Comparison Between a Medical-Grade Device and a Cuffless Consumer-Grade Device for Day and Night Blood Pressure Monitoring

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Abstract

Hypertension affects 1 in 3 adults worldwide and is the leading global cause of death. Most hypertension cases remain undiagnosed, which poses a serious threat to global health. To address this, wearable cuffless devices aim to unobtrusively monitor blood pressure (BP). Our aim was to validate a consumer-grade cuffless wearable blood pressure monitor (WBPM) using a medical-grade ambulatory device (ABPM), for reference. 29 participants (range 20-62 years old, 16 females) simultaneously wore the WBPM and ABPM for 24 hours. The ABPM measured at set intervals of 30 or 60 minutes, during day and night-time respectively. Readings from the WBPM were automatically taken at rest only. Mean and standard deviation of systolic and diastolic BP readings were measured during 24-hours, during day (06:00-22:00) and night (20:00-06:00). Readings were paired if they were taken ≤10 minutes apart, and if heart rate was within ±10bpm. For all intervals, mean systolic and diastolic BP showed a low to moderate correlation (0.27 – 0.41), small biases (~ ±5 mmHg), large limits of agreement (~ ±30 mmHg for systolic and ±20 mmHg for diastolic) and median percentage absolute error ~10%. Agreement for standard deviation of BP was poor. This data can help to inform future research into the potential utility of WBPM in hypertension and cardiovascular disease prevention.

1. Introduction

Blood pressure (BP) measurements are formed of two components: systolic and diastolic, which represent blood flow during different stages of the cardiac cycle [1]. Hypertension, broadly classified by a measurement of >140/90mmHg, is a substantial global health issue, affecting 1 in 3 adults worldwide [2]. Hypertension is a significant risk factor for cardiovascular diseases, linked with 50% of all heart disease and stroke related deaths, as well as being a primary risk factor for deaths worldwide [1]. An important issue herein lies in the current diagnostic process, with approximately half of all hypertensive patients being unaware of their condition [2]. It is therefore clear that a more proficient and accessible method of BP monitoring would be beneficial to rapidly identify and treat hypertension, minimising its potential progression into cardiovascular diseases.

The most recent BP monitoring guidelines advocate for use of out-of-office BP monitoring, to provide a more holistic insight into a patient's BP over a sustained period (commonly 24 hours) and to reduce bias related to office BP monitoring, such as masked and white coat hypertension [3]. The current gold standard method for BP measurement is the Ambulatory Blood Pressure Monitor (ABPM). This is a cuff-based device that presents challenges to patients through intermittent disruption, discomfort, and inconvenience. Therefore, a continuous, non-invasive method of BP monitoring would revolutionise the hypertension diagnostic process, providing a comprehensive and efficient analysis of BP trends [4].

Aktiia is a consumer-grade cuffless wearable blood pressure monitor (WBPM) which generates readings based on photoplethysmography signals. Only a few studies have assessed its accuracy so far, and these have indicated potential clinical benefits [5,6,7]. Furthermore, thus far, there have been no direct comparisons between this WBPM and a medical-grade ABPM overnight, with present data limited to daytime hours only [8]. Data from night-time BP measurements can be crucial in informing decisions regarding patient care and can be a strong indicator of cardiovascular risk [9]. Therefore, data showing the validity of WBPMs during this critical period could prove useful when determining their use in clinical practice.

The aim of this study was to validate the WBPM over a continuous 24-hour period, using the ABPM (IEM Mobil-o-graph 24 hr ABPM) as a reference.

2. Methodology

2.1. Study Protocol

29 participants (20-62 years, 16 females, 18 of South Asian Heritage, weight 50-106 kg, height 152-190 cm) wore both the WBPM (Aktiia) and ABPM (Mobil-o-graph) simultaneously, for 24 hours. Participants were first fitted with the WBPM bracelet (Figure 1b), which was initialised and calibrated using a cuffed BP device (Figure 1a), allowing for patient specific parameters to be set. If the same patient were to use this WBPM, the current guidelines indicate for re-calibration of the bracelet every month. In this study, the bracelet was re-calibrated for every participant, so that personalised BP parameters could be accurately set. The ABPM was set up on the opposite arm to the bracelet, where it measured BP every 30 minutes between 08:00-22:00 and every 60 minutes between 22:00-08:00. While ABPM readings were taken at set intervals, the WBPM measured BP automatically, multiple times an hour and only at rest.

Figure 1. Equipment required for the initialization of the Aktiia bracelet (adapted from [10])

2.2. Statistical Analysis

Mean and standard deviation of systolic and diastolic BP was calculated from both devices during the 24 hours, during daytime (06:00-22:00) and night-time (22:00-06:00). For ABPM readings, only measurements which were classified as 'very good' or 'good' by the device software were used (this information was not available in 7 participants). To improve comparability, a pairing strategy was also implemented, in which mean BP estimates were taken only including readings taken no more than 10 minutes apart and with absolute heart rate differences ≤ 10 bpm. The results from both the WBPM and ABPM were compared using Pearson's correlation coefficient, Bland Altman analysis (bias and limits of agreement) and absolute percentage differences. Distributions are reported as median (interquartile range) and differences between measures are assessed using the Wilcoxon rank sum test.

3. Results

An example of systolic and diastolic readings from the two devices over 24 hours in a study participant is shown in Figure 2.

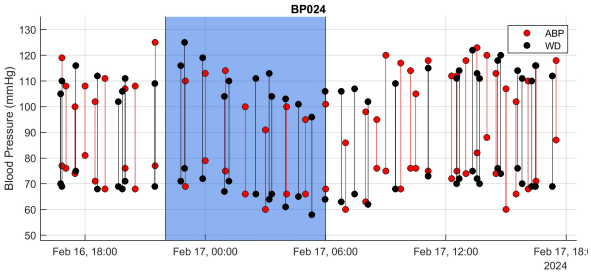

Figure 2. Example of diastolic and systolic readings from the ABPM (red) and WBPM (black) over 24 hours. The blue area represents night-time.

According to ABPM, the mean 24 hour systolic and diastolic readings were 117.1 (109.5 – 126.1) mmHg and 73.6 (68.7 – 80.2) mmHg, respectively, and SD across 24 hours was 13.0 (10.0 – 14.5) mmHg systolic and 10.4 (8.2 – 13.0) mmHg diastolic. WBPM conveyed similar mean systolic BP (114.4 (104.7 – 132.3) mmHg, P=0.45), lower mean diastolic BP (69.0 (62.4 – 75.9) mmHg, P=0.02), and much lower standard deviation for both systolic (7.0 (5.7 – 8.3) mmHg, P<0.001) and diastolic (4.9 (4.4 - 5.9) mmHg, P<0.001) BP.

Figure 3 shows correlation and Bland-Altman plots for mean systolic and diastolic BP across 24 hours, where average BP was estimated without pairing readings. For systolic BP, correlation, bias and limits of agreement were 0.32, -0.6 mmHg and -31.6 – +30.3 mmHg. For diastolic BP, they were 0.39, -5.3 mmHg and -21.4 – +10.9 mmHg.

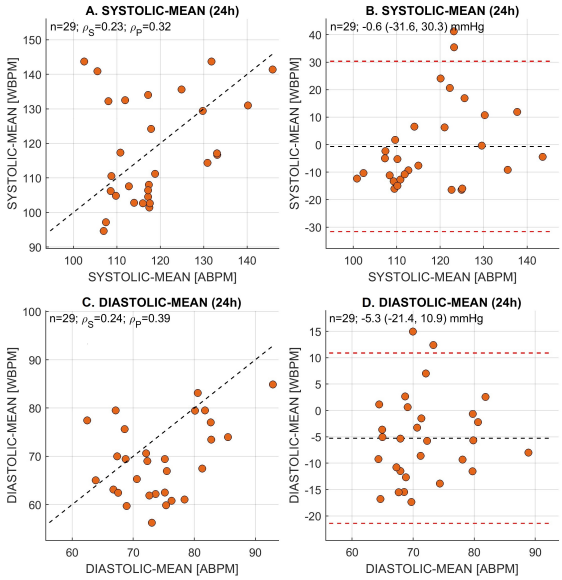

Figure 3. Correlation and Bland-Altman plots for 24-hour mean blood pressure. Estimates obtained without pairing readings based on timing or heart rate. ABPM and WBPM: Ambulatory and Wearable blood pressure monitors.

Table 1. Metrics of agreement for mean (m) and standard deviation (sd) of systolic (SBP) and diastolic (DBP) blood pressure measured over 24 hours, day (d) and night (n). cc: Correlation coefficient. LoA: Limits of agreement. Estimates obtained without pairing readings.

	cc	Bias (LoA) mmHg	Absolute Diff Med (IQR) (%)
SBP-m-24	0.32	-0.6 (-31.6, 30.3)	9.6 (5.7, 12.6)
SBP-m-d	0.32	-1.1 (-31.6, 29.3)	9.8 (5.8, 12.4)
SBP-m-n	0.27	4.1 (-30.6, 38.8)	9.6 (4.4, 17.4)
SBP-sd-24	0.01	-5.5 (-13.3, 2.2)	42.4 (35.1, 53.7)
SBP-sd-d	-0.04	-5.5 (-13.9, 2.8)	49.0 (31.0, 55.8)
SBP-sd-n	-0.05	-4.2 (-15.6, 7.2)	45.2 (21.9, 65.7)
DBP-m-24	0.39	-5.3 (-21.4, 10.9)	10.2 (4.4, 16.9)
DBP-m-d	0.41	-5.7 (-21.7, 10.3)	10.1 (5.5, 16.4)
DBP-m-n	0.41	-0.4 (-18.2, 17.4)	11.8 (5.3, 15.5)
DBP-sd-24	0.01	-5.2 (-11.9, 1.5)	49.1 (39.1, 58.8)
DBP-sd-d	-0.12	-5.0 (-12.4, 2.4)	50.1 (39.8, 64.8)
DBP-sd-n	0.45	-4.7 (-12.1, 2.8)	54.2 (44.0, 65.8)

Table 2. Metrics of agreement for mean (m) and standard deviation (sd) of systolic (SBP) and diastolic (DBP) blood pressure measured over 24 hours, day (d) and night (n). cc: Correlation coefficient. LoA: Limits of agreement. Estimates obtained pairing readings based on timing and heart rate.

	cc	Bias (LoA) mmHg	Absolute Diff Med (IQR) (%)
SBP-m-24	0.25	0.1 (-33.0, 33.1)	10.2 (5.4, 14.7)
SBP-m-d	0.24	-0.7 (-33.7, 32.3)	9.8 (5.5, 15.7)
SBP-m-n	0.38	3.7 (-31.3, 38.6)	10.6 (6.8, 14.5)
SBP-sd-24	-0.06	-5.0 (-14.2, 4.2)	39.7 (23.8, 55.6)
SBP-sd-d	0.00	-4.9 (-13.9, 4.1)	44.2 (31.4, 60.4)
SBP-sd-n	0.40	-2.2 (-13.1, 8.8)	53.3 (26.6, 73.1)
DBP-m-24	0.34	-4.5 (-22.5, 13.5)	11.0 (5.6, 16.9)
DBP-m-d	0.32	-5.2 (-23.5, 13.1)	11.6 (5.5, 16.5)
DBP-m-n	0.38	-0.5 (-22.1, 21.1)	14.6 (4.6, 18.2)
DBP-sd-24	0.25	-4.4 (-10.3, 1.6)	50.0 (38.3, 61.4)
DBP-sd-d	-0.04	-4.0 (-11.2, 3.2)	52.5 (26.7, 71.0)
DBP-sd-n	0.49	-3.5 (-13.0, 6.1)	63.9 (50.0, 83.3)

Metrics of agreement for mean and standard deviation of systolic and diastolic BP measures before and after pairing readings based on timing and heart rate are reported in Table 1 and 2, respectively. Agreement was similar during day and night-time, and after only pairing the readings within 10 minutes, with a similar heart rate. Across the 6 configurations, mean diastolic and systolic BP showed correlation coefficient ranging between 0.24 – 0.41, bias between -5.7 – 4.1 mmHg, limits of agreements ranging between ±20 mmHg for diastolic and ±30 mmHg for systolic BP, with median absolute percentage differences ~10%. Agreement for intra-participant variability of systolic and diastolic BP was poor, with correlation coefficients, bias, limits of agreements and median percentage error for standard deviations ranging between (-0.12 – 0.49), (-5.7 – -2.2 mmHg), (-15 – +3 mmHg), and ~50%, respectively.

4. Discussion

The aim of this study was to compare a novel cuffless wearable blood pressure device with a standard medical-grade ambulatory blood pressure monitor. From both devices, we calculated mean and standard deviation of systolic and diastolic BP over 24 hours, daytime, and night-time. Compared to the ABPM, mean systolic and diastolic BP from the wearable device showed a correlation coefficient ≤0.41, low bias (≤ ±5 mmHg) and median percentage error (≤ 15%), but wide limits of agreement (~ ±30 mmHg and ~ ±20 mmHg for systolic and diastolic BP, respectively), indicating poor precision. Blood pressure variability, assessed by measuring the standard deviation of systolic and diastolic reading over the 24 hours (or day/night-time), was underestimated by the wearable device: in most cases the bias ranged between -3 and -6 mmHg, the median percentage error was ~50% and correlation was <0.2.

Previous studies on this device have been limited to daytime testing only [5,6,7,10]. The initial studies used double-blinded auscultation as a reference for their measurements, involving two trained observers to validate the readings generated from the WBPM [5,6]. One study was conducted to confirm the use of the Aktiia bracelet in various positions, using an average of the readings generated through double-blinded auscultation. For a sitting position, with wrist at heart level, the mean and standard deviation of the difference between WBPM and double blinded auscultation were calculated. The reported differences were (mean ± standard deviation) 0.46 ± 7.75 mmHg for systolic BP and 0.39 ± 6.86 mmHg for diastolic BP. However, this significantly changed when a participant was standing up, shown by mean and standard deviation of − 0.62 ± 12.51 mmHg for systolic BP and − 4.85 ± 9.11 mmHg respectively [9] . This reduction in precision when standing compared to sitting may provide an explanation for the results generated in our study, as participants were undertaking their normal daily activities, which resulted in WBPM readings taken in a variety of body positions. A study which has directly compared 7 days average BP from WBPM with 12-hours averaged BP from ABPM in 52 participants, has reported a difference of 1.6 ± 10.5 mmHg for systolic and −2.2 ± 8.0 mmHg for diastolic BP. Thus far, there have been no studies on this WBPM to validate its use overnight. As previously mentioned, night-time BP readings are critical in monitoring potential hypertensive patients. We believe that through conducting this validation study, we have bridged this knowledge gap and provided data that can be applied

into the further development of wearable BP monitoring. The data we have collected provides a strong insight into the potential utility of WBPM, whilst highlighting the areas that can be improved to provide a reliable, continuous method of BP measuring.

It is important to note that this wearable device only measures blood pressure at rest, with resting periods most probably identified using data from the embedded accelerometer. This may mean that the readings generated by the WBPM are not fully representative of a patient's BP variation in their day-to-day activities and can in part explain the underestimation of the standard deviation of BP readings. Furthermore, since the ABPM measured BP at pre-set time intervals, whereas the WBPM measured BP automatically, readings from both devices were not always taken at the same time. To mitigate the impact of this issue, we formulated a pairing strategy to allow for close comparison of readings. We set the boundary at 10 minutes, limiting the HR change to ≤10 bpm, to ensure maximum similarity in the circumstances under which readings from the two devices were taken. However, short term blood pressure variability could in part explain the differences between the two devices reported in this study. Furthermore, another limitation of our study may lie within the small sample size of 29 participants, mainly normotensive. This study was carried out in participants of a wide age range, but their mainly normotensive state may mean that our data may not be directly applicable to that of a hypertensive population.

Our data can help to inform and guide future research on how WBPMs can be potentially used for long-term BP monitoring. It would be interesting to evaluate the length of time that the WBPM would need to be worn to replace the ABPM in hypertension screening. There is the potential for more valuable research in the field of wearable BP devices, as enhancing the accuracy and reliability of the WBPM could allow for a more efficient hypertension diagnostic and management process.

5. Conclusion

This validation study provides a comprehensive comparison between BP measurements taken by a novel cuffless wearable blood pressure device and a medical-grade ambulatory blood pressure monitor.

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