

Comparison of a tonometric with an oscillometric blood pressure monitoring device over 24 hours of ambulatory use

Martin Miranda Hurtado, Javiera Reyes Vasquez and Maria Rodriguez-Fernandez

Purpose Multiple devices capable of measuring ambulatory blood pressure without cuffs have been recently developed and it is required that they offer high-accuracy measurements. The purpose of this prospective study was to compare the performance of a tonometric blood pressure monitor with that of an oscillometric cuff-based device used as a reference in healthy and hypertensive subjects over 24 hours of ambulatory use.

Materials and methods Conventional oscillometric cuff-based device (Oscar 2; Sun Tech Medical) was placed in the left arm of 33 subjects, and a watch-type device based on the tonometric method (Bpro; HealthSTATS International, Singapore) was positioned in the right wrist. Both devices were synchronized to measure simultaneously over 24 hours.

Results The difference between the means over 24 hours of the oscillometric and the tonometric devices was -0.9 mmHg for SBP and -4.5 mmHg for DBP; the standard deviations were 14.7 and 12.2 mmHg, respectively. Greater differences in bias and dispersion were observed overnight than during the daytime. The accuracy of the tonometric

device for diagnosing hypertension was 75% and for detecting the non-dipper profile, 48%.

Conclusion The test device presented a high disagreement (especially during the night) compared to the oscillometric cuff-based device against which it was initially calibrated. This disagreement resulted in limited accuracy for diagnosing patients with suspected arterial hypertension and detecting non-dipper profiles. *Blood Press Monit* 26: 149–155 Copyright © 2021 Wolters Kluwer Health, Inc. All rights reserved.

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Institute for Biological and Medical Engineering, Schools of Engineering, Medicine and Biological Sciences, Pontificia Universidad Catolica de Chile, Macul, Santiago, Chile

Correspondence to Maria Rodriguez-Fernandez, PhD, Institute for Biological and Medical Engineering, Schools of Engineering, Medicine and Biological Sciences, Pontificia Universidad Catolica de Chile, Avda. Vicuña Mackenna 4860, Macul, Santiago 7820436, Chile
Tel: +56 2 2354 1106; e-mail: marodriguezf@uc.cl

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Introduction

Hypertension has a high prevalence worldwide and it is considered one of the most important risk factors for the development of cardiovascular diseases, such as heart failure or stroke [1]. About 3.5 billion adults have high blood pressure (BP) worldwide, and one in four adults are hypertensive [2]. Because of this pathology's impact, healthcare providers routinely assess BP in primary health care; however, a large percentage of patients are not diagnosed opportunely [3]. The auscultatory technique in the office or clinic is the most accurate method to obtain a patient's BP. Still, it is not exempt from operator-dependent errors and delivers BP's values at a single time of the day [4].

Automatic devices capable of performing 24 hours ambulatory BP monitoring (ABPM) are used to obtain a complete BP profile. This information allows the clinician to detect abnormalities in BP regulation, such as non-dipper profile (a decline of BP during the night lower than 10%), and to optimally schedule the administration of antihypertensive medications during the day [5]. Disadvantages of ABPM using standard oscillometric devices are limitations in the patients' regular activities

and discomfort due to cuff inflation, particularly during nighttime sleep.

Multiple devices capable of measuring BP without cuffs, such as those based on pulse transit time [6] and peripheral arterial tonometry [7], have been recently developed. Given the high impact of hypertension on patient's health, new monitoring devices should offer high-accuracy measurements. Several validation protocols have been developed to establish minimum accuracy standards. A BP monitor is considered acceptable if it reaches a certain BP measurement accuracy with an estimated probability of tolerable error (≤ 10 mmHg) $\geq 85\%$ [8].

In 2008, a cuffless, wrist-type ABPM based on radial artery applanation tonometry called BPro was developed. The first validation study used a modified version of the European Society of Hypertension (ESH) protocol [9] and the Association for the Advancement of Medical Instrumentation (AAMI) standard [10] and found that BPro was accurate under various stationary conditions [11]. A few years later, BPro was compared with a standard invasive method showing widespread differences of central SBP measurements; therefore,

the level of accuracy required by the AAMI, the British Hypertension Society (BHS), and the ESH was not fulfilled [12]. Komori *et al.* [7] tested the BPro device under ambulatory conditions for the first time showing fair agreement with an oscillometric monitor and stability to arm positions changes. Hornstrup *et al.* [13] recently compared the BPro with a conventional oscillometric device under ambulatory conditions showing that BPro leads to misclassification of hypertension and non-dipping in patients diagnosed with hypertension. However, these two studies did not take the BP measurements with both devices simultaneously so they compared average values.

The current study aims to compare BPro's performance over 24 hours of ABPM with a validated oscillometric cuff-based monitor typically used to diagnose hypertension. The tonometric device's performance was separately evaluated during daytime and sleep time. Further, its ability to diagnose hypertension and the non-dipper profile was assessed.

Methods

Device details

Bpro (HealthSTATS International, Singapore) is a watch-type device with a tonometer positioned in the radial artery to measure its pulse wave. The device requires calibration with a brachial BP monitor before starting the measurements. The average of three measurements taken on the same arm was used for the calibration. As a reference device, a conventional cuff device based on the oscillometric method (Oscar 2; Sun Tech Medical, Morrisville, North Carolina, USA) and validated by the BHS and the ESH 2002 [14] was used.

The BPro was introduced in the laboratory in August 2018 and the whole team was familiar with BPro, Oscar 2, and the procedure at the beginning of the study. All the measurements were obtained by experienced nurses (M.M.H. and J.R.V.).

Recruitment

In this single-center study, 33 individuals were recruited voluntarily between September 2018 and July 2019 through social media and flyers posted at the Pontificia Universidad Católica de Chile, where the study took place. Participants were normotensive and hypertensive consecutive adults older than 25 years. The number of subjects and the inclusion criteria were chosen following the ESH-IP protocol [15]. Each participant was informed about the procedure and gave informed consent. Anthropometry was performed on each of the subjects, including brachial circumference. Subjects with a difference in SBP or DBP between arms higher than 10 mmHg were not considered for the study.

Ethics approval

The study protocol complies with the Declaration of Helsinki. It was approved by the Scientific Ethics Committee of the Faculty of Medicine of the Pontificia Universidad Católica de Chile on 21 June 2018 (Project 170706006) and registered (NCT 03997461).

Procedure

Left-arm brachial circumference was measured for each participant to select the cuff according to the provider's instructions of the oscillometric device. Three measurements were made on each arm with the reference device to assess the pressure difference between both extremities. For the calibration of the BPro, the average of three measurements of the oscillometric device on the right arm with differences between them less than 10 mmHg was used. Measurements were made with patients seated, resting on the back of the chair, legs apart, and the arm at the heart's level as indicated by the manufacturer. The tonometric device was placed on the right wrist and the oscillometric device on the left arm. BPro performed measurements every 15 minutes for 24 hours, while the cuff-based device was programmed to measure every 15 minutes while the subject was awake and every 30 minutes during sleep time. BPro could not be scheduled every 30 minutes during sleep time but additional measurements do not increase sleep disturbances as the tonometric device does not inflate or change at all during measurements. Participants were asked about their sleep schedules to program the device, and they were instructed to keep a sleep diary to define real sleep and awake BP values. Both devices were synchronized to perform the measurements simultaneously.

Statistical analysis

In the presence of missing data in one of the devices, the other device's measurement was eliminated to use both devices' information at each time. Bland-Altman plots [16] comparing the differences between the two devices' measurements with their averages were used to assess both devices' agreement. Differences greater than 30 mmHg were set at 30 mmHg in the graph, as recommended in O'Brien [15].

Normality of continuous variables was determined by visual inspection of the histogram and the Q-Q plot, and by the Kolmogorov-Smirnov test. Due to the lack of normality in the distribution of the differences, a non-parametric method was used to compare both devices' measurements, namely, the Wilcoxon signed-rank test. The average values for each subject's measurements are shown as the mean \pm SD.

The diagnosis criteria for hypertension using ABPM differ from the office. The limit for normal BP is 130 mmHg for the mean of the SBP over 24 hours and 80 mmHg for the mean of the DBP, while the limits for daytime

averages of SBP and DBP are 135 and 85 mmHg, respectively. Finally, during nighttime, the mean SBP limit is 120 mmHg, and 70 mmHg for DBP. Moreover, a nocturnal BP fall of more than 10% of daytime values was used to classify patients as dippers [17]. These criteria were used to diagnose the subjects using the values of the measurements obtained for each of the devices and the results were compared.

To assess whether the BPro device losses calibration over time, the values of the differences between devices were grouped in 1-hour groups by the time they were taken with respect to the beginning of the measurements, and every group was represented graphically as a box and whisker plot. The time course of the absolute differences was fitted to a linear regression model to determine the slope's value.

Results

Study participants

In the current study, 33 subjects were enrolled and 42.4% were men. The mean age was 38.9 ± 12.2 and the mean

BMI was $26.5 \pm 3.9 \text{ kg/m}^2$. Table 1 shows the baseline characteristics of the sample. The mean SBP and DBP for wrist device calibration were $120.8 \pm 17.3 \text{ mmHg}$ and $72.3 \pm 8.1 \text{ mmHg}$. The mean arm circumference was $29.2 \pm 2.8 \text{ cm}$, while the mean of the SBP and DBP difference between both arms were $4.0 \pm 3.0 \text{ mmHg}$ and $3.3 \pm 2.7 \text{ mmHg}$, respectively.

Effective ambulatory blood pressure monitoring measurements

The mean of the absolute differences in time between the measures of both devices was 1.8 ± 1.7 minutes and the mean of the relative differences was 0.4 ± 2.5 minutes. The tonometric device had 62.9% of effective measurements in 24 hours, while the oscillometric device had 80.4% of effective measurements. The total number of measurements taken simultaneously by both devices was 1100 during wakefulness, 363 during sleep and, therefore, 1463 over 24 hours.

Agreement between paired measurements

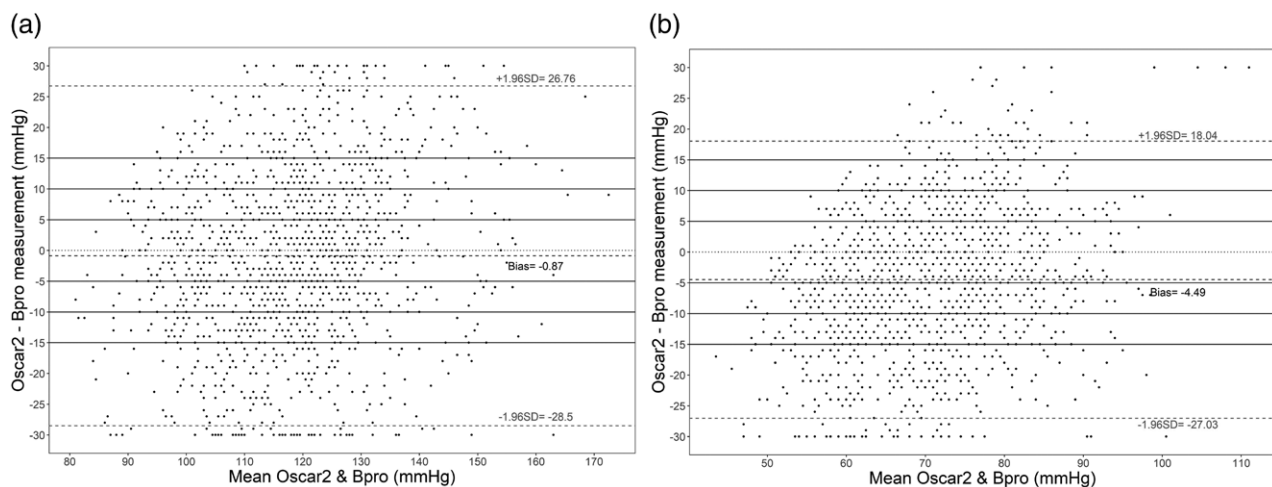
Figures 1–3 show Bland–Altman plots comparing the measurements between both devices over 24 hours, during wakefulness and sleep, respectively. For SBP and DBP in 24 hours, the bias was -0.9 and -4.5 mmHg , respectively. The limits of agreement for SBP were $+26.3$ and -28.5 mmHg , while for DBP they were $+18.5$ and -27.0 mmHg . For the measurements obtained during the day, while the subjects were awake, SBP bias was 0.4 mmHg with a limit of agreement of $+27.6$ and -26.8 mmHg , while DBP bias was -3.0 mmHg with a limit of agreement of $+19.7$ and -25.6 mmHg . Finally, for the measurements made during the night sleep, SBP bias was -4.8 mmHg with limits of agreement of $+22.9$ and -32.4 mmHg , while DBP bias was -9.1 mmHg with limits of agreement of $+10.4$ and -28.7 mmHg .

Table 1 Baseline characteristics of the participants

Characteristics	Overall (<i>n</i> = 33)
Sex (male), <i>n</i>	14 (42.4)
Age (years)	38.9 (12.2)
BMI (kg/m^2)	26.5 (3.9)
Arm circumference (cm)	29.2 (2.8)
SBP difference right versus left arm (mmHg)	4.0 (3)
DBP difference right versus left arm (mmHg)	3.3 (2.7)
Calibration SBP (mmHg)	120.8 (17.3)
Calibration DBP (mmHg)	72.3 (8.09)
Mean valid 24-hour cuff device readings (<i>n</i>)	73.5 (10.3)
Mean valid 24-hour wrist device readings (<i>n</i>)	60.4 (24.8)
Time differences between devices (minutes)	1.8 (1.7)
Antihypertensive treatment (<i>n</i>)	4 (12.1)

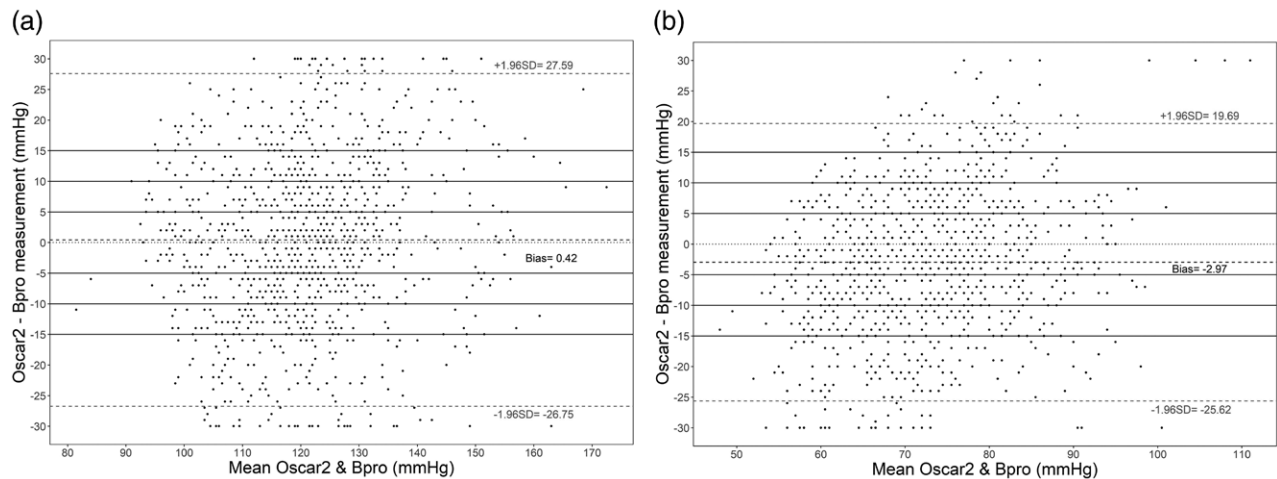
Data are mean (\pm SD) or counts (percentage), as appropriate.

Fig. 1



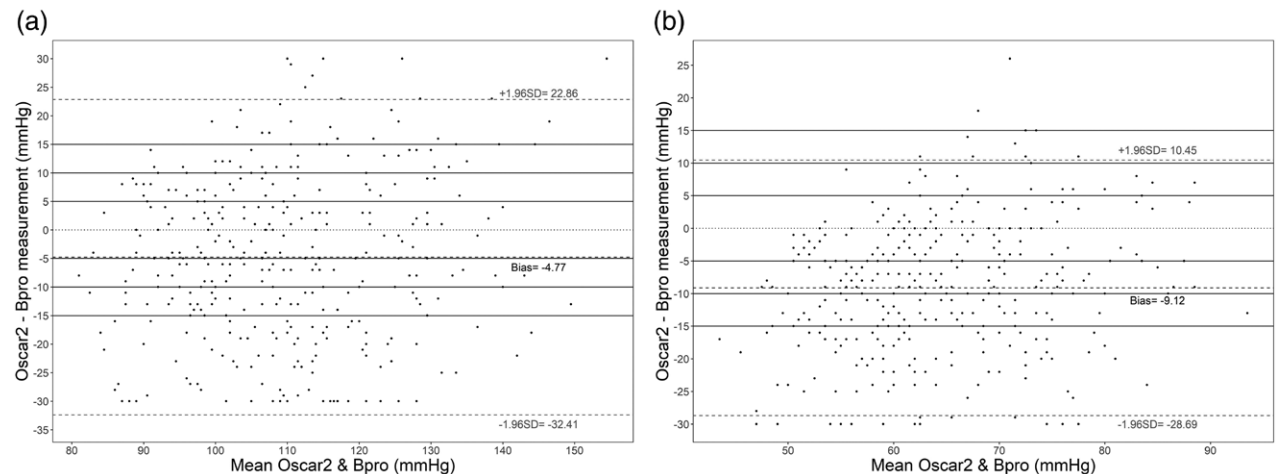
Bland–Altman plot comparing paired (a) SBP and (b) DBP values taken by the wrist and the arm devices over 24 h.

Fig. 2



Bland-Altman plot comparing paired (a) SBP and (b) DBP values taken by the wrist and the arm devices while the subjects were awake.

Fig. 3



Bland-Altman plot comparing paired (a) SBP and (b) DBP values taken by the wrist and the arm devices while the subjects were asleep.

The histogram of the differences between both devices and the Q-Q plot showed a non-normal distribution. Also, the Kolmogorov-Smirnov normality test returned a *P*-value of 0.001 and $7e-5$ for SBP and DBP, respectively. Therefore, the non-parametric Wilcoxon Signed-Rank test was selected to compare both devices' paired data over 24 hours, awake and asleep (Tables 2 and 3).

As shown in Table 2, the 24-hour means of the SBP of the oscillometric and the tonometric device were 117.2 ± 17.4 mmHg and 118.6 ± 15.1 mmHg, respectively. Although the difference between the means is only -0.9 mmHg, the SD is 14.7 mmHg and the mean of the absolute value of the differences between paired measurements is 11.6 mmHg. The 24-hour mean DBP

of the oscillometric and the tonometric device was 68.5 ± 13.4 mmHg and 73 ± 10.2 mmHg, respectively, with a mean of the absolute differences of 10.0 mmHg. The mean absolute difference during wakefulness was 11.3 mmHg for SBP and 9.6 mmHg for DBP. During night sleep, the mean absolute disagreement during wakefulness was 12.6 mmHg for SBP, and 11.2 mmHg for DBP. The differences between the two devices' measurements were statistically significant in all the cases except for SBP during wakefulness.

Agreement per subject

Regarding the degree of agreement of SBP over 24 hours between the arm and the wrist device per subject, Table 3

Table 2 Comparison of mean SBP and DBP measurements

	Oscar 2	Bpro	Mean diff	Mean abs diff	P-value
SBP					
24 hours	117.7 (17.4)	118.6 (15.1)	−0.9 (14.7)	11.6 (9.0)	0.037
Awake	121.2 (16.1)	120.8 (14.4)	0.4 (14.4)	11.3 (8.9)	0.24
Asleep	106.8 (16.6)	111.9 (15.2)	5.1 (15.0)	12.6 (9.5)	<2.1e-9
DBP					
24 hours	68.5 (13.5)	72.0 (10.2)	−4.5 (12.2)	10.0 (8.3)	<2.2e-16
Awake	71.5 (12.7)	74.4 (10.1)	−3.0 (12.3)	9.6 (8.1)	<2.2e-16
Asleep	59.5 (11.4)	68.8 (9.6)	−9.3 (10.5)	11.2 (8.5)	<2.2e-16

Data are mean (±SD).

Table 3 Agreement between the wrist device and the cuff device, mean of the differences between SBP and DBP values

n (%)	SBP (33)	DBP (33)
24-hour		
≤5 mmHg	12 (36.4)	15 (45.5)
≤10 mmHg	29 (87.9)	26 (78.8)
≤15 mmHg	31 (93.9)	32 (97.0)
Awake		
≤5 mmHg	10 (30.0)	16 (48.5)
≤10 mmHg	27 (81.8)	27 (81.8)
≤15 mmHg	32 (97.0)	32 (97.0)
Asleep		
≤5 mmHg	12 (36.4)	7 (21.2)
≤10 mmHg	20 (60.6)	16 (48.5)
≤15 mmHg	28 (84.8)	26 (78.8)

shows that 36.4% of the subjects had a mean value of the differences between paired measurements less than or equal to 5 mmHg, while 87.9 and 93.9% had a mean difference of less than or equal to 10 and 15 mmHg, respectively. Similarly, for DBP over 24 hours, the percentage of subjects with mean absolute differences less than or equal to 5, 10, and 15 mmHg were 45.5, 78.8, and 97.0%, respectively.

However, when the absolute values for the differences between paired measurements are considered (Table 4), no subject had a mean less than or equal to 5 mmHg, while 18.2 and 87.9% had a mean difference of less than or equal to 10 and 15 mmHg, respectively. For the 24-hour DBP, the percentage of subjects with mean absolute differences less than or equal to 5, 10, and 15 mmHg were 0, 57.6, and 87.9%, respectively.

Diagnosis accuracy

More interestingly, with the results obtained, 12 patients would be diagnosed with hypertension following the BPro measurements but only five of them would have the same diagnosis when using the cuff-based device. Moreover, one subject would be diagnosed with hypertension by the cuff-based device and missed by BPro, showing a diagnostic accuracy of 75%. From these subjects, six showed a 24-hours mean BP higher than the normotensive limit with each device but only four of these subjects coincide. Regarding measurements during wakefulness, only three subjects exceeded the limit with BPro and four with the oscillometric device, although only two subjects exceeded the limits with both devices.

Table 4 Agreement between the wrist device and the cuff device, mean of the absolute differences between SBP and DBP values

n (%)	SBP(33)	DBP(33)
24-hour		
≤5 mmHg	0	0
≤10 mmHg	6 (18.2)	19 (57.6)
≤15 mmHg	29 (87.9)	29 (87.9)
Awake		
≤5 mmHg	0 (0.0)	1 (3.0)
≤10 mmHg	11 (33.3)	19 (57.6)
≤15 mmHg	30 (90.9)	31 (93.9)
Asleep		
≤5 mmHg	0 (0.0)	1 (3.0)
≤10 mmHg	9 (27.3)	14 (42.4)
≤15 mmHg	26 (78.8)	24 (72.7)

Concerning nighttime sleep measurements, BPro found 12 subjects with nocturnal hypertension but only five cases were confirmed with the oscillometric device. Moreover, concerning the nocturnal dip, BPro measurements indicate that 20 subjects are non-dipper (60.7%) but only five of these cases (15.1%) were confirmed by the cuff-based monitor. In comparison, two subjects (6.1%) were classified as dipper by BPro and as non-dipper as per the oscillometric device. This results in a 48% accuracy for detecting non-dippers.

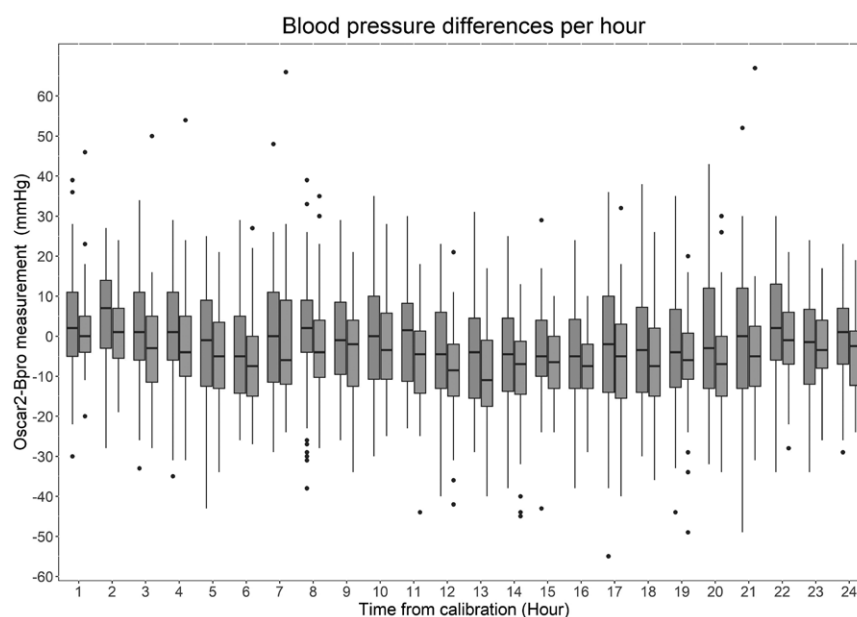
Performance over time

Figure 4 shows a box-and-whisker plot depicting BP differences between both devices for all the subjects at the different hours from the beginning of the experiment. Moreover, the time course of the absolute values of the differences between devices was fitted to a linear regression showing that the slope is not significantly different than zero, suggesting no loss of calibration overtime at the time frame considered by the study.

Discussion

In this study, a BP monitor based on radial artery tonometry was compared with an oscillometric device typically used in outpatient monitoring. The methodology was designed considering some aspects of international validation protocols such as the ESH-IP. However, since there is no recognized standard protocol for cuffless monitors, validation of the test device was not the objective of this study. Moreover, none of the standard validation protocols considers the pair-wise comparison

Fig. 4



Box and whisker plot. Each box and whisker represents the group of the differences between measurements taken for all subjects over 1 hour. The red boxes represent the SBP and the blue boxes the DBP.

of simultaneously taken measurements of the test device with respect to the reference device for 24 hours, as performed in this study.

The differences in the means between both devices are close to zero but the SD is not lower than 10 mmHg as required by most validation standards [18]; moreover, the mean of the absolute differences over 24 hours is higher than 10.0 mmHg for both SBP and DBP. Also, the mean of the absolute differences was higher than 5 mmHg for all the subjects. A high dispersion and large confidence intervals represent a low agreement of the test device, which could lead to errors in the diagnosis of hypertension and the detection of altered circadian patterns.

Bigger differences in bias and dispersion were observed during nighttime sleep time than during wakefulness. The reason for this result could be that the calibration of the device was performed in a sitting position, so the device may not be able to adjust well to the hemodynamic changes produced by changes in position, giving worse results when the subject is sleeping in horizontal position. The differences between devices showed no tendency to increase over time, so it can be assumed that the calibration was maintained from the beginning of the test but might change depending on the posture.

The average time difference between both devices was lower than in previous studies but no improvement in the performance of Bpro was seen by this reduction as

hypothesized in Komori *et al.* [7]. The monitors were compared for a larger window of time than in previous studies and under normal living conditions, representing a more realistic scenario of ABPM.

Since not all the aspects of the ESH-IP protocol [18] were considered, this study presents the following limitations. In the first place, the BP ranges of the participants were limited (most participants were healthy subjects), with a narrow range of brachial circumferences (only the standard cuff was used), and with a limited age range (most participants were young adults). Considering this lack of diversity, the results cannot be considered definite and more studies are needed to define the performance of the tonometric device in the general population.

To sum up, the results obtained in the present study show that BPro has a low agreement with the reference device over 24 hours of ambulatory conditions. Moreover, BPro showed limited accuracy for diagnosing patients with suspected arterial hypertension and non-dipper profile so its use for this purpose should be further investigated.

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Clinical trial registration: NCT03997461.

Conflicts of interest

There are no conflicts of interest.

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