2018

Systolic blood pressure and outcomes in patients on continuous flow LVAD support: An INTERMACS analysis

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Recommended Citation

Cowger JA, Chamogeorgakis T, Borgi J, Grafton G, Selektor Y, Nemeh H, Williams C, Tita C, Lanfear D. Systolic blood pressure and outcomes in patients on continuous flow LVAD support: An INTERMACS analysis. J Heart Lung Transplant. 2018;37(4):S30-S31.

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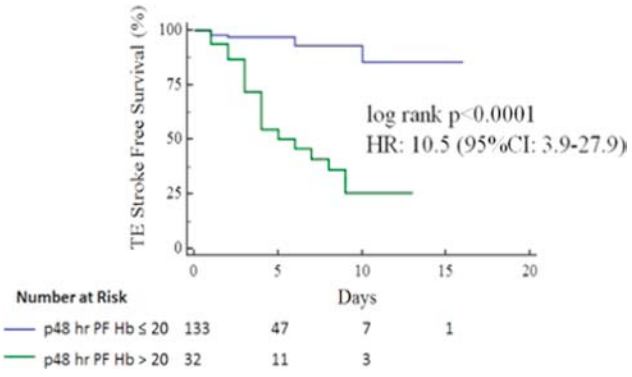

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Is Cerebral Near-infrared Spectroscopy Monitoring Predictive of Neurological Injury During ECMO?

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Purpose: Neurological complications are the major causes of death in patients on ECMO. Near-infrared spectroscopy (NIRS) is used as a noninvasive method of surveillance for cerebral perfusion. Cerebral oxygen saturation monitoring by NIRS may predict neurological injury in ECMO patients
Methods: NIRS was performed routinely on venoarterial and venovenous ECMO patients. Data recording clinical neurological signs and head CT findings were retrospectively collected from medical records. Patients who underwent CT scans were grouped into those with neurological signs and NIRS drop (Group A), neurological signs without NIRS drop (Group B), NIRS drop without neurological signs (Group C), and no neurological sign or NIRS drop (Group D). NIRS drop was defined as having a lower NIRS reading at time of CT scan compared to baseline NIRS reading. Incidence of neurological injury by CT indication was evaluated in each group.
Results: A total of 73 patients [Group A (14), Group B (40), Group C (0), Group D (19)] had appropriate NIRS documentation for study and 28 patients had a positive CT scan confirming neurological injuries [12 patients (85%) in Group A, 13 patients (33%) in Group B, and 3 patients (16%) in Group D, p=0.0006]. Sensitivity and specificity of predicting positive CT scan findings in these groups were 43% and 96% in Group A, 46% and 40% in Group B, and 28% and 71% in Group D. Among group A patients that demonstrated comas despite sedation vacation, 10/12 (83%) patients had positive CT findings while 7/33 patients (21%) within group B had positive CT findings (p=0.0001).
Conclusion: ECMO patients that developed neurological signs with NIRS drop correlated with clinical neurological injury. NIRS monitoring was a useful modality to identify neurological injury among comatose patients.

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Estimation of Mean Arterial Pressure in HeartMate II Patients Using Doppler Blood Pressure and Pump Speed

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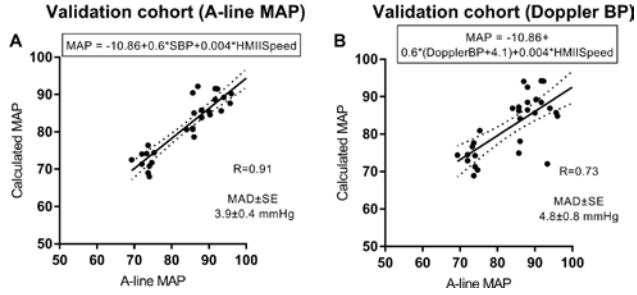
Purpose: In continuous-flow left ventricular assist device (CF-LVAD) pts, blood pressure (BP) measurement is challenging. Current guidelines recommend a mean arterial pressure (MAP) ≤80 mmHg, but no target for systolic BP (SBP) is specified. Automated BP monitors are accurate, but their success rate is low (<70%), particularly in pts with reduced pulse pressure (PP). Doppler BP is uniformly successful (100%) and accurately estimates SBP. Doppler BP is on average 4.1 mmHg lower than SBP by arterial line (A-line). However, Doppler BP approximates mean arterial pressure (MAP) only in a setting of reduced PP, which in turn is influenced by pump speed. We tested a novel approach to estimate MAP in pts on HeartMate II (HMII) combining Doppler BP and HMII parameters.
Methods: BP measurements and concomitant HMII parameters (speed and pulsatility index (PI)), were retrospectively analyzed in two groups: 1) a derivation cohort (DC, n=39); and 2) a validation cohort (VC, n=30). BP was measured by A-line in the DC and by A-line and Doppler in the VC. The relation between A-line MAP and A-line SBP, HMII speed and PI was assessed using multiple linear regression in the DC. The accuracy of the resulting formula in estimating A-line MAP was tested in the VC. SBP estimated by Doppler BP (SBP=Doppler BP+4.1 mmHg) was also used to reproduce a *real-world* scenario.
Results: A formula incorporating A-line SBP and HMII speed (MAP = -10.86+0.6*SBP+0.004*Speed) predicted A-line MAP in the DC (R=0.89, p<0.001; MAD±SE 3.0±0.3 mmHg; MOD±SE 0±0.6) and in the VC (R 0.91, p<0.001; MAD±SE 3.9±0.4 mmHg; MOD±SE -2.6±0.7) (Fig.A). Adding PI values to this model did not improve the accuracy of the formula. In the VC, success rate for Doppler was 100%. The formula using Doppler BP and HMII speed accurately predicted A-line MAP (R=0.73, p<0.001 ; MAD±SE 4.8±0.8 mmHg; MOD±SE -1.9±1.1 mmHg) (Fig.B).
Conclusion: Doppler BP and pump speed based formula offers an alternative method for accurate estimation of MAP in HMII pts in the outpatient settings.



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Systolic Blood Pressure and Outcomes in Patients on Continuous Flow LVAD Support: An INTERMACS Analysis

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Purpose: High mean arterial pressures in continuous flow (cf) LVAD patients are associated with increased stroke and pump thrombosis risks. Optimal thresholds for systolic blood pressure are unknown.
Methods: Systolic blood pressure (SBP) measurements in operative survivors of cfLVAD implant were obtained from the INTERMACS registry at 3, 6, and 12 months after implant. Survival was estimated with Kaplan-Meier methods and Cox Hazard Ratios [95% CI] for 1 year mortality were calculated.
Results: SBPs were available in 7738 operative survivors at 3 and 6 months. The mean±std SBPs at discharge, 3, 6, and 12 months were 91.8±14.9, 98.9±16.1, 100.3±16.4, and 101.0±16.3 mmHg. Patients with an SBP <80 at 3 months were more likely to be INTERMACS 1 or 2, Bridge to transplant, and less likely to be African American. Survival was worse in those with low systolic blood pressure (table, p<0.001). Compared with having an SBP >100 at 3 months, SBPs <80 (HR 2.0 [1.6-2.4]) and 81-100 (HR 1.2 [1.1-1.4]) were associated with increased 1-year mortality. Controlling for

age, race, sex, axial-flow configuration, preoperative albumin, preoperative creatinine, INTERMACS profile, 1Y mortality was still higher with SBP <80 (HR 2.0 [1.6-2.5]) and SBP 81-100 (HR 1.2 [1.02-1.4], p=0.03) vs. an SBP >100 mmHg.

Conclusion: Lower SBP after cfLVAD is independently associated with worse survival. This raises concern that excessive SBP control may be harmful in these patients. Dedicated trials to determine optimal BP targets are warranted.

Survival by Systolic Blood Pressure (mmHg)

	3mo SBP	3mo SBP	6mo SBP	6mo SBP
	1Y Survival	2Y Survival	1Y Survival	2Y Survival
SBP <75	75±2.4%	60±3.0%	86±2.2%	66±3.3%
SBP 75-80	86±1.6%	70±2.4%	90±1.5%	76±2.4%
SBP 81-90	88±0.9%	75±1.3%	92±0.8%	79±1.4%
SBP 91-100	88±0.8%	76±1.2%	92±0.7%	80±1.2%
SBP 101-109	91±0.8%	81±1.3%	95±0.7%	82±1.3%
SBP 110-120	89±1.0%	76±1.6%	94±0.8%	80±1.5%
SBP 121-130	89±1.6%	79±2.4%	89±1.6%	78±2.5%
SBP >130	90±1.9%	78±2.9%	90±1.9%	78±2.9%

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Blood Pressure Control as a Risk Factor for Stroke in LVAD Patients- Single Center Experience

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Purpose: The ENDURANCE trial suggested an increased stroke (CVA) risk in Heartware HVAD compared to Heartmate 2 (HM2); a risk that could be mitigated with improved blood pressure control as demonstrated in the ENDURANCE 2 supplemental study. We hypothesized that better blood pressure control reduced the stroke risk in all LVAD supported patients.

Methods: A retrospective review of all adult patients with end-stage heart failure who underwent implantation of a HVAD or HM2 LVAD from January 2010-June 2016 was conducted. Aggressive blood pressure management has been practiced at our program for all device supported patients since the start of ENDURANCE 2. Mean arterial pressure (MAP, mmHg) was compared in all LVAD patients by era. Medians are reported for non-normally distributed continuous variables. The Mann-Whitney test was used for comparison of non-normal continuous and ordered categorical variables. Statistical analysis was performed as a between-group comparison examining outcomes. A p-value < 0.05 was significant.

Results: 187 patients underwent continuous-flow LVAD implantation therapy at a single institution; 133 patients (71%) received a HM2, and 54 patients (29%) received a HVAD. Pump thrombus was more common in HM2 group while postoperative right ventricular dysfunction was more common in the HVAD (p<0.01). **See Table 1**. MAP between groups was different (HM2 80.0, HVAD 76.6; p<0.001). MAP was not increased in stroke patients with HM2 (79.9 CVA, 80.0 no CVA; p=0.669). MAP in HVAD treated patients with CVA was higher (77.1 CVA, 76.1 no CVA; p=0.073) but this was not statistically significant. Pre-ENDURANCE 2 MAP was increased compared to Post-ENDURANCE 2 (80.4, 77.5; p=0.002). MAP in stroke patients pre-ENDURANCE 2 was higher (83.0 CVA, 80.1 no CVA; p=0.023).

Conclusion: MAP was significantly higher in stroke patients in the Pre-ENDURANCE 2 but not thereafter. MAP seemed to influence stroke rates in HVAD but not HM2 patients. The data suggest some risk factors leading to stroke may be different between devices.

TABLE 1

Variables	HM2 (n=133)	HVAD (n=54)	p
Adverse Events			
Major Bleeding	47.3%	35.2%	0.13
Gi Bleeding	36.2%	38.9%	0.72
Cardiac Arrhythmia	45.1%	40.7%	0.58
Infection	40.6%	44.4%	0.62
Drive Line Infection	34.6%	40.7%	0.42
Neuro Event	27.8%	24.1%	0.58
Ischemic Stroke	10.5%	9.3%	0.79
Hemorrhagic Stroke	15.0%	14.8%	0.97
TIA	6.0%	1.9%	0.45
Renal Dysfunction	13.5%	16.7%	0.58
Right heart Failure	30.1%	50.0%	**0.01**
Pump Thrombus	24.8%	11.1%	**0.04**
Pump Exchange	9.0%	1.9%	0.11
Device Complications requiring urgent transplant	18.1%	13%	0.39

HM2 = HeartMate 2 HVAD = HeartWare

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Risk Predictors for Ischemic Stroke in CF-LVAD Patients by Pump Flow Type

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Purpose: Risk of stroke continues to be a major adverse event post-LVAD implantation, limiting wider application and utility of the device. Even with aggressive blood pressure control, patients with LVADs are at higher risk of stroke due to combination of pump-dependent factors including loss of natural pulsatility, anticoagulation, and thrombosis risk from blood-pump interaction. We used a Bayesian Network machine-learning approach to derive comparative risk factors for ischemic stroke in patients with axial versus centrifugal flow pumps at 3 months post LVAD implant. Our goal was to explore the pre-implant factors that drive risk for ischemic stroke for patients with each type of pump and compare them to understand any differences.

Methods: We used INTERMACS data from 2012-2016 for patients (n=12,068) with a primary CFLVAD including those with axial flow (n = 9,159) versus centrifugal flow (n = 2,909). A portion of each dataset (20%) was reserved for test validation. The model was made using Naïve Bayesian analysis (GeNie) and performance was assessed by test validation. Predictors were ranked by their diagnostic value.

Predictive features for ischemic stroke in patients with axial and centrifugal flow pumps at 3 month

Axial Flow		Centrifugal flow	
Variable	Influence	Variable	Influence
CRP	0.019	Uric acid	0.0125
Temporary MCS	0.014	Device strategy	0.023
LVEDD	0.014	Hospital implant volume	0.017
Pre-albumin	0.012	Inotopes	0.013
Ventilator dependence	0.011	LVEDD	0.013
Acute MI pre LVAD	0.010	Previous sternotomy	0.012
Ischemic etiology	0.008	ECMO	0.012
Previous CABG	0.008	BMI	0.010
ECMO	0.008	Age	0.009
PASP	0.008	Frailty	0.008