

Cuffless 24-Hour Ambulatory Blood Pressure Monitoring

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High blood pressure (BP), or hypertension, is the main risk factor for cardiovascular diseases and the root cause for approximately ten million deaths each year. Its formal diagnosis often requires 24-hour ambulatory blood pressure monitoring (ABPM), with cuff-based BP measurements cycling at 20- or 30-minute intervals. The procedure can be quite obtrusive, particularly during nighttime, where the inflation of the cuff can disturb sleep and lead to non-representative BP readings. In the present study, we demonstrate the feasibility of using a cuffless optical watch-like sensor for 24-hour ABPM, paving the way for a new branch of cuffless and patient-friendly solutions in the thriving market of hypertension diagnosis.

ABPM is increasingly used in clinical practice for the formal diagnosis of hypertension, and particularly indicated in cases of suspected white-coat effect, masked, or nocturnal hypertension. However, the use of cuffs for ABPM may be painful and cause discomfort, particularly at night, where it may even provoke arousal from sleep and lead to non-representative nighttime BP values^[1]. The purpose of the present study was to investigate the feasibility of using a cuffless watch-like photoplethysmographic (PPG) sensor for 24-hour ABPM by comparing the PPG-based BP estimates with conventional cuff-derived ABPM values.

Our study (clinicaltrials.gov: NCT04119518) was conducted in 70 participants (43±18 y, 35 with hypertension, 41 male) undergoing cuff-based ABPM. Systolic (SBP) and diastolic (DBP) BP values were estimated by our patented pulse wave analysis algorithm oBPM™^[2,3] from the measured PPG signals. At the contralateral side of the cuff, a CSEM-designed PPG sensor was worn at the wrist or upper arm. Following a calibration procedure, the PPG-based daytime and nighttime BP estimates were compared to their cuff-based counterparts. The agreement between both methods was evaluated via the mean and standard deviation (SD) of their differences by Bland-Altman analysis. The agreement on the nocturnal dipping estimates of both devices was also assessed. Finally, the concordance rate was assessed as the percentage of dipping values showing a concordant direction (dipping vs. non-dipping) between both methods.

The data of 4 participants were incomplete due to technical issues and had to be rejected prior to analysis. In 4 additional participants, the PPG data quality was insufficient to provide enough BP estimates, probably due to poor sensor tightening. As shown in Table 1 and Figure 1, for the remaining 62 participants, we found differences between the daytime PPG-based and cuff-based BP estimates all falling within the limits required by the ISO 81060-2:2013 standard for non-invasive sphygmomanometers.

Good agreement was found between the PPG-based and the cuff-based daytime and nighttime BP averages, with generally negligible (~1 mmHg) biases. The direction of dipping was highly concordant between both methods. The estimation of its amplitude showed a low bias (~1%) but a non-negligible spread (SD), which can be in part attributed to the uncertainty on the cuff-based dipping estimates (95% confidence interval range of 12.5% and 16.5% on average for SBP and DBP, respectively),

more than twice than their PPG-based counterparts (5.7% and 7.8%). Although our study was designed as a method-comparison feasibility study, these results open the way for the development of highly demanded cuffless alternatives in the growing field of hypertension diagnosis.

Table 1: Agreement (bias and SD of the differences) between the PPG-derived BP values estimated by our pulse wave analysis algorithm oBPM™^[2,3] compared to conventional cuff-based measurements.

BP	Daytime bias ± SD	Nighttime bias ± SD	Dipping bias ± SD (concordance rate)
SBP	-0.9 ± 3.6 mmHg	-0.8 ± 6.8 mmHg	0.1 ± 6.8% (97%)
DBP	-1.4 ± 2.9 mmHg	0.5 ± 5.3 mmHg	-2.0 ± 8.6% (97%)

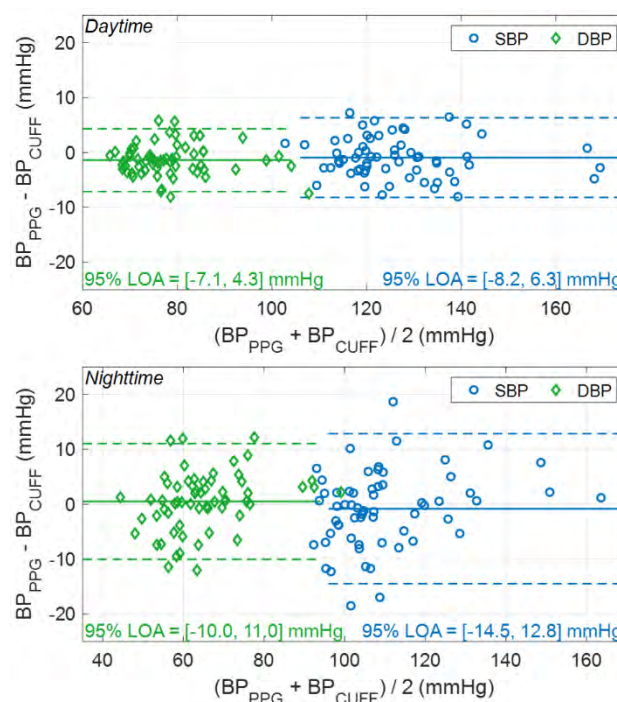


Figure 1: Agreement (Bland-Altman plots) between the PPG-based and cuff-based daytime and nighttime BP values. LOA: limits of agreement.

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