

Original Paper

A Comparison of Blood Pressure Data Obtained From Wearable, Ambulatory, and Home Blood Pressure Monitoring Devices: Prospective Validation Study

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Abstract

Background: Blood pressure (BP) is an important marker for cardiovascular health. However, a person's BP data cannot usually be obtained simultaneously from different sources.

Objective: This study aimed to analyze and compare BP data obtained from 3 different sources, namely, wearable, ambulatory, and home BP monitoring devices.

Methods: During recruitment, we recorded participants' BP using a standardized digital BP monitoring device and simultaneously over 24 hours using wearable and ambulatory devices. In addition, participants' BP was measured over 7 days using wearable and home BP monitoring devices. Data from the wearable BP monitoring devices were extracted. The 24-hour ambulatory BP data were downloaded from the device to a computer. Home BPs were recorded 3 times per day (in the morning, afternoon, and evening, at regular times convenient to the participants) for 7 days and on a BP sheet.

Results: A total of 9090 BP measurements were collected from 20 healthy volunteer participants (females: n=10; males: n=10, mean age 20.3 years, SD 5.4 years). The mean (SD) systolic BP and diastolic BP values measured at enrollment were 112.35 (9.79) mm Hg and 73.75 (9.14) mm Hg, respectively. The 24-hour mean (SD) systolic BP and diastolic BP values measured using the wearable device were 125 (5) mm Hg and 77 (9) mm Hg, respectively. The 24-hour mean (SD) systolic BP and diastolic BP values recorded using the ambulatory device were 126 (10) mm Hg and 75 (6) mm Hg, respectively. The 7-day mean (SD) systolic BP and diastolic BP values measured using the wearable device were 125 (4) mm Hg and 77 (3) mm Hg, respectively. The 7-day mean (SD) systolic BP and diastolic BP values measured using the home device were 112 (10) mm Hg and 71 (8) mm Hg, respectively.

Conclusions: Our datasets serve as the basis for further studies where these data can be combined reasonably with data from similar studies to understand the impact of different devices on BP measurement. Moreover, the BP data acquired noninvasively from wearable, ambulatory, and home devices can be integrated with similar data from other studies to determine the utility of wearable BP monitoring devices in different groups of people.

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KEYWORDS

wearable devices; mobile phones; blood pressure; ambulatory blood pressure monitoring; home blood pressure devices

Introduction

High blood pressure (BP) is a major risk factor for cardiovascular diseases globally and leads to increased morbidity

and mortality [1-5]. However, a large number of people with high BP remain undetected and untreated [6,7]. Accurate BP measurement is essential for the diagnosis and management of hypertension [8]. Clinical BP measurements by health care

professionals may be inaccurate due to measurement bias and white coat hypertension, and these BP measurements can only provide BP readings at one point in time [9]. Several guidelines have suggested the use of home blood pressure monitoring (HBPM), but HBPM cannot measure nighttime BP, which has etiological importance [10]. Ambulatory blood pressure monitoring (ABPM) devices can measure the average 24-hour BP, but these are costly and not user-friendly [11].

In recent years, several cuffless wearable BP monitoring devices have been developed, which are unobtrusive, overcoming the barriers of other BP measurement techniques and offering the possibility to provide continuous measurements [12-15]. These wearable devices have the potential to estimate long-term average BP and nighttime BP, which is used to monitor adherence to BP-lowering therapy and BP control [16]. However, none of these devices have been approved as an alternative to standard sphygmomanometers or claimed comparable validity. Therefore, wearable devices' use for clinical purposes has not been established.

A number of studies have reported validation of wearable cuffless BP devices and smartphone sensors against cuff-based BP measurements [15,17,18]. However, most of these studies were conducted in laboratory and nonambulatory settings and provided little information on how these devices might work in a free-living environment. Therefore, in this study, we collected BP data using standard clinical BP at baseline, 24-hour BP using wearable and ambulatory devices, and 7-day BP using wearable BP monitoring and HBPM devices. The primary objective of this research was to validate the wearable device against an ABPM device. The secondary objective was to compare the mean 7-day wearable and home BP data. This dataset could be used to evaluate wearable BP monitoring devices and gain insights into the impact of different devices on measurement of BP. Furthermore, these data can be combined with BP data from similar devices for a meta-analysis to better understand the validity of wearable BP monitoring devices.

Methods

We conducted a prospective study to validate a wearable BP monitoring device against 24-hour data from ABPM and HBPM devices. A total of 20 healthy adult participants were recruited from Melbourne, Australia, using convenient sampling. As per the inclusion criteria, the study participants were adults (aged ≥ 18 years) with normal BP ($<140/90$ mm Hg) who were willing to wear an ambulatory device for 24 hours, a wearable device for 7 days, and record home BP 3 times per day for 7 days. Persons with high BP ($>140/90$ mm Hg), severe health conditions, and limited mobility and persons taking BP

medication were excluded. The study was conducted from October 2017 to April 2018.

Participants were provided a wearable BP monitoring device (Tmart Technologies) and an HBPM device (Omron HEM1, Omron Corp) to use for 7 days along with a 24-hour ABPM device for 1 day. Clinical BP was measured using an automated BP device (Omron Corp) at the time of enrolment. We recorded 3 clinical BP readings. The first reading was discarded, and the mean of the remaining 2 readings was calculated. Data from the wearable BP monitoring device were extracted, and 24-hour ambulatory BP data were downloaded from the device to a computer. Measurements of Home BP were taken 3 times per day (in the morning, afternoon, and evening at regular times convenient to the participants) for 7 days and were recorded on a BP sheet.

A research assistant was trained in data collection procedures and device operation for 1 week at Deakin University. Participants' demographic, anthropometric, and clinical data (including age, gender, education, marital status, occupation, income, weight, height, systolic and diastolic BP, pulse rate, waist and hip circumference, and race/ethnicity) were collected using a standardized questionnaire. Data on self-reported comorbidities, physical activity, diet, and medication use were collected.

Data were analyzed using MATLAB 2017a software and reported as mean, standard deviation, and range. We compared the measurements recorded by wearable BP monitoring device against the corresponding reference ambulatory and home measurements (eg, W1 vs R1, as shown in Table 1). We used a nonparametric Mann-Whitney *U* test to assess systemic biases between devices. The measurement biases for systolic and diastolic BP for the wearable BP monitoring devices were measured as reference BP (W1, when comparing against ABPM and R1, when comparing against HBPM). We also evaluated measurement accuracy by calculating the mean absolute difference and mean absolute percentage difference between the devices. Standardized Bland-Altman scatterplots and limits of agreement (LOA) were used to assess absolute reliability and the variability of measurement biases across the measurement range. Absolute reliability was measured by calculating the SE of measurement and 95% LOA. A *P* value of $<.05$ was considered statistically significant. Missing data were not imputed.

Written informed consent was obtained from all participants at the time of enrollment. The Deakin University Faculty of Health Human Ethics Advisory Group (HEAG-H 135_2017) approved the study.

Table 1. Procedure for reference and validation of wearable device blood pressure measurements.

Procedures	Measurement code
Initial BP^a measurements	
Take reference BP measurement (clinical BP)	R0 ^{b,c}
Take BP measurement using wearable device	T0 ^c
Validation BP measurements for accuracy evaluation	
Take first reference BP measurement (mean 24-hour, ABPM ^d device)	R1
Take first wearable device BP measurement (mean 24-hour, wearable BP monitoring device)	T1
Take second reference BP measurement (mean 7-day, HBPM ^e device)	R2
Take second wearable device BP measurement (mean 7-day, wearable BP monitoring device)	T2
Take third reference BP measurement (mean daytime, ABPM device)	R3
Take third wearable device BP measurement (mean daytime, wearable BP monitoring device)	T3
Take fourth reference BP measurement (mean nighttime, ABPM device)	R4
Take fourth wearable device BP measurement (mean nighttime, wearable BP monitoring device)	T4

^aBP: blood pressure.

^bNot used in the evaluation of reference BP distribution and variability criteria.

^cNot used in the assessment of the test device accuracy.

^dABPM: ambulatory blood pressure monitoring.

^eHBPM: home blood pressure monitoring.

Results

BP data obtained by different devices are shown in [Table 2](#), and the validation of the wearable device ([Figure 1](#)) has been reported in a previous study [13]. A total of 9090 BP measurements were collected from 20 healthy volunteer participants (females: n=10; males: n=10; mean age 20.3 years,

SD 5.4 years). The mean BP at baseline during enrollment was 112 (SD 74) mm Hg. Mean (LOA) biases and precision between the wearable and ambulatory devices over 24 hours were 0.5 (−10.1 to 11.1) mm Hg for SBP and 2.24 (−17.6 to 13.1) mm Hg for DBP. The mean biases (LOA) and precision between the wearable and home device over 7 days were −12.7 (−28.7 to 3.4) mm Hg for SBP and −5.6 (−20.5 to 9.2) mm Hg for DBP [10].

Table 2. Blood pressure data measured using different devices.

BP ^a data	Wearable BP monitoring device (24 hours)	ABPM ^b device (24 hours)	Wearable BP monitoring device (7 days)	HBPM ^c device (7 days)
SBP^c, mm Hg				
Mean (SD)	125 (5)	126 (10)	125 (4)	112 (10)
Range	119-138	111-150	113-139	85-135
DBP^d, mm Hg				
Mean (SD)	77 (9)	75 (6)	77 (3)	71 (8)
Range	72-87	64-90	68-87	50-90

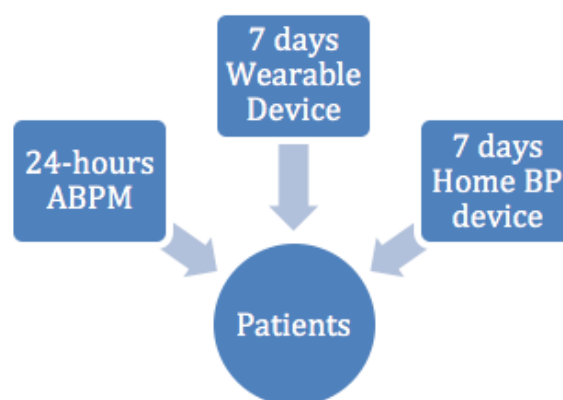
^aBP: blood pressure.

^bABPM: ambulatory blood pressure monitoring.

^cHBPM: home blood pressure monitoring.

^cSBP: systolic blood pressure.

^dDBP: diastolic blood pressure.

Figure 1. Validation process of the wearable blood pressure monitoring device. ABPM: ambulatory blood pressure monitoring; BP: blood pressure.

Discussion

In this study, we collected BP data using a standard digital BP device at baseline, a gold-standard ABPM device for 24 hours, and a cuffless wearable device and a standard HBPM device for 7 days. Our results suggest that the wearable device compared well with the gold-standard ambulatory device over 24 hours, as BP measurement biases were within acceptable limits. However, these findings are not sufficient on their own to recommend wearable devices as a replacement for established ambulatory devices. In contrast, measures of wearable BP monitoring device differed systematically from those of HBPM device over 7 days. Given the comparability of wearable and ambulatory measures, this finding suggests that the home device systematically underestimated BP.

The utility of the wearable BP monitoring devices is in their ability to measure BP in free-living environments and during daily activities, providing a better assessment of a person's BP and cardiovascular health. Further, the recent development of new technologies, such as smartphone apps, sensors, and wearable devices might allow cuffless BP devices to support remote BP monitoring as part of a telemedicine package [19,20]. This will enable patients to review their periodic BP, communicate with health care providers, and titrate their BP

medications. Such technologies can be useful, effective, and cost-effective interventions for managing BP in future routine clinical practices [21-23]. Such interventions could also be useful in low-income settings where hypertension is highly prevalent and there is a lack of trained professionals to provide health care services [24-29].

However, the use of wearable BP monitoring devices for remote monitoring will require validation of these devices in free-living environments in robust studies. The wearable BP monitoring devices, along with a care platform, might allow provision of automated personalized interventions based on the individual user. Previous studies have reported that simple approaches such as mobile phone text messages might help to reduce cardiovascular risks [4,30,31]. Thus, automated text messaging with health information, behavior change components [32], high BP alerts, and titration options might change future BP management and allow it to be integrated with a telemedicine service [23].

Our study has several limitations. Data were collected from a small number of healthy participants using convenience sampling. Wearable and home BP data were collected over 7 days only, and we did not consider seasonal or other variations. Moreover, data from people with high BP are needed to better

understand how BP changes with different activities in daily life.

Future research is needed to understand how the wearable BP monitoring devices perform over long term in different groups of people against standard BP measurement using a standardized

protocol for the validation of wearable BP monitoring devices. These data measured by wearable BP monitoring devices can be further analyzed for a daytime versus nighttime comparison or can be included in a meta-analysis of similar studies to support our initial findings and provide insights into cardiovascular health.

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Conflicts of Interest

None declared.

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Abbreviations

- ABPM:** ambulatory blood pressure monitoring
- BP:** blood pressure
- DBP:** diastolic blood pressure
- HBPM:** home blood pressure monitoring
- LOA:** limits of agreement
- SBP:** systolic blood pressure

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