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**BJAN-D-20-00328 - Original Investigation****Agreement analysis of Stroke Volume and Cardiac Output measurement between a Oscillometric Device and Transthoracic Echocardiogram in normotensive individuals: a preliminary report****Alejandro Godoy<sup>a,\*</sup>, Alejandro Contreras<sup>b,c</sup>, Aldo Tabares<sup>a,c</sup>**

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**Abstract**

*Introduction:* The evaluation of stroke volume (SV) is useful in research and patient care. To accomplish this, an ideal device should be noninvasive, continuous, reliable, and reproducible. The Mobil-O-Graph (MOG) is a noninvasive oscillometric matrix validated for measuring aortic and peripheral blood pressure, which through conversion algorithms, can estimate hemodynamic parameters.

*Objectives:* To compare the Mobil-O-Graph (MOG) measurement of stroke volume, cardiac output, and cardiac index with the transthoracic echocardiogram (TTE).

*Methods:* Healthy volunteers aged 18 years or older were included. Two-dimensional TTEs were performed by a single operator. Subsequently, the measurement of noninvasive hemodynamics with MOG was performed with the operator blind to the results of the echocardiogram. Correlation analyses between stroke volume, cardiac output, and cardiac index parameters were performed. The degree of agreement between the methods was verified using the Bland Altman method.

*Results:* A total of 38 volunteers were enrolled with a mean age of  $27.6 \pm 3.8$  years; 21 (55%) were male. The SV by TTE was  $76.8 \pm 19.5$  mL and  $75.7 \pm 19.3$  mL by MOG,  $Rho = 0.726$ ,  $p < 0.0001$ . The CO by TTE was  $5.04 \pm 0.8$  mL.min<sup>-1</sup> and  $5.1 \pm 0.8$  mL.min<sup>-1</sup> by MOG  $Rho = 0.510$ ,  $p = 0.001$ . Bland-Altman plots showed a good concordance between the two techniques.

*Conclusions:* Our study shows that the measurement of SV and CO by noninvasive hemodynamics with the MOG device offers a good concordance with the TTE with very few values beyond the confidence limits.

## **KEYWORDS**

Stroke volume;

Cardiac output;

Noninvasive hemodynamics oscillometric method;

Mobil-O-Graph

## **Introduction**

The measurement of stroke volume and different hemodynamic parameters is useful in clinical scenarios such as surgical risk assessment, follow-up of patients taking cardiotoxic drugs, follow-up of patients with heart failure, and continuous monitoring in intensive care units.[1,2]

Traditionally, hemodynamic evaluation is performed through the use of invasive methods, such as thermodilution, which is considered the gold standard technique.[3] The disadvantage of these methods is the invasiveness, the associated risks, and the difficulty of repeating the measurements over time.

Recently, devices that study the functional dynamics of the cardiovascular system have been incorporated as an aid in the management of arterial hypertension and heart failure, optimizing pharmacological therapy and improving morbidity and mortality.[4,5]

Noninvasive methods commonly used in hemodynamic evaluation include impedance cardiography and echocardiography. Thoracic impedance cardiography (ICG) provides continuous beat-by-beat data using algorithms to derive stroke volume from thoracic volume changes.

Echocardiography is well-established clinically, providing a detailed and accurate evaluation of cardiac function and anatomy. However, its results are highly operator-dependent and sometimes limited by the position and physical structure of the patient.[1]

Recently, noninvasive pulse wave analysis methods that depend on personal data, such as age, height, and weight, have been incorporated into clinical practice.[6]

Within the systems that analyze the pulse wave, the Mobil-O-Graph (MOG) pulse wave analysis (PWA) monitoring system (I.E.M. GmbH, Stolberg, Germany) is a commercially available oscillometric matrix. Through the aortic waveform and by using PWA and wave separation, the central aortic augmentation index (Aix), increase pressure (AP), feed (Pf), and recoil (Pb) are obtained as components of the pulse wave and the reflection coefficient.[7]

MOG measures central pressures using brachial waveforms and the ARCSolver algorithm and estimates the cardiac index. Central systolic pressure, calculated with a transfer-function-like method (ARCSolver algorithm), using waveforms using brachial cuff-based waveform recordings, is suited to provide a realistic estimation of central systolic pressure.

This method is based on the arterial tree model in what receives a prescribed input aortic flow waveform or is coupled with a time-varying elastance model for the contractility of the left ventricle.

The arterial tree model is fully characterized by its geometry, the distensibility of all arterial segments, and the peripheral impedances (described by terminal compliances and resistances). Additionally, aortic flow is needed as a proximal boundary condition.

In clinical practice, MOG PWA is used to evaluate pulse wave velocity (PWV) and central aortic pressure (CAP), for which it has been validated against reference methods.[8]

Incorporating the noninvasive assessment of stroke volume (SV) and cardiac output (CO) in addition to CAP and PWV within a single measurement would be of value in the bedside evaluation and treatment of hypertensive and cardiac failure patients.

The objective of the present work is to compare a noninvasive, alternative MOG in the measurement of SV, CO, and cardiac index (CI) versus the measurements made by transthoracic echocardiogram (TTE) in normotensive healthy individuals.

## Methods

A prospective, open, non-randomized study was conducted on healthy volunteers. Patients aged 18 years or older were included. At the time of the study, all the participants were in sinus rhythm and had no significant valvulopathies or stenosis of the upper limb arteries. Patients with trivial mitral regurgitation were not excluded.

Anthropometric parameters and risk factors for cardiovascular disease were reviewed. All the participants signed informed consent. This protocol was previously approved by the Institutional Committee for Health Research Ethics (CIEIS) of the Hospital Privado Universitario de Córdoba.

Transthoracic echocardiography was performed using a commercially available GE Vivid E9 (GE Medical Systems) with a 3.5-MHz transducer. Two-dimensional images and Doppler data were acquired according to current guidelines (Lang RM), ensuring the normality of the cardiac anatomy.

Stroke volume was calculated by multiplying the velocity-time integral of systolic flow velocities in the left ventricular outflow tract by the cross-sectional area of the outflow tract calculated from the diameter of the aortic annulus, assuming a circular geometry. All standard measurements were averaged from three beats.[9]

Left ventricular outflow tract (LVOT) velocity and velocity time integral (VTI) were acquired using pulsed-wave Doppler in the apical five-chamber view. The sample volume was positioned at valve level and then moved apically until valve noise was no longer detected. Pulsed-wave Doppler signals of LVOT systolic flow were manually traced on the modal curve. A sweep speed of  $100 \text{ mm}\cdot\text{s}^{-1}$  was used. Three cardiac cycles were averaged.

LVOT diameter was measured in a zoomed longitudinal parasternal long-axis view in a mid-systolic frame, using the inner edge-to-inner-edge technique from the point of aortic cusp insertion into the interventricular septum to the point of aortic cusp insertion into the intervalvular fibrosa. LV SV was calculated using pulsed-wave Doppler as LV outflow tract area\* LV outflow tract velocity-time integral.

For the performance of noninvasive hemodynamics, the MOG system, a blood pressure cuff was placed on the left arm. The device determines the brachial (peripheral) (PAS) and diastolic (DBP) systolic pressure and the waveform.

The data acquisition process for the algorithms is divided into two separate cycles. The first is used to calculate systolic and diastolic pressure by analyzing the oscillometric amplitudes recorded. The pulse wave is recorded during the second period. The algorithm for determining systolic and diastolic blood pressure is based on the analysis of the characteristics of the wavelengths of the oscillations.

The signal strength is recorded in the pressure sensor employing a 10-bit analog-digital converter, while the blood pressure cuff placed on the upper arm continuously deflates a super-systolic pressure level to zero.[6]

Depending on the blood pressure determined, the pulse wave is recorded and prepared for additional numerical treatment. By processing the signal by applying various filter techniques, the peripheral pressure wave is obtained.

Based on the generated aortic pulse wave, cardiovascular parameters are calculated using the idea that left ventricular ejection is subject to a principle of optimization.[10]

### *Statistical analysis*

The quantitative variables were expressed as mean  $\pm$  standard deviation and the median (range) where appropriate. The categorical variables were expressed as percentages. The normality in the distribution of the data was evaluated by the Shapiro-Wilk test.

Correlation analyses were performed between SV, CO, and CI parameters measured between TTE and MOG. For this analysis, the Spearman correlation coefficient was used. It was estimated that a good degree of correlation would be  $r \geq 0.5$ .

It was calculated that 35 individuals should be included in the study to account for an alpha error of 5% and a statistical power of 80%, and considering 20% of measurement errors or loss of measurements. The degree of agreement between the methods was calculated using the Bland Altman plot.[11]

A value of  $p < 0.05$  was considered statistically significant.

Statistical analysis was performed with IBM SPSS Statistics Base 22.0 and Med Calc® V10.2.0.0

### **Results**

From April 1, 2018, to January 31, 2019, 38 healthy volunteers 18 years of age or older were enrolled in the study. The mean age of the participants was  $27.6 \pm 3.8$  years, and 21(55%) were male. The baseline and clinical characteristics of the population are detailed in Table 1.

Table 2 presents the mean and correlation values of SV, CO, and CI as measured by MOG and TTE. It was observed that the SV and CO values were very close as measured by both devices and that the correlation values were good and statistically significant. The agreement values presented by the Bland-Altman analysis in Figure 1 showed good values with very few cases beyond the 95% confidence interval range.

### **Conclusions**

Our study shows that the measurement of SV, CO, and CI with MOG offers measurements with good agreement with the transthoracic echocardiogram. Concordance is good in both men and women (data not shown).

Previous studies that compared the ejection fraction measurement by impedance cardiography with echocardiography showed a poor correlation between both methods due to the difficulty of applying an algorithm based on the truncated cone model.[12,13]

Our hypothesis is based on Bauer et al., who demonstrated the validity of ejection duration measurement with the oscillometric MOG compared with the tonometric device SphygmoCor.[14] Previously, different mathematical algorithms were correctly validated for the calculation of SV, comparing the oscillometric methods to the value obtained by thermodilution as a reference instrument. The measurement of stroke volume with oscillometric devices may be affected by artifacts caused by patient movement, cardiovascular diseases, or vascular tree alterations. However, it offers a rapid measurement, with a good correlation with invasive devices that are available for medical use in outpatient practice.[15]

Critchley and Critchley[16] point out that any evaluation of cardiac output measurement devices must take into account the accuracy of the reference method. Previous studies categorize the echocardiogram validation as satisfactory against the gold standard of thermodilution, adding validity to the reference method used in this study.[17,18]

The measurement of cardiac output with magnetic resonance has been validated in previous studies presenting difficulties such as time management and processing of images, costs, and operator dependence.[19,20]

Our work has limitations. First, the study population comprises young people without proven heart disease, and therefore our results cannot be extrapolated to patients with impaired cardiac output, arrhythmias, valve abnormalities, or upper extremity arterial stenosis. Second, although the study conditions were standardized, the SV measurements were not simultaneous, which could have introduced differences in the values obtained.

Third, although the echocardiogram could be argued to be a reference standard in the calculation of SV, in clinical practice, the echocardiogram is the most commonly used noninvasive technique to evaluate the left ventricular ejection fraction since it is readily available in most institutions and can be performed at the bedside. Finally, even though the cohort of patients is small, it manages to demonstrate the usefulness of this method.

We conclude that the measurement of SV and CO by the oscillometric MOG offers results comparable to TTE in a population of healthy, young, normotensive adults.

If these data are confirmed in studies with a greater number of patients and with different alterations to left ventricular function, the measurement of SV by this noninvasive and inexpensive technique could be used in the follow-up and monitoring of patients with impaired left ventricular function.

### **Conflicts of interest**

The authors declare no conflicts of interest.

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**Table 1** - Demographic and clinical characteristics of the population.

	n = 38	Mean $\pm$ SD
Male sex	21	
Age (years)		27.63 $\pm$ 3.8
Weight (kg)		69.16 $\pm$ 13.1
Height (cm)		169.76 $\pm$ 12.6
BMI (kg.m <sup>-2</sup> )		23.8 $\pm$ 2.7
Body surface area (m <sup>2</sup> )		1.8 $\pm$ 0.2
Smoking	2	
Arterial hypertension	0	
Diabetes	0	
Systolic blood pressure		118 $\pm$ 12.5
Diastolic blood pressure		73 $\pm$ 8
Central systolic blood pressure		108 $\pm$ 11
Central diastolic blood pressure		74 $\pm$ 8

BMI, body mass index.

**Table 2** - Spearman correlation of stroke volume, cardiac output, and cardiac index by echocardiogram and Mobil-O-Graph.

	MOG	TTE	Rho	95% CI	<i>p</i>
Stroke Volume (mL)	75.7 $\pm$ 19.3	76.8 $\pm$ 19.5	0.73	0.530–0.849	< 0.0001
Cardiac Output (mL.min <sup>-1</sup> )	5.04 $\pm$ 0.8	5.1 $\pm$ 0.8	0.51	0.232–0.716	0.0018
Cardiac Index (mL.min <sup>-1</sup> .m <sup>-2</sup> )	2.80 $\pm$ 0.4	2.85 $\pm$ 0.4	0.368	0.055–0.615	0.0251

The values were expressed as mean  $\pm$  SD.

TTE, transthoracic echocardiogram; MOG, Mobil-O-Graph.

**Figure 1** - Bland-Altman plot showing the mean difference between the SV, CO, and CI by echocardiogram (Echo) and Mobil-O-Graph (Mobil). The black line is the mean of the differences; dotted lines show both lower and upper 95% confidence intervals (n = 38).

