. Additionally, the data herein suggest that automated cuff estimation of MAP may be preferred over DOP estimation of MAP in patients on HM3 support, especially in those with a palpable radial pulse or pulse pressures known to be over 20 mmHg.

Our findings add to those of other studies highlighting the limitations of noninvasive methods for assessing BP in patients on cf-LVAD support.[6,12,14,15] In a study by Lanier *et al*., of 60 patients on HeartMate II (HMII, Abbott Inc) cf-LVAD support, a device that tends to impart less arterial pulsatility, DOP was shown to

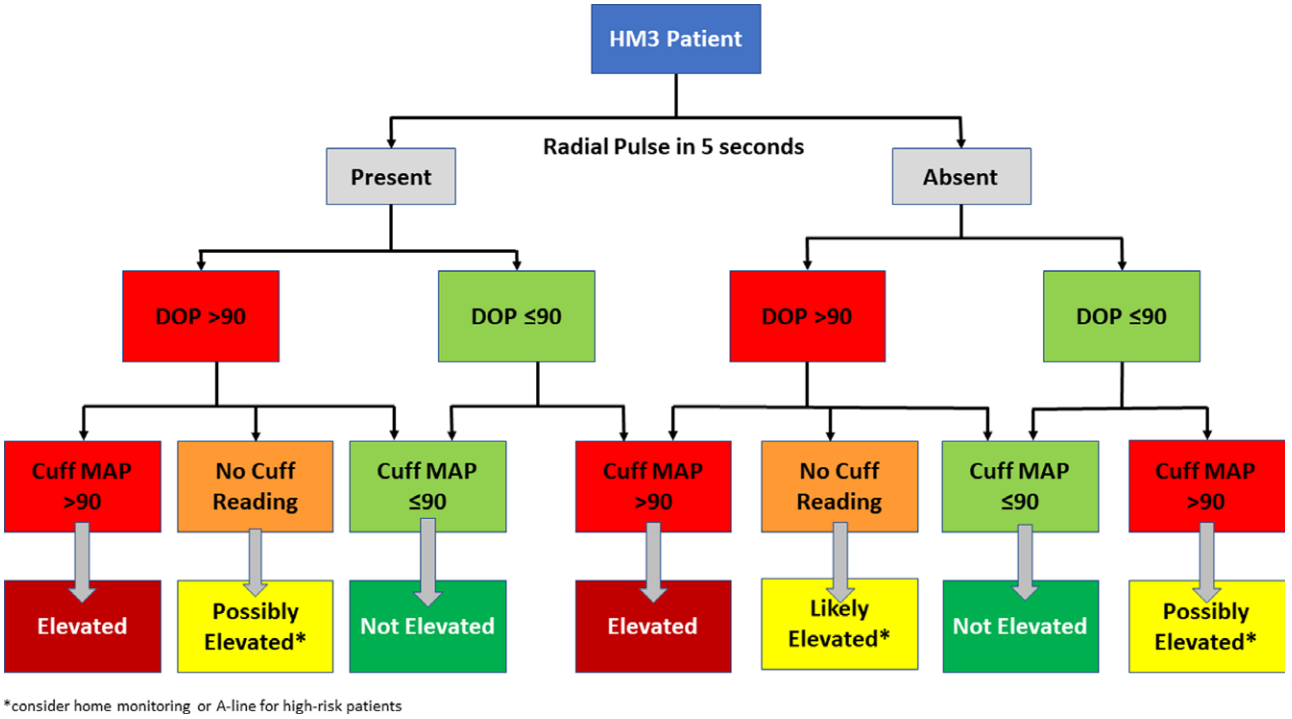

Figure 5. Considerations for BP assessment and management in patients on HM3 support. This figure demonstrates steps for BP assessment using a multi-modality approach in a patient supported by a HM3 device. Patients with divergent Doppler and cuff blood pressure readings (yellow boxes) may benefit from home blood pressure monitoring or (in high risk patients) A-line assessment. Cuff accuracy can be evaluated before A-line discontinuation while inpatient. We recommend that the same automated cuff model/manufacturer be used on all LVAD patients within your program and staff should be trained on radial pulse assessment and blood pressure documentation.

more closely approximate A-line SBP than MAP, with the DOP being 4.1 mmHg lower than SBP and 9.5 mmHg higher than MAP.[6] The linear correlation between DOP and A-line was also lower for MAP (R = 0.53) than SBP (R = 0.73). The same authors also demonstrated the important influence of patient pulse pressure on noninvasive BP measurement during HMII support. Contradictory findings were reported in a subsequent study of 154 patients on HeartMate II (n = 81) or HeartWare ventricular assist device (HVAD) (n = 80, Medtronic, Inc, MN) cf-LVAD support by Li *et al.*[14] In their analysis, DOP was found to be a better approximation of A-line MAP than SBP (mean error 2.4 mmHg *vs* – 8.4 mmHg with SBP), and linear correlations (R = 0.74) were higher for DOP *versus* A-line MAP than those identified by Lanier *et al.* The authors similarly did not note an impact from patient pulse pressure on DOP validity. Some of the differences reported in these studies may have been the result of differences in patient cohort pulse pressures, cf-LVAD models, and baseline characteristics at the time of A-line and DOP measurement (including volume status and use of inotropes).

Our results further highlight the influence pulse pressure has on the accuracy of noninvasive BP monitoring and the importance it plays in the interpretation of DOP values. Unfortunately, the field lacks a standardized definition of pulsatility as well as a reliable means of determining pulse pressure in outpatients on cf-LVAD support.[16] In the current study, roughly 90% of measurements (285/319 DOP and 251/281 cuff) had a pulse pressure >10 mmHg. Unfortunately, the magnitude of pulse pressure required to palpate a radial pulse remains undetermined. To assess pulse pressure, some have advocated using a hand-held echo in clinic to assess aortic valve opening as a surrogate for pulsatility.[17] However, in patients on HMII and HVAD support, aortic valve opening has not been found to be an accurate marker of pulse pressure (AUC 0.64).[18] In this evaluation of patients on HM3 support, the presence of a radial pulse was associated with aortic valve opening only 61.8% of the time. Furthermore, the absence of a radial pulse did not exclude aortic valve (AV) opening, which was present 45.8% of the time in such circumstances and pulse pressure poorly correlated with AV opening. We hypothesize that this is due to the elastic nature of the aorta (providing intrinsic recoil and pressue pulsatility) and the HM3 rotor magnetic levitation pulsation and speed algorithm, delivering variable flow through the outflow cannula. Thus, a wider arterial pulse pressure may be present in some patients regardless of aortic valve opening status.

Based on data herein, some recommendations can be made regarding BP assessment in patients on HM3 support. First, we feel that simultaneous DOP and automated cuff measurements should be obtained for each patient in the ICU while an A-line is still present to examine correlations. It would be best to obtain these pressures when the patient is on minimal inotropic support and as close to euvolemic as possible. While in the outpatient clinic setting, both DOP and automatic cuff pressures should be obtained simultaneously, and the radial pulse should be palpated for at least 5 seconds to assist in the interpretation of DOP values. Recording these values (cuff SBP, DBP, cuff measured MAP, DOP, and the presence or absence of a radial pulse) in both the inpatient and outpatient charts will ensure consistency of BP documentation between providers and ensure that providers are considering all the complexities that impact MAP assessment in patients on HM3 support. Because of the inaccuracy

of cuff SBP and DBP, the reported cuff MAPs should be preferentially followed. When DOP and cuff MAP align (both above or both below 90 mmHg), one should manage patients accordingly (Figure 5). When they diverge with one or the other above and below 90 mmHg, guidance can loosely be provided by the presence of a palpable pulse. In such instances when the radial pulse is present, preference should be directed toward treating cuff measured MAP, as the DOP may over-estimated MAP. In general, a DOP ≤ 90 mmHg will very rarely be associated with an actual MAP >90 mmHg. In patients with divergent MAP and DOP numbers and/or orthostasis, home BP monitoring or admission with A-line MAP assessment may be beneficial.

Limitations

There are some inherent limitations to this secondary analysis. We did not standardize the BP measurement protocol for patients enrolled into MOMENTUM 3 and centers were permitted to use any manufacturer's automated cuff and cuff brand/model were not tallied herein. The sensitivity analysis of patients with data from all three modalities yielded similar findings to those observed in patients without triple modality assessment. We also did not capture the frequency of unsuccessful noninvasive measurement attempts, but it is reasonable to assume that noninvasive measures were unable to be obtained in some patients. This inherently biases cuff accuracy and precision estimation. Another limitation is that patients in this cohort were very early postoperative and many were on inotropic agents. Furthermore, some may have had vasoplegia, volume overload, transient RV dysfunction, and/or pharmacologic hypertension, introducing confounding through the impact this may have had on cardiac contractility, vasculature tone, pulse pressure, and the ability to obtain a noninvasive BP measurement. A-line requirements limited our ability to make these BP comparisons in stable outpatients. Finally, these results do not necessarily apply to other cf-LVAD devices or patients on biventricular assist device support, as difference in pulsatility algorithms, peripheral vascular tone, and HQ curves will likely impact validity of findings across devices.

In summary, BP assessment in patients on HM3 support remains challenging. In this analysis, we found only a modest correlation between invasive and noninvasive BP measurements. Pulse pressure appears to heavily influence the validity and reliability of DOP's ability to estimate MAP, reducing its accuracy when pulse pressure is elevated. When automatic cuff measurements are successfully obtained, the cuff MAP appears to be a reliable estimate of A-line MAP. A multimodality approach to BP assessment, using both DOP and automated cuff with radial pulse assessment may be the best means of estimating patient MAP on HM3 support. Importantly, the presence of a palpable pulse is not a reliable indicator of aortic valve opening and does not reliably distinguish MAP *versus* SBP using Doppler.

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