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Non-invasive measurement of peripheral, central and 24-hour blood pressure in patients with continuous-flow left ventricular assist device. — Source link

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NONINVASIVE MEASUREMENT OF PERIPHERAL, CENTRAL AND 24-HOUR BLOOD PRESSURE IN PATIENTS WITH CONTINUOUS-FLOW LEFT VENTRICULAR ASSIST DEVICE

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In continuous-flow left ventricular assist devices (CF-LVAD) patients, blood pressure (BP) measurement outside the intensive care unit (ICU), relies on non-invasive methods such as automated oscillometric BP monitors and Doppler. However, the success rate of automated monitors is low due to the reduction in arterial pulse pressure (PP) (1) and Doppler readings are limited to a single BP number, making it difficult to acertain which BP component (i.e. systolic BP (SBP) or mean arterial pressure [MAP]) is being measured. Terumo Elemano™ BP monitor largely overcomes this limitation (2). Unfortunately, its production has been discontinued since 2014. Thus, introduction of alternative BP monitor devices appears necessary.

The Mobil-O-Graph device (IEM, Stolberg, Germany) is an automated oscillometric BP monitor, previously validated in non-LVAD patients (3). Beyond brachial BP readings, this monitor carries important additional features as it provides: i) estimation of central aortic BP and aortic pulse wave velocity (aPWV) through analysis of brachial pulse wave morphology, and ii) 24-hour ambulatory BP monitoring (ABPM) (4).

The present study tested the Mobil-O-Graph system with respect to: A) success rate, reproducibility and validity of BP measurement against the "gold standard" arterial-line (A-Line); B) estimation of central aortic BP and its relationship with peripheral brachial BP before and after CF-LVAD implantation; C) reliability of aPWV measurements on CF-LVAD support; and D) feasibility of 24-Hour ABPM in this patient population.

Methods are detailed in the online data supplement.

A) Success Rate, Reproducibility and Validity of Mobil-O-Graph Brachial BP Measurements

Thirty patients implanted with a HeartMate II (Abbott, IL, USA) were studied. Baseline characteristics are presented in Supplemental Table 1. In 27 (90%) patients, both A-line and Mobil-O-Graph measurements were obtained during the hospitalization for device implantation, 5.4±4.6 days after surgery. In 3 patients (10%), data were collected during readmission to the ICU.

We performed 90 measurement attempts in total using the Mobil-O-Graph. Seventy-four (82%) were successful (Supplemental Table 2). We were unable to obtain any valid reading in 3 patients (10%). A-line success rate was 100%. HeartMate II speed (range 8400 - 9800 rpm, median 9000 rpm) was associated with Mobil-O-Graph measurement success. Every 100 rpm increase in speed was associated with a 6.24% decrease in Mobil-O-Graph success ($P<0.05$). None of the other parameters listed in the Supplemental Methods section were associated with measurement success.

A-line and Mobil-O-Graph measurements were reproducible. Results of repeat within-device measures are presented in Supplemental Table 3 and Supplemental Table 4.

Mobil-O-Graph measurements demonstrated good correlations with A-line measurements (Figure 1 A-B-C). Overall, the correlation coefficients for A-line vs. Mobil-O-Graph were 0.84 ($P<0.001$) for SBP; 0.82 ($P<0.001$) for diastolic BP (DBP); and 0.87 ($P<0.001$) for MAP. Correlations and mean absolute differences (MADs) are presented in Supplemental Table 5. The respective MADs±SE between A-line and Mobil-O-Graph for SBP, DBP and MAP were 4.5±0.7 mmHg, 5.2±0.7 mmHg and 4.0±0.6 mmHg, respectively. Average differences±SD between A-line and Mobil-O-Graph were: -0.7±5.7 mmHg, -3.2±5.4 mmHg, and -2.4±4.5 mmHg for SBP, DBP and MAP, respectively (Supplemental Figure 1). Bland-Altman plots are presented in Figure 1 D-E-F and demonstrate an overall excellent agreement between A-line and Mobil-O-Graph independent of BP values. Notably, 93% of SBP, 93% of DBP and 100% of MAP values measured by Mobil-O-Graph were within 10 mmHg of A-line corresponding measurements.

B) Mobil-O-Graph Estimation of Central Aortic and Brachial BP Before and After LVAD Implantation

Central aortic and brachial BP was measured 1.9 ± 1.3 days pre- and 5.3 ± 5.6 days post-LVAD implantation in a subgroup of 10 patients. Baseline characteristics are presented in Supplemental Table 6. As expected, both central aortic and brachial PP were significantly lower after CF-LVAD implantation: 30±8 vs. 21±7 mmHg ($P=0.017$) and 40±10 vs. 25±8 mmHg ($P=0.002$), respectively

(Supplemental Table 7). Comparison of pre- vs. post-implantation brachial/central BP ratios (amplification) was significantly different for SBP (1.09 vs 1.03, $P<0.001$), MAP (1.03 vs 1.00, $P<0.001$) and PP (1.36 vs 1.19, $P<0.001$). A possible explanation of this finding is that CF-LVADs generate a more continuous and smother flow than normal hearts that may, in turn, create less peripheral wave reflections and, therefore, reduce the PP amplification.

C) Reliability of Mobil-O-Graph aPWV Measurement After LVAD Implantation

Pre- and post- implantation aPWV measurements were obtained 7.1 ± 5.6 days apart in the previous subgroup of 10 patients (Supplemental Table 6). No significant differences were observed between pre- and post- implantation measurements of aPWV: 8.4±1.5 vs. 8.4±1.6 m/s, $P=0.72$. In addition, data showed excellent correlations between pre and post measurement values ($r=0.99$, $P<0.001$) and Bland-Altman plot demonstrated an overall and valid (5) agreement between pre- and post-implantation aPWV independent from aPWV values, with all values within 0.6 m/sec difference between pre and post LVAD measurements (Supplemental Figure 2). These results suggest that implantation of a CF-LVAD did not impact the ability of the Mobil-O-Graph to provide reliable aPWV readings since structural properties of the aorta, which regulate aortic stiffness, are not expected to change over the time course of a few days (i.e. before vs. after LVAD surgery).

D) Mobil-O-Graph 24-Hour BP Monitoring

Characteristics of 15 HeartMate II outpatients fitted with the ABPM are presented in Supplemental Table 8. One patient was excluded because no valid measurement were obtained despite three attempts during the clinical encounter. Participants had an average of 24.8±9.5 valid measurements out of an average of 36.7±6.4 attempts (68%) over the 24-hour period. Only 2 patients had less than 50% BP readings. Results are shown in Supplemental Table 9. Fourteen (93%) patients had 24-hour MAP above 80 mmHg, thus exceeding values recommended by current guidelines (6). Blood pressure significantly declined at night, with a SBP and DBP night dipping of 5.5±5.0% and 4.2±4.0%, respectively. However, heart rate values remained similar during day and night time. Importantly, ABPM enabled identification of systolic hypertensive peaks (SBP≥140mmHg)

(Figure 2) in 4 (27%) patients and "unmask hypertension" (MAP values ≤ 80 mmHg during the clinical encounter, but >80 mmHg over a 24 hour period) in 2 (13%) patients.

This study reports for the first time that the Mobil-O-Graph device: a) has a high measurement success rate and offers accurate and reliable measurement of SBP, DBP and MAP; b) provides concurrent estimation of central aortic and brachial BP; c) offers aPWV measurements post-LVAD, which are consistent with those obtained pre-implantation; and d) provides 24-hour ABPM in CF-LVAD patients on HeartMate II support. The ability to assess central aortic and 24-hour BP in CF-LVAD patients appears particularly important as these hemodynamic parameters are more indicative, compared to isolated brachial BP readings, of the actual afterload the pump (and the left ventricle) has to operate against during support.

While the Mobil-O-Graph BP monitor offers providers an overall successful and valid technique for BP measurement, it carries a margin of error. For this reason, we agree with the current American Heart Association recommendation that the Mobil-O-Graph, similar to all oscillometric BP monitors, should be validated with each patient, against the gold standard A-line postoperatively, before the readings are accepted as reliable and valid (7). Successful BP readings were less frequent during ABPM than in the controlled ICU settings. However, ABPM was informative of 24 hour BP patterns in the majority of our patients since only 2 of them had a success rate <50%. One additional limitation is that our study did not include patients supported with centrifugal CF-LVADs.

Overall, our data suggest that the Mobil-O-Graph provides more advanced and comprehensive BP data than other BP devices in HeartMate II patients. This additional information may help providers to tailor antihypertensive management in the individual patient. Future studies in CF-LVAD patients may investigate whether Mobil-O-Graph guided BP management could help to reduce the risk of pump thrombosis, stroke and other cardiovascular complications which have been associated to poor BP control.

Disclosures

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Dr. Wassertheurer is inventor (not holder) of a patent used in the ARCSolver@ algorithms.

Dr. Cockcroft received equipment and travel grants from IEM.

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FIGURE LEGENDS

Figure 1. Scatter Plots of: A) Mean Mobil-O-Graph SBP vs. Mean A-line SBP; B) Mean A-line DBP vs. Mobil-O-Graph Mean DBP; C) Mean A-line MAP vs. Mean Mobil-O-Graph MAP.

Bland–Altman Plots Comparing: D) A-line SBP to Mobil-O-Graph SBP; E) A-line DBP to Mobil-O-Graph DBP; F) A-line MAP to Mobil-O-Graph MAP.

A-line = Arterial line; DBP = Systolic blood pressure; MAP = Mean arterial pressure; SBP = Systolic blood pressure.

Figure 2. Example of 24-hour Blood Pressure Profile in a Continuous Flow –Left Ventricular Assist Device Outpatient.

The gray area indicates night time. Hypertensive systolic blood pressure peaks are present at 8 PM, 1 AM, 12 PM.

SUPPLEMENTAL METHODS

Patient Population

A total of 30 inpatients implanted with an axial flow CF-LVAD, the Heart Mate II (Abbot, IL, USA), were prospectively studied using the Mobil-O-Graph device while their arterial BP was monitored from an arterial line (A-Line) in the intensive care unit at Columbia University Medical Center. Central aortic and brachial blood pressure (BP) and aortic pulse wave velocity (aPWV) were measured pre- and post- implantation in a subgroup of 10 patients. Finally, ambulatory blood pressure monitor (ABPM) was prospectively studied in a separate group of 15 outpatients on HeartMate II support. The study protocol was approved by the Columbia University Institutional Review Board and all patients provided a written consent.

Study Protocol

A) Success rate, reproducibility and validity of Mobil-O-Graph Brachial BP Measurement

Ability to provide a reading on any BP measurement attempt was defined as success. Peripheral BP was measured sequentially from an A-line and then the Mobil-O-Graph, as previously described (1)

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All Mobil-O-Graph measurements were obtained in the same arm as the A-line. The A-line was positioned approximately 15 cm distal to the antecubital fossa. Prior to recording, the A-line was flushed once, leveled to the pressure transducer and zeroed to barometric pressure (IntelliVue, Phillips, city, Netherlands). Mobil-O-Graph BP readings were taken according to manufacturer instructions (2) in triplicates, and the average of all valid measurements was used for subsequent analyses. All measurements were performed with the patient relaxed and in supine position. Mean arterial pressure for both the A-line and Mobil-O-Graph readings was calculated using the following formula*(3)*:

$$MAP = (SBP+2*DBP) / 3$$

During each assessment, systolic BP (SBP), diastolic BP (DBP), mean arterial pressure (MAP), Pulse Pressure, heart rate (HR), regularity of HR (based on telemetry monitoring), presence of pace maker, PR segment duration, QRS segment duration, QTC segment duration, ECG axis, age, gender, body mass index, cardiomyopathy etiology, bridge to transplantation status, flow, speed, power and pulsatility index were recorded. Of note, patients in atrial fibrillation but with regular ventricular pacing rate were labeled as "regular"; atrial fibrillation with an irregular ventricular rate and sinus rhythm with frequent premature atrial or ventricular complexes were labeled as "irregular".

B) Mobil-O-Graph estimation of central aortic BP and aPWV

The Mobil-O-Graph software uses the ARCSolver® algorithm to reconstruct aortic pressure waveform and thereby derives aortic BP and characteristic impedance. Design and function of this software is described in details elsewhere (4, 5). Briefly, the method assesses brachial artery pulse waves after a traditional oscillometric pressure measurement at diastolic pressure level for approximately 10 seconds using a conventional BP cuff. The peripheral wave forms are then transformed into the aortic wave by the means of a generalized transfer function utilizing frequency domain methods. Pulse wave analysis and wave separation based on impedance analysis are performed utilizing the derived aortic wave form. Vascular impedance is dependent on PP and arterial stiffness, wave shape and heart rate. Due to the generic model approach used by the ARCSolver® algorithm, transient changes in hemodynamics such as increased heart rate, altered pulsatility or pressure fluctuations, can be managed by the software without external control or statistical adjustment. Furthermore, the integration of impedance and central BP data allows estimation of aPWV (6).

All components of ARCSolver® software have been successfully validated invasively and non-invasively by different research groups in various cohorts, including coronary artery disease or end-stage renal disease patients (5-7). The frequency domain based approach further enables a flexible unsupervised adaption to changing pulse wave profiles by design. The above features support the use of ARCSolver® and Mobil-O-Graph® in the CF-LVAD patient population.

C) Reliability of Mobil-O-Graph aPWV measurement after LVAD implantation

Aortic PWV was measured and compared in 10 patients before and immediately after LVAD implantation. This design was based on the following rationale: i) Mobil-O-Graph aPWV measurements have been validated against intra-aortic catheter (6) and against Magnetic Resonance Imaging (MRI) (7) in patients without a CF-LVAD; and ii) structural properties of the aorta, such as aortic stiffness, are not expected to change over the time course of a few days (i.e. before vs. after LVAD surgery) (8, 9). Measurements were performed in triplicates with the Mobil-O-Graph before and after the implantation of the CF-LVAD and on the same arm. All patients measured pre implantation were free of mechanical circulatory support at the time of measurement.

D) Mobil-O-Graph 24-Hour BP monitoring

Ambulatory CF-LVAD patients on HeartMate II support who agreed to wear the Mobil-O-Graph device for 24 hours during their usual daily activities were studied. The Mobil-O-Graph BP cuff was placed around the patient's upper non-dominant arm during an outpatient clinical visit according to the manufacturer's guidelines. Patients were excluded if no valid measurement was obtained despite three attempts during the clinical encounter. Frequency of BP readings was set every 30 minutes during the day and every 60 minutes during the night. Day- and night-time periods were defined based on individual patient sleep habits (10). Twenty-four-hour BP and HR were recorded and analyzed.

Statistical Analysis

All analyses were performed in SAS version 9.4. Descriptive data are presented as proportions or means±SD (unless otherwise specified). Wilcoxon signed-rank test was used to compare pre- and post-implant measurements of aPWV. Validity and reliability were assessed using multiple approaches as previously described (1). Briefly, to investigate reproducibility of BP measures, mean absolute differences (MAD) was computed between the first and second repeat measures within each device. Additionally, intraclass correlation coefficients (ICC) were calculated using all three BP measures within each device and Pearson correlation coefficients were calculated between the 2^{nd} and 3^{rd} BP measures within the same device. To assess validity, MAD was calculated comparing BP values between A-line and Mobil-O-Graph. Bland-Altman plots were constructed to assess agreement between the two devices. Coefficients of variation were computed to compare the variability of BP measurements relative to the mean. To investigate predictors of device measurement success, Poisson regressions with robust error variances were used to regress measurement success on levels of clinically relevant variables and generate risk ratios. Pearson's correlation coefficients were also used to assess between-device agreement.

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SUPPLEMENTAL FIGURE LEGEND

Figure S1. Average Blood Pressure Values (±Standard Error) According to Measurement Device Among 27 Inpatients.

A-line = Arterial line; MAP = Mean arterial pressure.

Figure S2. A) Scatterplot of the Aortic Pulse Wave Velocity Pre- vs. Post-LVAD Implantation Among Inpatients; B) Bland–Altman Plot Comparing Pre-Implantation Aortic Pulse Wave Velocity to Post-Implantation Aortic Pulse Wave Velocity Among Inpatients.

Figure 1
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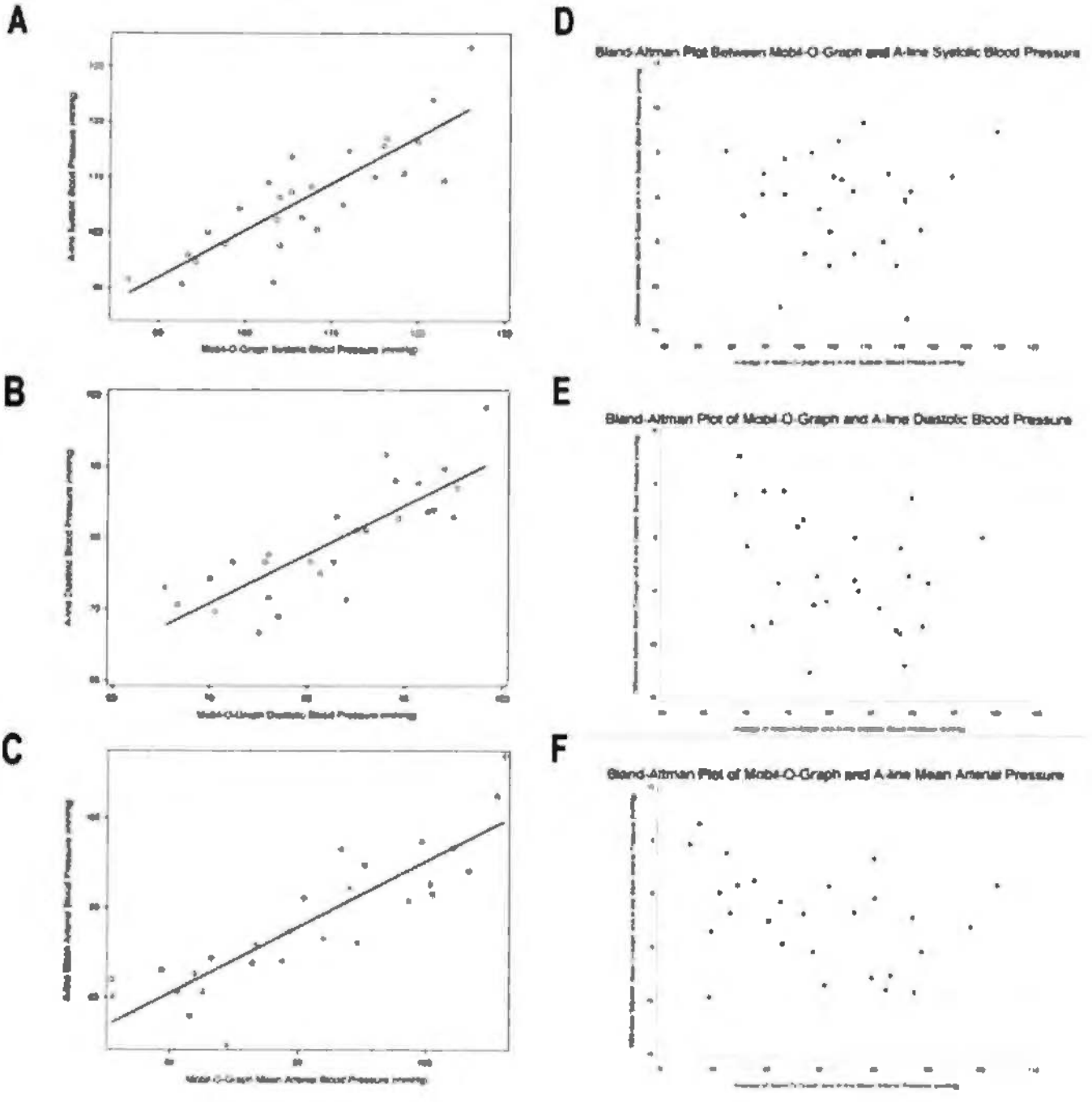

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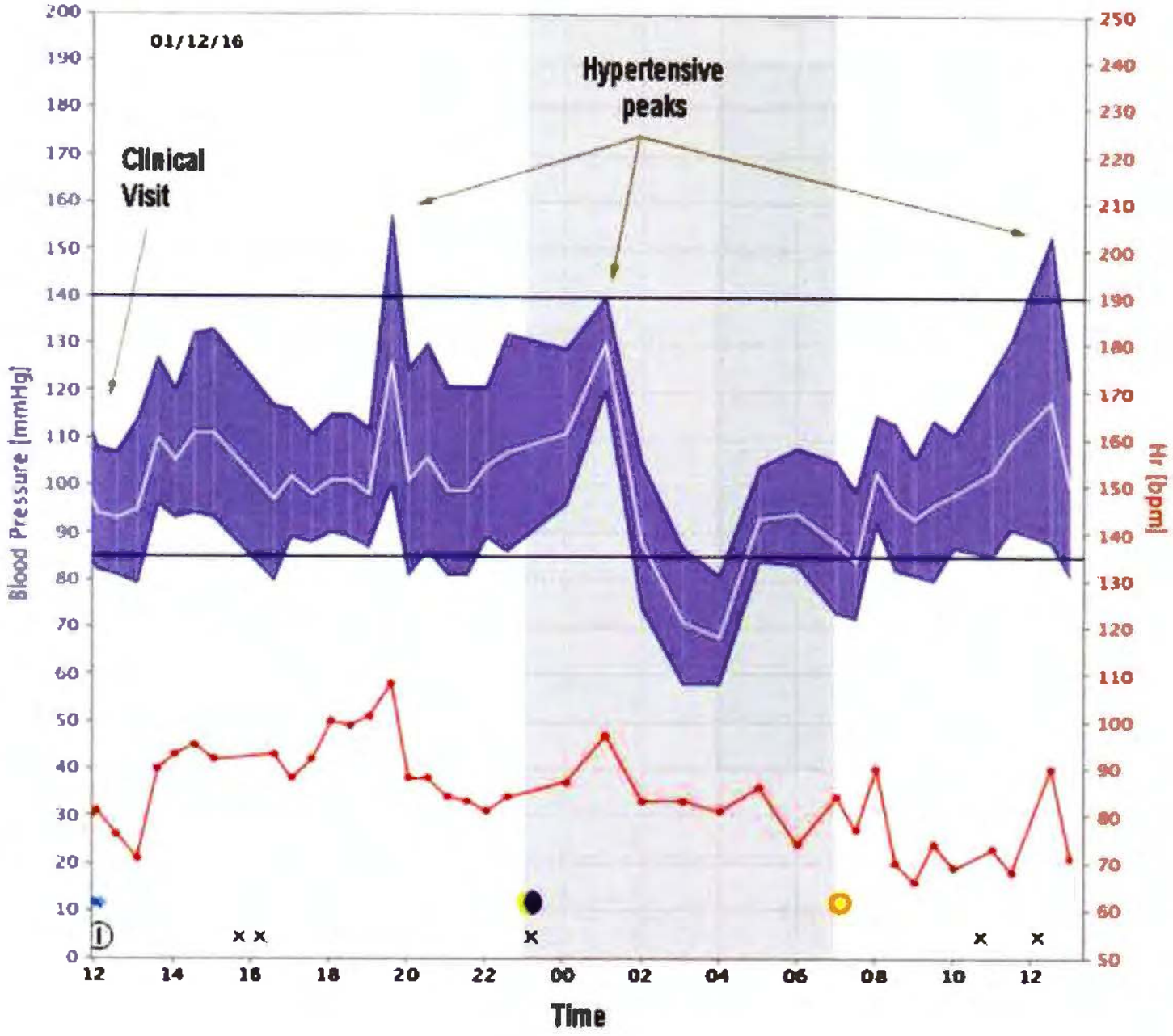

Figure S1
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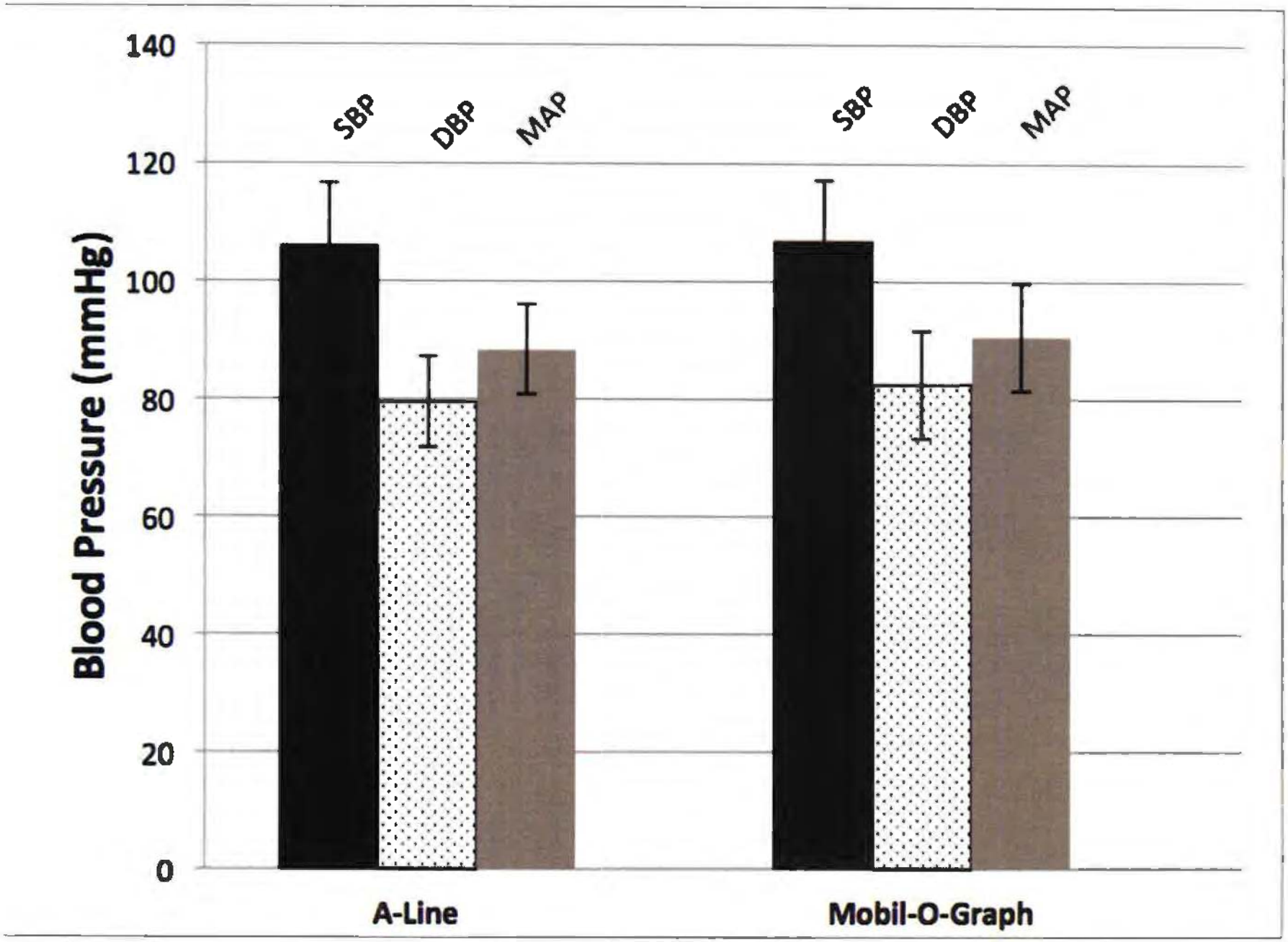

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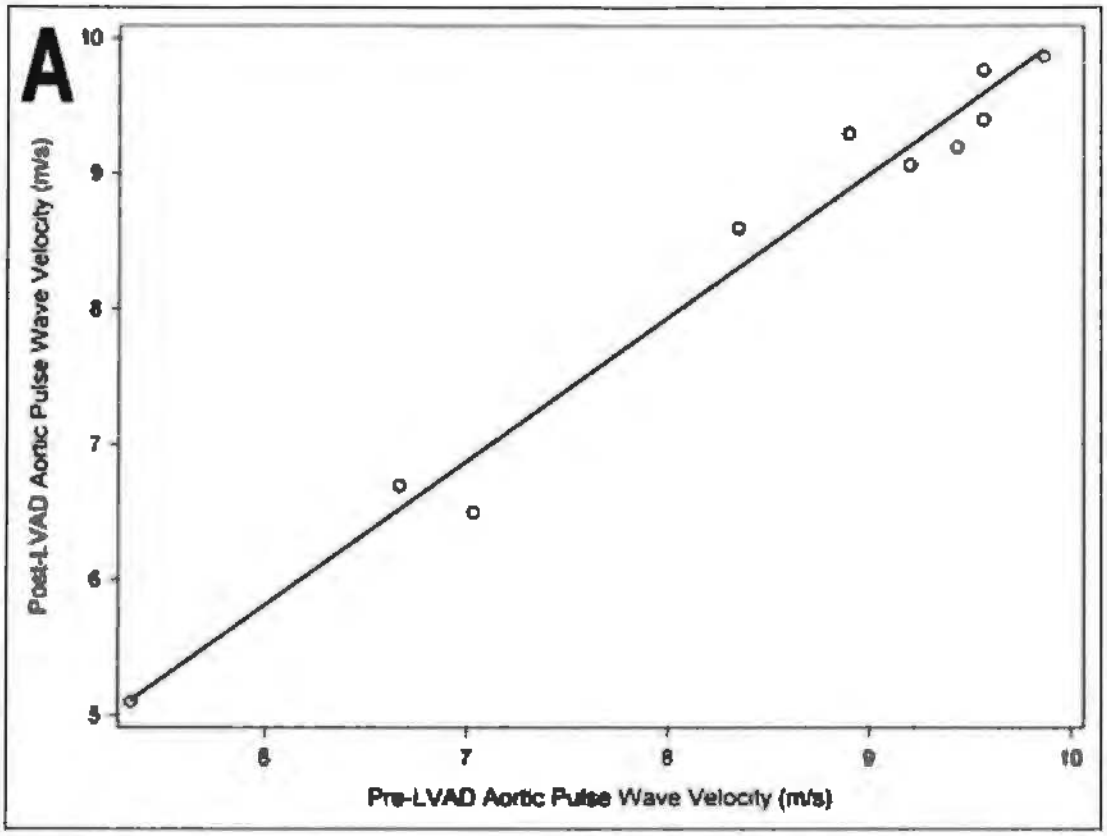

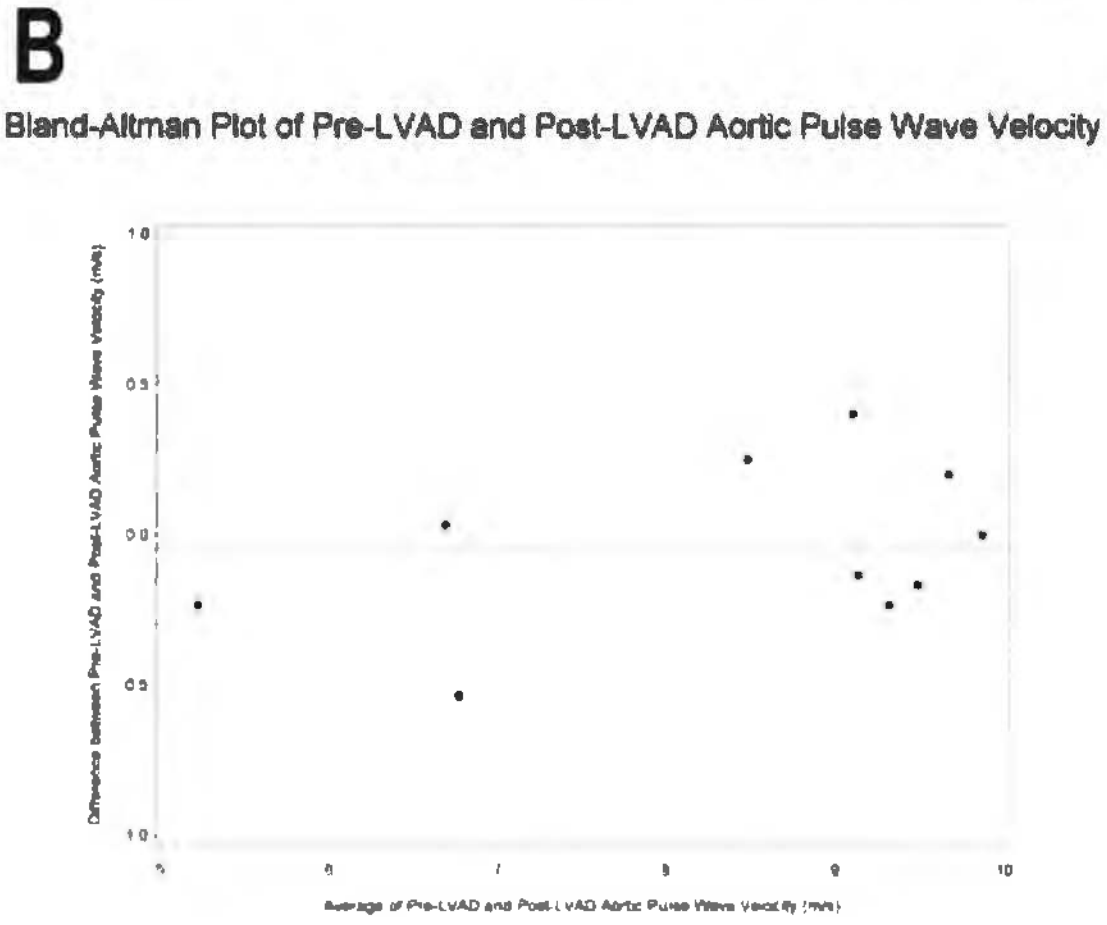

Table S1

Table S1. Characteristics of Patients Implanted With a Continuous-Flow Left Ventricular Assist Device Enrolled in the Validation Cohort of Mobil-O-Graph Against Arterial Line

	N=30
Age, years	56±13
Male, %	80
Ischemic etiology, %	47
Bridge to transplant, %	40
BMI (kg/m^2)	26.6±5.3
LVAD speed, rpm	9033±345
LVAD flow, l/min	4.9±1.3
LVAD Pulsatility index	6.9±1.0
LVAD Power, watt	5.2±0.9
HR, bpm	85.4±15.8

BMI = Body Mass Index; HR = Heart rate; LVAD = Left ventricular assist device.

Table S2. Blood Pressure Measurement Success Rates [95% Confidence Intervals] by Monitoring Device Among Inpatients With Continuous-Flow Left Ventricular Assist Device

	Total Successful BP Attempts	3 Successful BP Attempts	At Least 2 Successful BP Attempts	At Least 1 Successful BP Attempt
A-line, %	100	100	100	100
Mobil-O-Graph, %	82 [74,90]	73[57,89]	83 [69,97]	90 [79,101]

A-line= Arterial line; BP = Blood pressure

Table S3

Table S3. Within Device Reproducibility of Blood Pressure Measurements Defined Using Interclass (Pearson's R) and Intraclass Correlation Coefficients (ICC) Among Patients With Continuous-Flow Left Ventricular Assist Device.

Method	SBP		DBP		MAP	
	r	ICC (CI 95%)	r	ICC (CI 95%)	r	ICC (CI 95%)
A-line	0.91	0.90 (0.88,0.91)	0.95	0.93 (0.92,0.94)	0.95	0.92 (0.91,0.93)
Mobil-O-Graph	0.85	0.85 (0.83,0.87)	0.89	0.89 (0.87,0.91)	0.93	0.91 (0.90,0.92)

All correlation coefficients have $P<0.0001$.

A-line = Arterial line; SBP = Systolic blood pressure; DBP= Diastolic blood pressure; MAP = Mean arterial pressure; r = Pearson interclass correlation coefficient; ICC = Intra class correlation coefficients. Intra class correlation coefficients can be interpreted as the percentage of total variation in a given blood pressure measure that is explained by between Person's variation. Higher numbers indicated better reproducibility; for example a value of 1 means that 100% of blood pressure variation is due to between Person's variation or in other words, the measure is perfectly reproducible.

Table S4. Comparison of Within Device Mean Absolute Differences (Standard Error) Among Patients With Continuous-Flow Left Ventricular Assist Device. Comparisons Restricted to Sample With at Least Two Measures for Each Respective Device

Method	SBP	DBP	MAP
A-Line (n=30)	3.3(0.5)	1.8(0.3)	1.9(0.3)
Mobil-O-Graph (n=25)	4.3(0.8)	3.6(0.6)	2.7(0.5)

A-line = Arterial line; SBP = Systolic blood pressure; DBP= Diastolic blood pressure; MAP = Mean arterial pressure.

Table S5. Between-Device Mean Absolute Differences (Standard Error, SE) and Correlations Among Inpatients With Continuous-Flow Left Ventricular Assist Device

	SBP		DBP		MAP	
	MAD (SE)	r (*P*- value)	MAD (SE)	r (*P*- value)	MAD (SE)	r (*P*-value)
Mobil-O-Graph vs. A-line (n=27)	4.5 (0.7)	0.84 (<0.001)	5.2 (0.7)	0.82 (<0.001)	4.0 (0.6)	0.87 (<0.001)

A-Line = Arterial line; DBP = Diastolic blood pressure; MAD = Mean absolute difference; MAP = Mean arterial pressure;; r = Pearson interclass correlation coefficient; SBP = Systolic blood pressure

Table S6

Table S6. Characteristics of Patients With Continuous-Flow Left Ventricular Assist Device Enrolled for Concurrent Central Aortic and Brachial Blood Pressure and Aortic Pulse Wave Velocity Analysis

	N=10
Age, years	62±12
Male, %	90
Ischemic etiology, %	50
Bridge to transplant, %	30
BMI, kg/m^2	23.5±2.4
LVAD speed, rpm	8939±267
LVAD flow, l/min	4.5±0.6
LVAD Pulsatility index	7.1±0.7
LVAD Power, watt	4.9±0.5

BMI = body mass index; LVAD = left ventricular assist device.

Table S7. Central and Brachial BP Comparison Pre- and Post-LVAD Implantation

	Pre	Post	*P*-Value
Central SBP, mmHg	103±13	104±10	0.68
Central DBP, mmHg	73±8	82±8	0.002
Central MAP, mmHg	83±9	90±8	0.007
Central PP, mmHg	30±8	21±7	0.017
Brachial SBP, mmHg	111±14	106±9	0.15
Brachial DBP, mmHg	72±8	81±8	0.001
Brachial MAP, mmHg	85±9	90±8	0.03
Brachial PP, mmHg	40±10	25±8	0.002

DBP = Diastolic blood pressure; HR = Heart rate; MAP = Mean arterial pressure; PP = Pulse pressure; SBP = Systolic blood pressure.

Table S8

Table S8. Characteristics of Patients With Continuous-Flow Left Ventricular Assist Device Enrolled for 24-Hour Blood Pressure Analysis

	N=15
Age, years	57±3.7
Male, %	75
BMI, kg/m^2	27.7±1.7
Ischemic etiology, %	31
Bridge to transplant, %	44
Duration of support, days	402±108
LVAD speed, rpm	8721±271
LVAD Flow, l/min	4.8±0.3
LVAD Pulsatility Index	6.4±0.3
LVAD Power, watt	5.2±0.3

BMI = body mass index; LVAD = left ventricular assist device.

Table S9. Average Results of 24-hour BP Analysis Among Outpatients With Continuous-Flow Left Ventricular Assist Device

	Average 24h	Average Day	Average Night	*P*-value Day vs. Night
SBP, mmHg	104±7	105±8	99±7	<0.001
DBP, mmHg	78±8	79±8	73±9	<0.001
MAP, mmHg	89±7	91±7	86±7	<0.001
HR, bpm	78±14	78±14	77±15	0.84
Max SBP, mmHg	128±17	128±17	111±10	<0.001
Min SBP, mmHg	81±6	81±6	86±10	0.12
Max DBP, mmHg	95±10	93±8	87±10	0.01
Min DBP, mmHg	57±11	58±12	64±12	0.04
Max MAP, mmHg	107±9	107±8	97±11	<0.001
Min MAP, mmHg	71±9	73±9	76±10	0.3

DBP = Diastolic blood pressure; HR = Heart rate; MAP = Mean arterial pressure; PP = Pulse pressure; SBP = Systolic blood pressure