

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

Authors (presenter underlined): J.A. Cowger¹, D.A. Rinde-Hoffman², M.M. Givertz³, A.S. Anderson⁴, D. Jacoby⁵, L. Chen⁶, A. Brieke⁷, C. Mahr⁸, S. Hall⁹, N. Dirckx¹⁰, A. Baker¹⁰, S.P. Pinney¹¹. ¹Cardiovascular Medicine, Henry Ford Hospital, Detroit, MI, ²Tampa General Med Grp, Tampa FL, ³Brigham and Women's Hospital, Boston, MA, ⁴Department of Medicine, UT Health, San Antonio, TX, ⁵Yale School of Medicine, Section of Cardiovascular Medicine, New Haven, CT, ⁶University of Rochester, Rochester NY, ⁷University of Colorado School of Med, Denver, CO, ⁸University of Washington, Seattle, WA, ⁹Baylor University Medical Center, Dallas, TX, ¹⁰Abbott, Inc, Abbott Park, IL., ¹¹Heart and Vascular Center, University of Chicago, Chicago, IL.



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Relevant Financial Relationship Disclosure Statement

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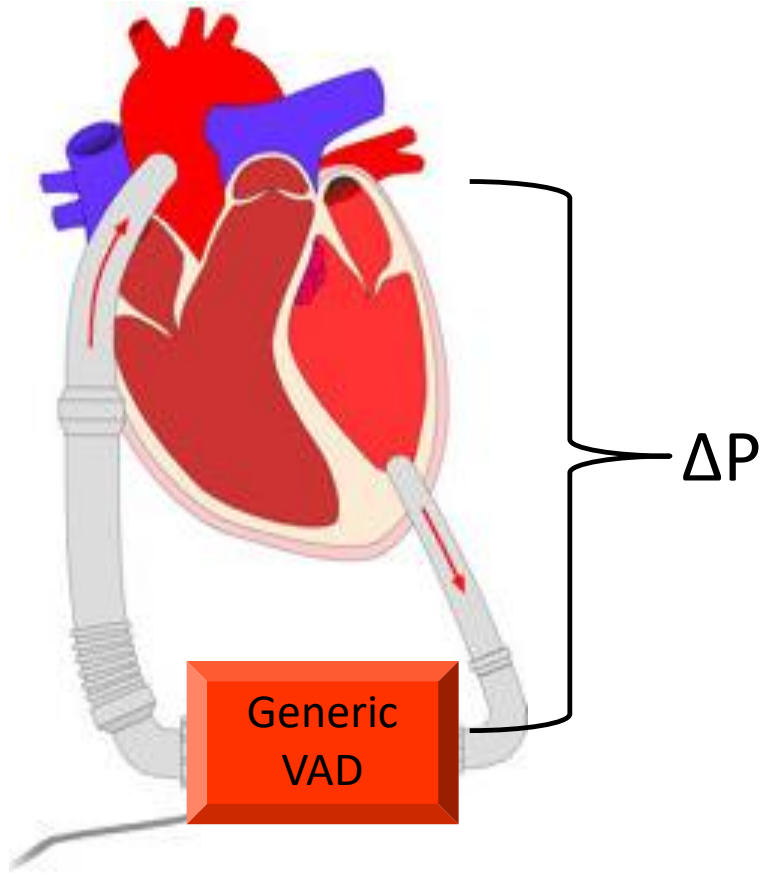
Jennifer Cowger, MD, MS

I will **not** discuss off label use and/or investigation use of left ventricular assist devices.

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Pressure-Flow Relationship: Afterload Sensitivity of Continuous Flow LVADs



ΔP = differential (aka head) pressure between inflow and outflow

- Hypertension during continuous flow LVAD support can reduce LVAD flows leading to:
 - **↑ left ventricular filling pressures**
 - Recurrent CHF symptoms
 - Persistent PVR elevation
 - Secondary RV dysfunction
 - **Stasis within the ventricle or LVAD:**
 - ↑ Stroke risk
 - ↑ Pump thrombosis/ingestion
- Hypertension promotes **aortic insufficiency** by increasing the gradient between the aortic root and the LV

BP Monitoring during HM3 support is complex

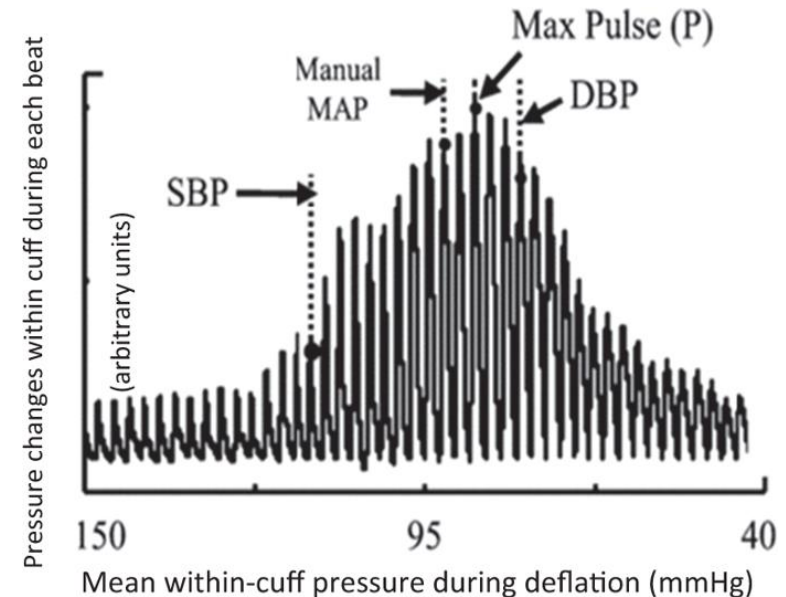
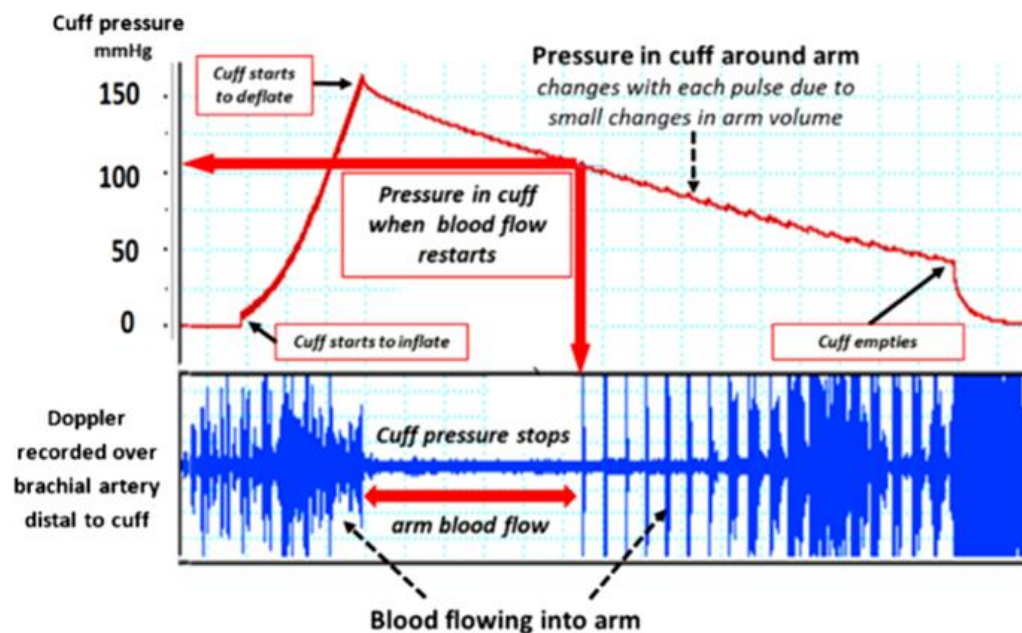
- Depending on **pulse pressure**, DOP may represent systolic BP alone or both systolic and mean arterial pressure (MAP)
 - If DOP >>> MAP, you could induce **hypotension** with med titration
- The accuracy of automated cuff technology in HM3 patients is not known
 - Is cuff accuracy impacted by irregular pulsation during continuous flow with a pulsatility algorithm?
 - Is cuff accuracy impacted by low pulse pressure?



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Measuring blood pressure in LVAD patients

- Automated cuffs calculate **MAP** by measuring vibration undulations imparted by blood flow through the artery or measure during cuff deflation
- In nonVAD patients, the MAP is the most accurate measure of BP from an oscillometric BP cuff
 - Automated cuffs “back-calculate” SBP and DBP through proprietary formulas that vary in accuracy between devices



Aims of this analysis

In patients on HeartMate 3 support:

- 1) Examine the correlation between arterial line (A-Line) systolic, diastolic, and mean arterial pressure with:
 - Automated cuff measurements of systolic, diastolic and mean arterial pressures
 - Doppler opening pressures (DOP)
- 2) Examine the impact of pulse pressure on automated cuff and DOP accuracy
- 3) Examine the impact of mean arterial pressure on automated cuff and DOP accuracy

Methods

- HM3 patients enrolled into the MOMENTUM 3 CAP study
 - 1685 patients enrolled August 2016 – October 2018
- Blood pressures measured postop days 1-7 using arterial line and/or automated cuff and/or DOP
 - Repeated measurements from the same modality were averaged
- Within-patient blood pressure measurements were paired as follows:
 - A-line + automated cuff
 - A-line + DOP
 - A-line + automated cuff + DOP

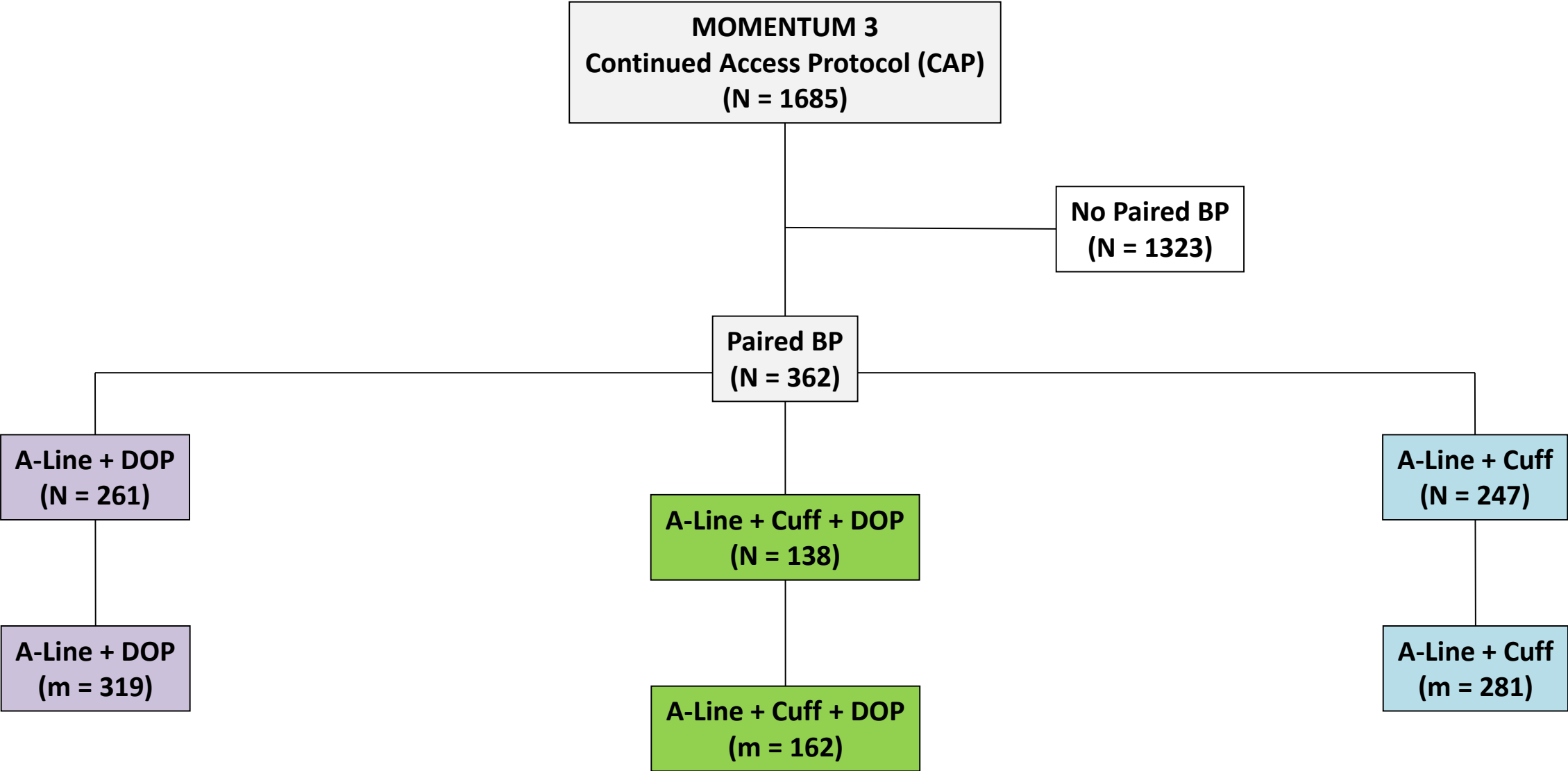
Methods- Statistical analyses

- Pearson (R) correlations were calculated for each paired analysis
 - R: value between -1.0 and +1.0 that describes how two continuous variables are linearly correlated, with directionality expressed by a positive or negative sign.
- Mean differences between the A-line reference measure (SBP or MAP) and the corresponding noninvasive measurement were calculated
- Mean absolute differences (MAD) were also calculated to evaluate the absolute magnitude of differences between the A-line and noninvasive measures
- Statistical analysis performed by sponsor

Results

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HeartMate 3 Patient Cohort



N = # of patients
m = # of paired measurements

Baseline Demographics

	A-line + Doppler Analysis (n=261 patients)	A-line + Cuff Analysis (n=247 patients)	A-Line + Doppler + Cuff Analysis (n=138 patients)
Age, years	61.2 ± 11.3	60.7 ± 12.6	62.2 ± 11.4
Male	208 (79.7%)	194 (78.5%)	109 (79.0%)
INTERMACS Profile			
Profiles 1-2	92 (35.2%)	73 (29.9%)	32 (23.2%)
Profile 3	142 (54.4%)	145 (59.4%)	89 (64.5%)
Profiles 4-7	25 (9.6%)	24 (9.8%)	15 (10.9%)
Ischemic cardiomyopathy	125 (47.9%)	118 (47.8%)	72 (52.2%)
History of hypertension	190 (72.8%)	183 (74.1%)	97 (70.3%)

Continuous variables shown as mean and SD. Categorical variables are shown as counts and percentage.

Post-Operative Medications at Time of BP Measurement

	A-line + Doppler Analysis (319 paired measures)	A-line + Cuff Analysis (281 paired measures)	A-Line + Doppler + Cuff Analysis (162 paired measures)
IV Inotrope(s)	297 (93.7%)	259 (92.2%)	149 (92.0%)
IV Vasopressor(s)	50 (15.7%)	50 (17.8%)	28 (17.3%)
Beta-blocker	50 (15.7%)	40 (14.2%)	29 (17.9%)
ACE-I	13 (4.1%)	8 (2.8%)	7 (4.3%)
ARB	3 (0.9%)	4 (1.4%)	3 (1.9%)
Spironolactone	3 (6.0%)	14 (5.0%)	13 (8.0%)

Categorical values shown as counts (%). ACE-I = angiotensin converting enzyme inhibitor; ARB= angiotensin receptor blocker; IV= intravenous.

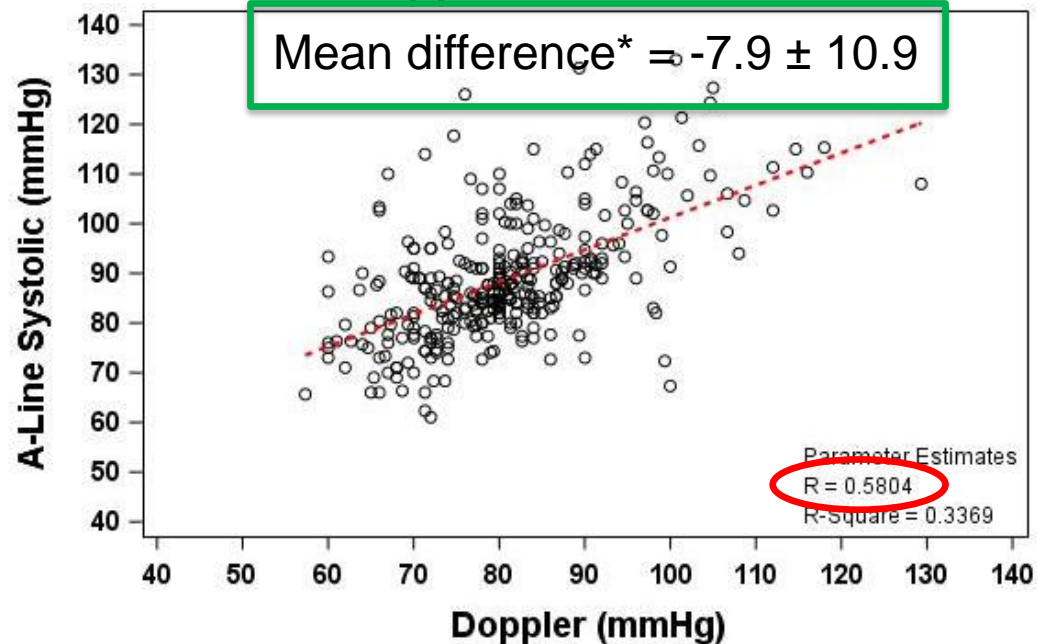
Post-Operative Blood Pressure Measurements

	A-line + Doppler Analysis (319 paired measures)	A-line + Cuff Analysis (281 paired measures)	A-Line + Doppler + Cuff Analysis (162 paired measures)
A-line Pressures, mmHg			
Systolic	88.8 ± 12.5	89.5 ± 13.3	89.7 ± 12.4
Diastolic	68.3 ± 9.2	67.9 ± 9.5	69.6 ± 9.2
MAP	76.9 ± 8.6	76.5 ± 8.8	77.7 ± 8.9
Pulse pressure	20.6 ± 10.9	21.6 ± 13.2	20.1 ± 10.4
Doppler Opening Pressure, mmHg	80.9 ± 11.2	N/A	83.0 ± 12.3
Cuff Pressures, mmHg			
Systolic	N/A	96.2 ± 15.5	94.5 ± 12.9
Diastolic	N/A	68.0 ± 11.6	68.1 ± 11.5
MAP	N/A	77.4 ± 11.8	76.6 ± 10.9
Palpable Radial Pulse*	110 (48.7%), m=226	86 (52.8%), m=163	57 (46.7%), m=122

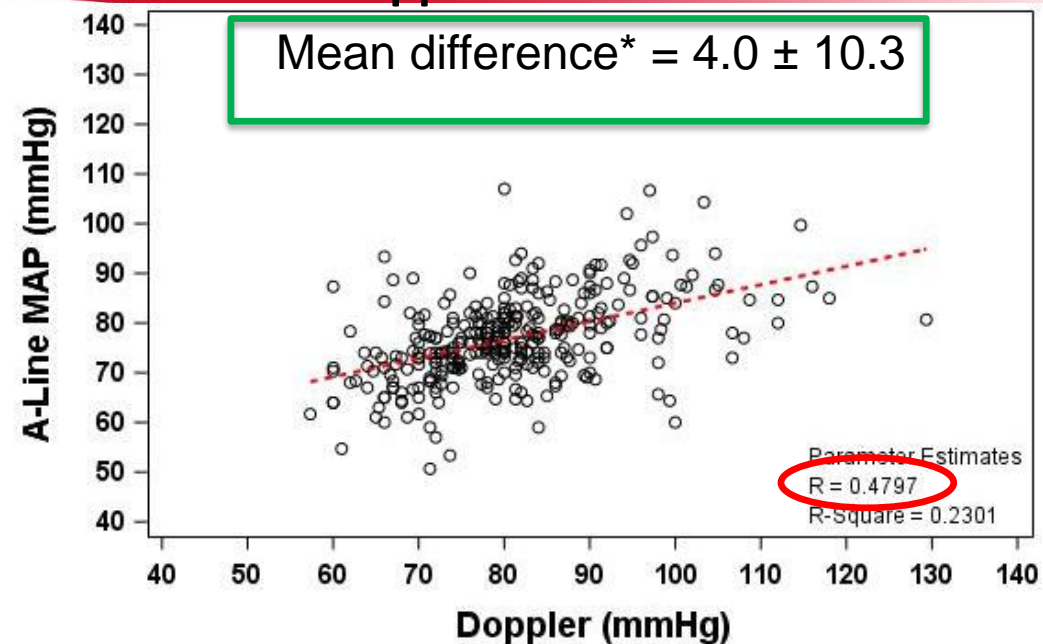
Categorical variables are shown as counts (%). Continuous variables are shown as mean ± SD.

*Palpable radial pulse is defined as ≥1 pulse in 5 seconds. Evaluation of radial pulse was not performed during every paired BP measurement. m represents number of paired BP measurements with radial pulse assessment.

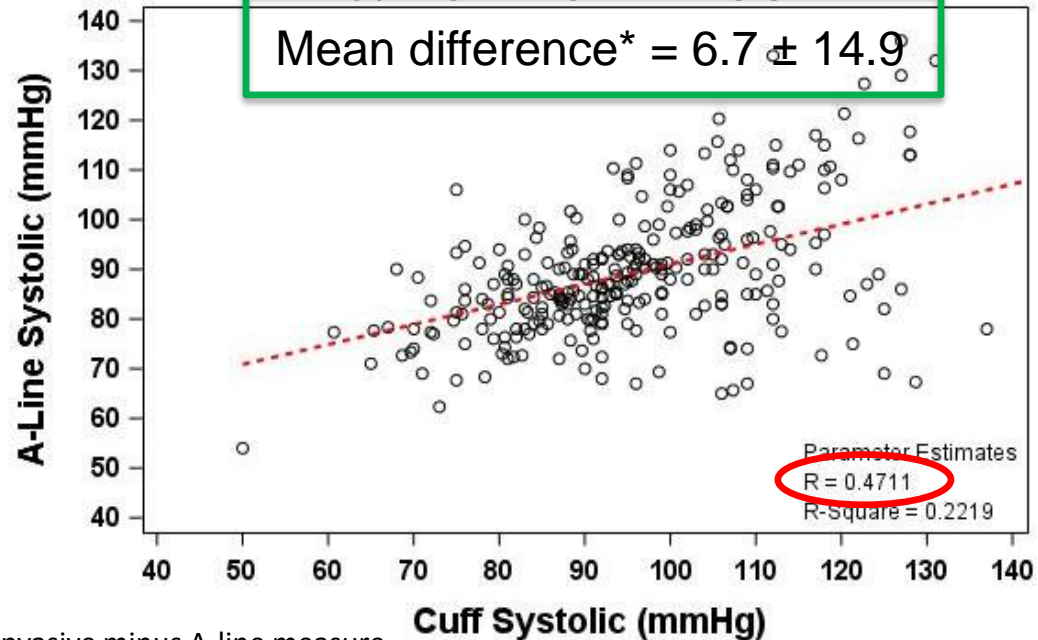
Doppler vs. A-Line SBP



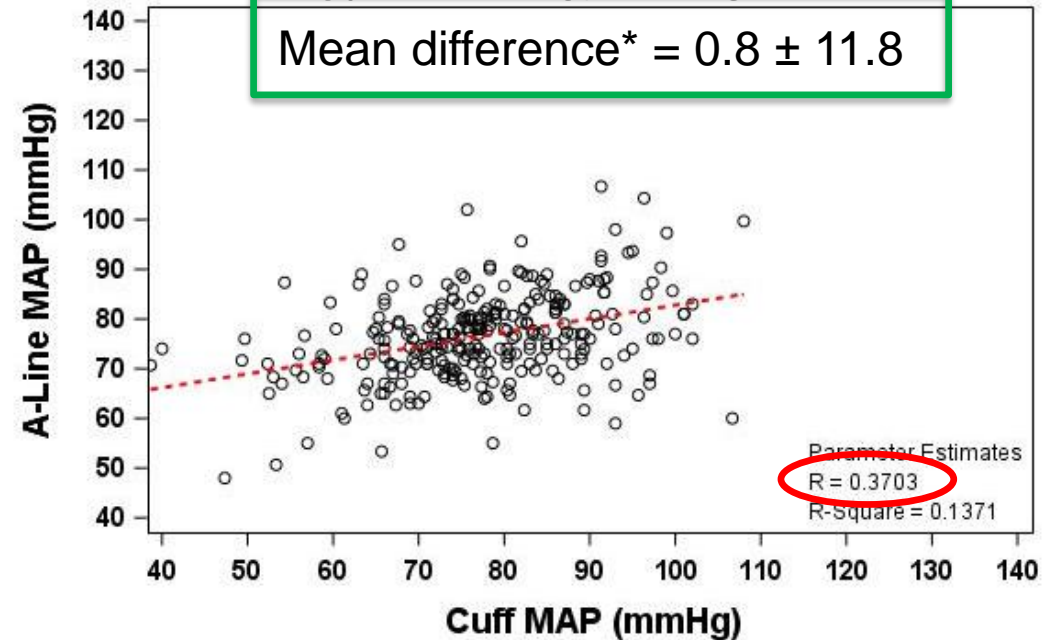
Doppler vs. A-Line MAP



Cuff SBP vs. A-Line SBP



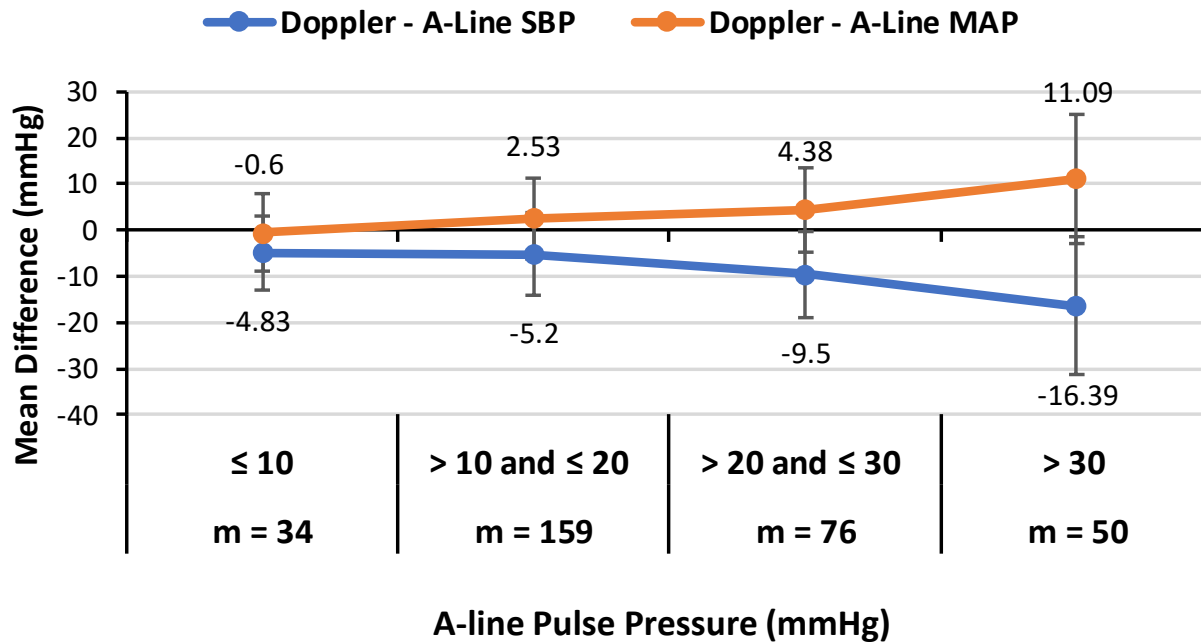
Cuff MAP vs. A-Line MAP



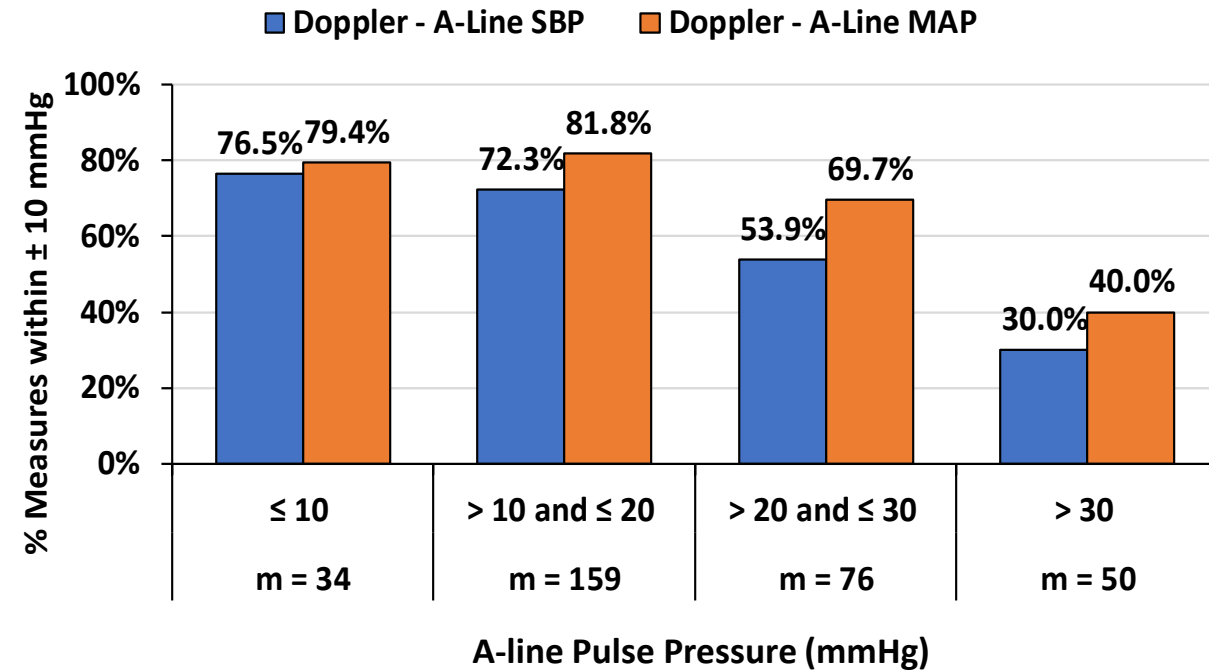
*Non-invasive minus A-line measure

Doppler vs. A-Line: Impact of A-Line Pulse Pressure

Mean Difference between DOP and A-line

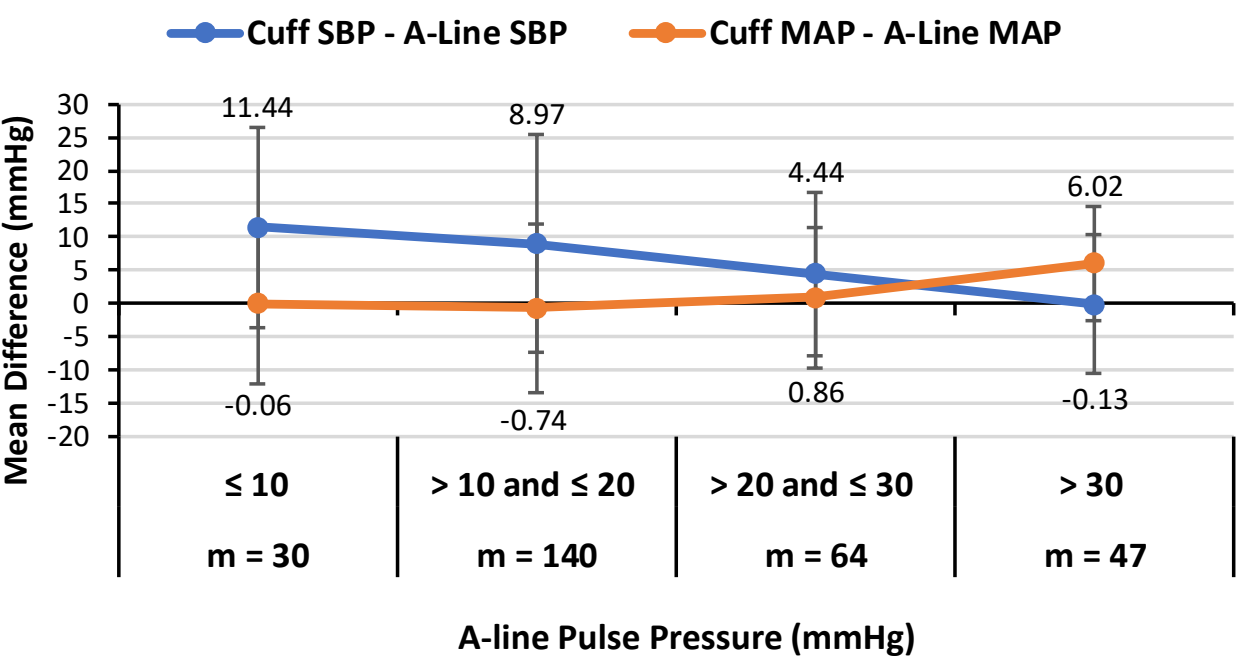


% of DOP Measurements within ± 10 mmHg of A-line

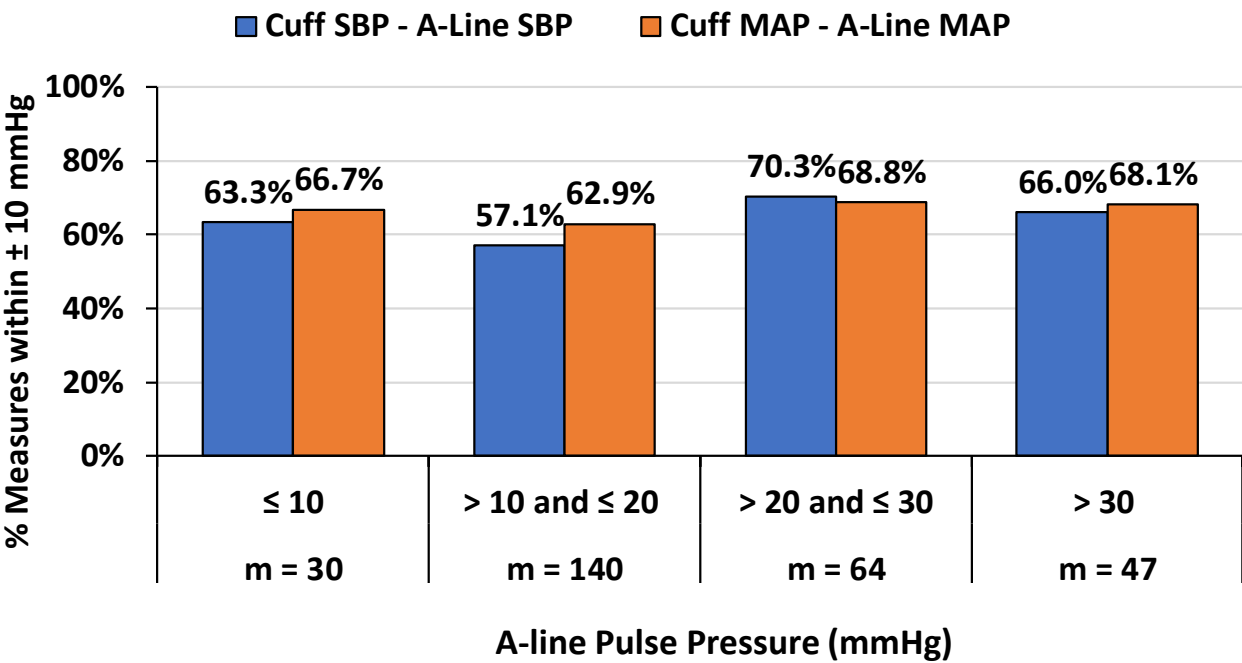


Automated Cuff vs. A-Line: Impact of A-Line Pulse Pressure

Mean Difference between Cuff and A-line

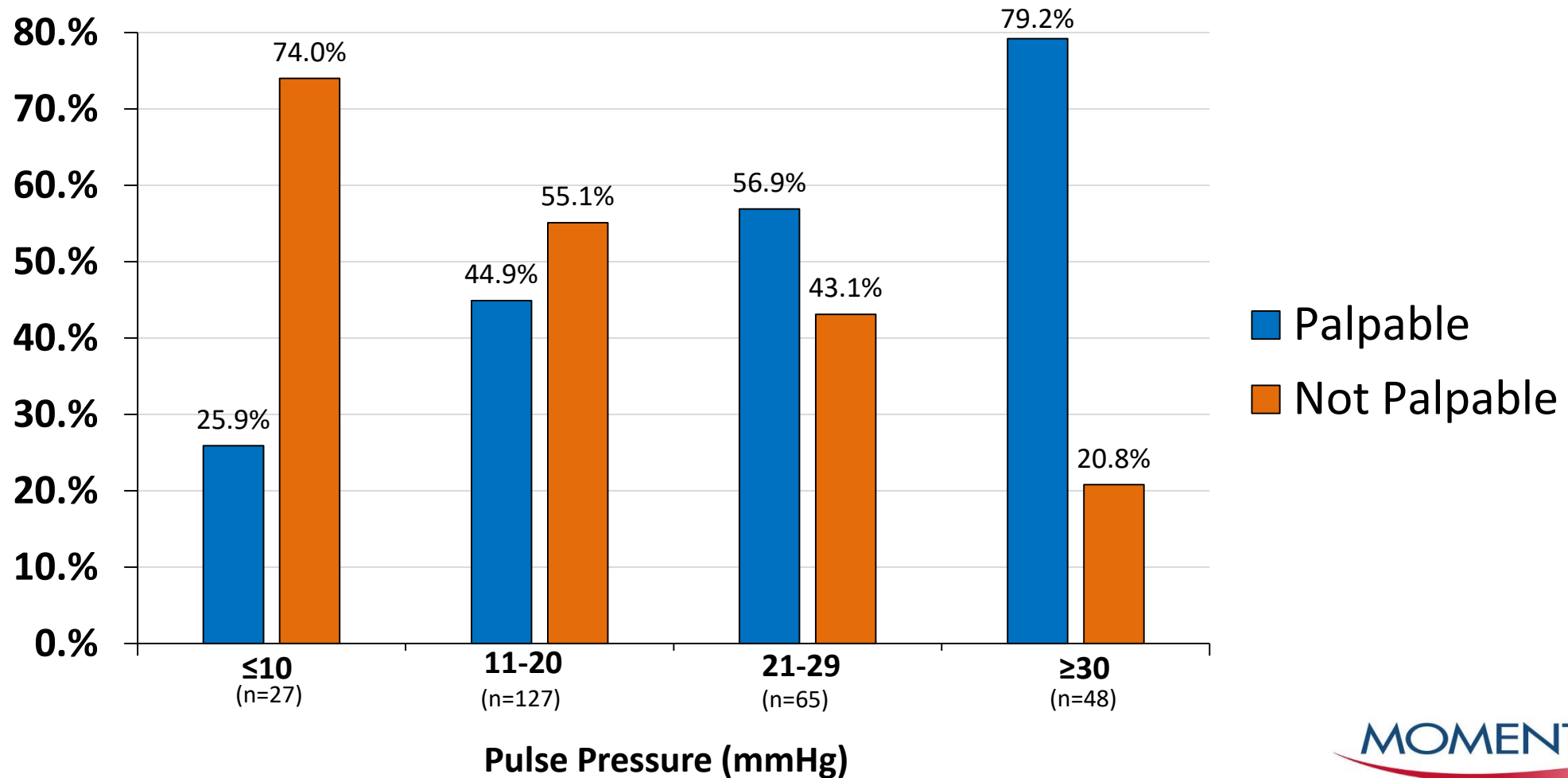


% of Cuff Measurements within ± 10 mmHg of A-line



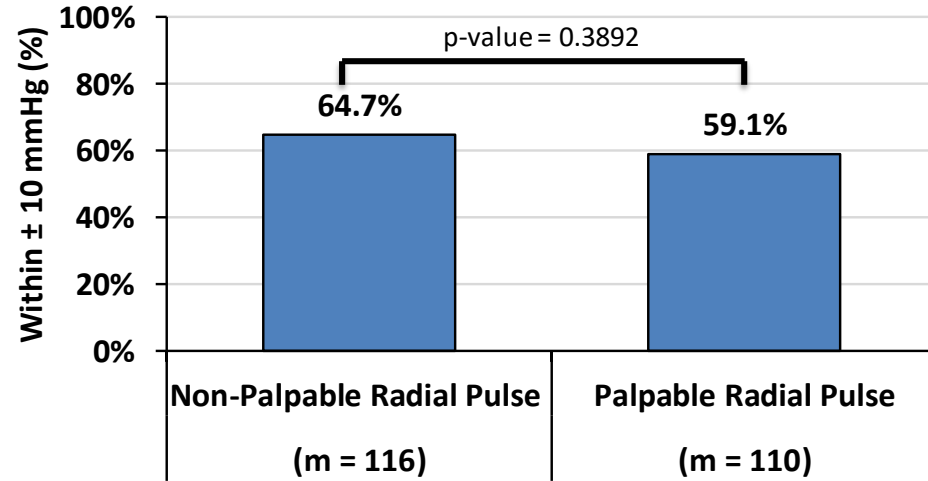
Correlation between Pulse Pressure and Radial Pulse

A palpable pulse was present in 52% of patients in combined cohort

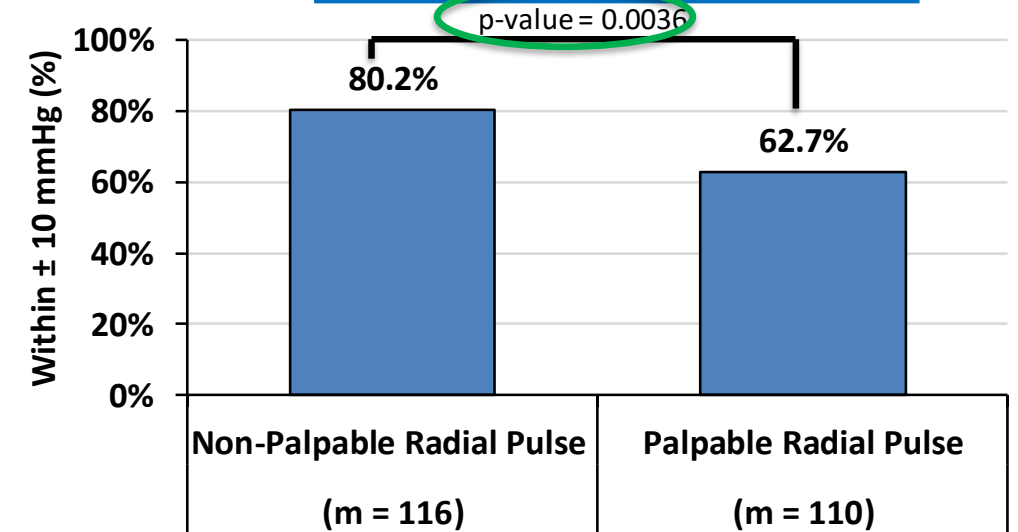


Impact of Palpable Radial Pulse on Noninvasive Measures of BP

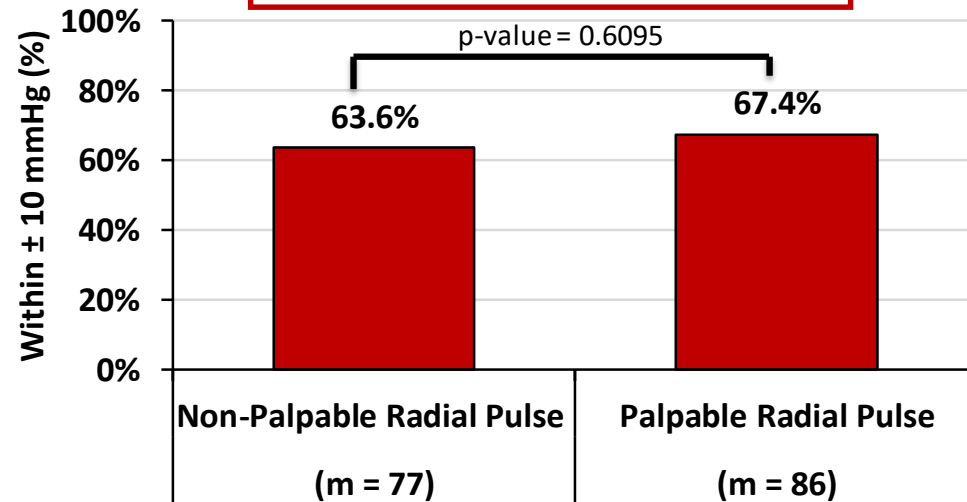
DOP and A-line SBP



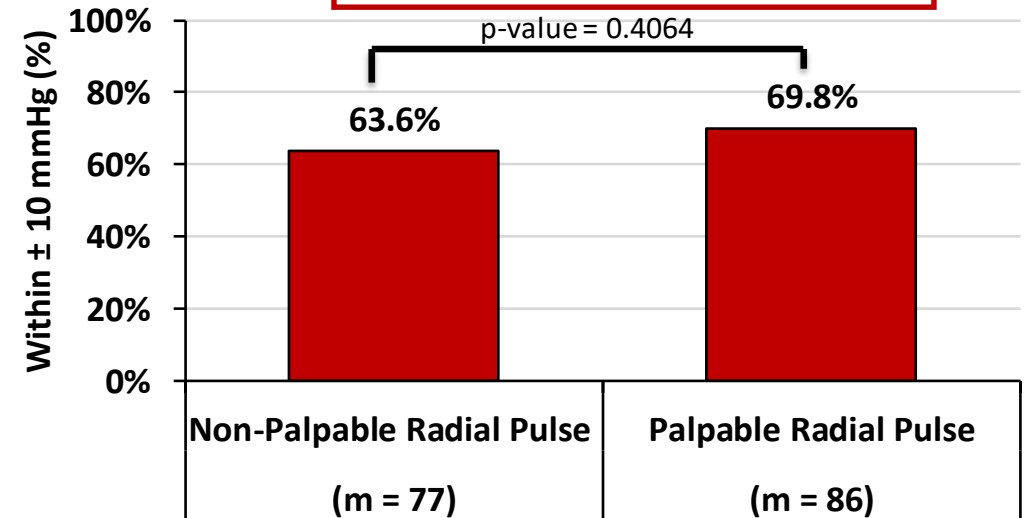
DOP and A-line MAP



Cuff SBP and A-line SBP



Cuff MAP and A-line MAP



Conclusions

In patients on HeartMate 3 LVAD support:

- DOP accuracy is highest in patients with no palpable radial pulse and those with low pulse pressure
 - DOP approximates both MAP and SBP when pulse pressure is <20 mmHg
 - It is reasonable to interpret DOP as MAP when there is no palpable radial pulse
 - The accuracy of DOP estimation of MAP is reduced ~20% in those with a palpable radial pulse.
 - MAPs tend to be over-estimated by DOP when the pulse pressure is >20 mmHg
- In HM3 patients with successful automated cuff measurements:
 - Medications should be titrated in response to MAP and not SBP
 - Assessment of MAP may be more accurate than DOP in those with higher pulse pressures and palpable radial pulses

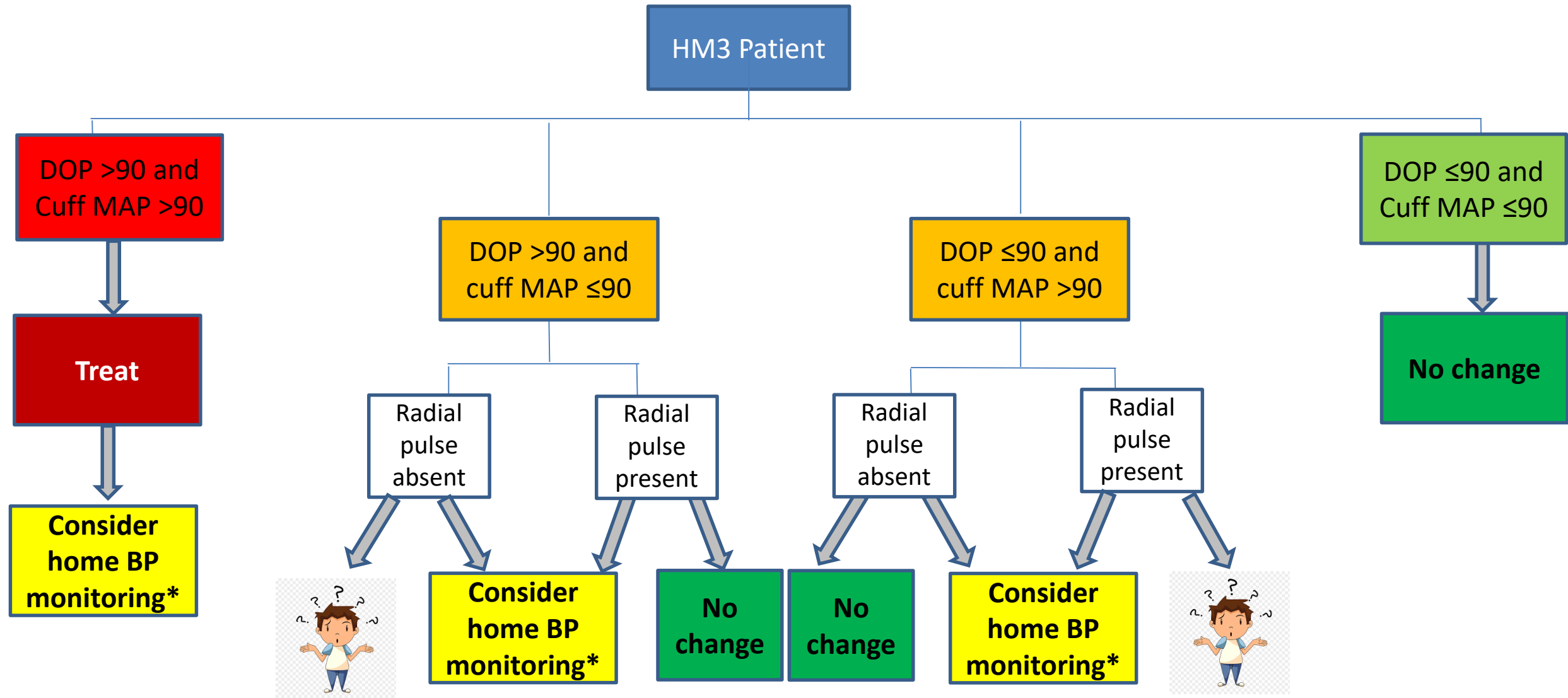
Limitations

- No data on brand/model of automated cuff used
- Majority of patients were early postoperative on inotrope support
 - Inotropes and volume status may impact pulse pressure
 - Inotropes and volume status may therefore impact non-invasive BP measurement accuracy
- Limited within-patient data using all three devices simultaneously
- Power limited

Practical Management Recommendations for HM3 Patients

- Use both Doppler and automated cuff simultaneously in the ICU to examine correlation with A-line
 - Optimal to get these measures near patient euvolemia on minimal inotrope support for extrapolation to outpatient support
- In clinic, obtain DOP and automated cuff simultaneously
- In clinic, palpate for presence of a radial pulse over 5 seconds to assist in interpretation of DOP values

Suggestions for Assessing HM3 Patients in Clinic



*Home BP monitoring 60-90 min after meds with cuff and Doppler may be helpful when results are divergent or when patients are very hypertensive to see patterns and trends in values and/or response to interventions



THANK YOU
