Validation of Omron Wearable Blood Pressure Monitor HeartGuide™ in Free-Living Environments

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Abstract. Hypertension is one of the most common health conditions in modern society. Accurate blood pressure monitoring in free-living conditions is important for the precise diagnosis and management of hypertension. In tandem with the advances in wearable and ubiquitous technologies, a medical-grade wearable blood pressure monitor–Omron HeartGuide™ wristwatch–has recently entered the consumer market. It uses the same mechanism as the upper arm blood pressure monitors and has been calibrated in laboratory settings. Nevertheless, its accuracy "in the wild" has not been investigated. This study aims to investigate the accuracy of the HeartGuide™ against a medical-grade upper arm blood pressure monitor HEM-1022 in free-living environments. Analysis results suggest that the HeartGuide™ significantly underestimated systolic pressure and diastolic pressure by an average of 16 mmHg and 6 mmHg respectively. Lower discrepancy between the two devices on diastolic pressure was observed when diastolic pressure increased. In addition, the two devices agreed well on heart rate readings. We also found that device accuracy was related to systolic pressure, heart rate, body temperature and ambient temperature, but was not related salivary cortisol level, diastolic pressure, ambient humidity and air pressure.

Keywords: Personal informatics · Consumer wearables · Blood pressure · Quantified self

1 Introduction

Hypertension is the biggest risk factor for cardiovascular diseases and other health conditions from kidney problems to respiratory disorders [1,2]. The rate of hypertension rose substantially in the past three decades and deaths associated with hypertension also increased [3]. The American Heart Association recommends self-monitoring for all people with high blood pressure. Previous meta-analyses have shown that self-monitoring can improve blood pressure control and is an increasing common part of hypertension management [4,5].

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Such monitoring can help the healthcare provider determine the effectiveness of treatment and can be accompanied by additional support from doctors [6].

Self-monitoring on blood pressure can also enable more precise diagnosis of hypertension. Blood pressure fluctuate during the course of a day [7]. Office blood pressure–the one blood pressure measurement when people visit a clinic–is a snapshot that only tells the blood pressure at the moment of the measurement. Such snapshots may lead to false positive (e.g., "white coat hypertension" [8]) and false negative (e.g., "masked hypertension" [9]) in diagnosis. On the flip side, a record of readings taken over time provides a "time-lapse" picture of blood pressure fluctuations. Such information, with clinical accuracy, can generate powerful insights into heart health, help predict the onset of cardiovascular diseases and guide proper medication on hypertension [10,11]. Hence, the 2015 U.S. Preventive Services Task Force (USPSTF) report recommended around-the-clock blood pressure monitoring as the preferred method for screening hypertension and predicting cardiovascular disease risk [12].

To this end, accurate monitoring of blood pressure in free-living environment is critical for hypertension diagnosis and management. Many digital home blood pressure monitors have been developed in recent years. These devices leverage the oscillometric method for measuring systolic and diastolic blood pressure, and can be either worn on wrist or upper arm. Despite of their affordability and convenience, the portability of these devices is still limited. For example, a user will not be able to measure blood pressure using her home digital upper arm monitor when she is in workplace or during outdoor activities. It was not until last year the first medical-grade wearable blood pressure monitor–the Omron HeartGuide^{TM} wristwatch–entered the consumer market. The HeartGuide^{TM} combines oscillometric method and wearable technology to achieve both accuracy and convenience.

The HeartGuide^{TM} has been validated in laboratory settings and achieved good agreement with sphygmomanometer (deviation within ± 5 mmHg). Nevertheless, its accuracy in free-living environment is yet unclear. Previous validation studies on consumer wearable wristbands indicate that device accuracy is often compromised in free-living environment where users operation on the device is unconstrained. Therefore, the objective of this study is to investigate the accuracy of the HeartGuide^{TM} against medical-grade upper arm blood pressure monitor. We also explore what factors may be associated to device accuracy.

2 Related Work

2.1 Blood Pressure Monitoring

Blood pressure refers to the pressure of circulating blood against the walls of the large arteries and is usually expressed in the terms of the systolic pressure over diastolic pressure. Blood pressure can vary throughout a day and normally shows a circadian rhythm over a 24-h period [7]. Blood pressure also changes in response to stress, diet, exercise, changes in posture, and smoking [7]. Hypertension occurs when the force against blood vessel walls becomes too high.

High blood pressure may come with no perceivable symptoms and is thus called "the silent killer". However, in the long run, chronic hypertension may can lead to serious health problems like heart attack and stroke [1,13,14]. In addition, blood pressure variability also has prognostic significance for cardiovascular complications [10,11].

Conventional blood pressure measurement in clinical settings uses a sphygmomanometer. A cuff fits over the upper arm and inflates, constricting the arteries. When the air is released, the first sound detected with a stethoscope is the systolic pressure. The silence that follows marks the diastolic pressure. Blood pressure readings obtained in clinics or hospitals are called office blood pressure. These readings only represent snapshots of blood pressure at the time of the clinic visits and are not sufficient to provide a holistic view of how blood pressure may fluctuate at different time of a day. For example, morning hypertension may not be diagnosed using office blood pressure. Moreover, in some cases high office blood pressure may not be pathological but rather due to nervousness during clinic visits. The likelihood of false positive and false negative of office blood pressure demands alternative ambulatory blood pressure measuring technologies that can be used in free-living environment.

Many portable and affordable consumer blood pressure monitors have been developed for home use. These devices largely fall into two categories: upper arm monitors and wrist monitors. An upper arm blood pressure monitor usually consists of a pre-formed cuffs and a digital screen. The measurement process is automated and users only need to press a start button. The advantage of upper arm type is that the cuff naturally rests at the same level as heart, saving the trouble of adjusting device placement and the posture during measuring. Wrist blood pressure monitors are devices that worn on the wrist. Wrist monitors are less bulk and more portable, and they are also ideal for people with arm mobility limitations. Many of these devices use the oscillometric method for simplicity and reliability, but motion artifact is considered a major drawback of this method [15,16].

2.2 Quantified Self and Consumer Wearables

The Quantified Self has become a popular everyday practice where people use digital devices and smartphone apps to gather real-time physiological, behavioral and emotional data from themselves [26]. The purpose of the self-tracking practices ranges from obtaining self-knowledge [17,18], improving productivity [19], preventing diseases [20], to managing health condition [21].

The Quantified Self phenomenon has attracted burgeoning interdisciplinary research interest. An extensive range of digital devices and apps have been developed to support self-tracking on physical fitness (e.g., Fitbit activity tracker), mental status (e.g., MUSE medication headband, Happify app), sleep (e.g., Neuroon eye mask, SleepAsAndroid app) and other dimensions of their bodies and lives. A growing body of research has investigated the accuracy of self-tracking technologies [22,23], how people interact with these technologies [24], and how

people make sense of their data [18], and the obstacles for self-tracking technologies to make real-world impact [25].

A variety of wearable activity and sleep tracking devices have exist in the consumer market for a while. The development of wearable blood pressure monitor has somewhat lagged behind other types of wearable. It was not until last year that the first wearable blood pressure monitor–the Omron HeartGuide™–entered the consumer market. The HeartGuide™ is a medical-grade blood pressure monitor in the shape of a wristwatch. It miniaturizes the components of traditional oscillometric measurement and uses an inflatable cuff within the watch band to take blood pressure readings. HeartGuide™ also has the functions of tracking steps, distance, calories burned and sleep as well as setting daily reminders and getting notifications, so that it allows users to explore how lifestyle directly may be associated to heart health. Nevertheless, the device is more bulky compared to activity tracker that offer the same set of lifestyle tracking functions (e.g., Fitbit, Mi Band). Despite of being validated in laboratory settings, it remains unclear whether the HeartGuide™ can produce accurate readings in the wild. Hence, this paper set out to validate HeartGuide™ in free-living environments.

3 Methodology

3.1 Devices

To validate the accuracy of the HeartGuide™ wristwatch, we compare its readings with a medical-grade upper arm blood pressure monitor Omron HEM-1022. Both devices uses the clinically validated oscillometric method to measure blood pressure.

The appearance of an HeartGuide™ is depicted in Fig. 1. The major difference between HeartGuide™ and other smart watches or activity tracker is the cuff below the wristband. One measurement takes 30 s. After completing the measurement, users can view the latest reading on the display of the HeartGuide™ watch. The battery lasts for approximately 2 days after a full charge. The device can store up to 100 blood pressure readings. The HeartGuide™ can be used in tandem with the HeartAdviser smartphone app. Figure 2 shows two screenshots HeartAdviser's dashboard. The blood pressure values are color-coded, with green and red representing safe and high blood pressure respectively. Users can compare the latest readings with previous readings or observe patterns and trends in historical data.

3.2 Data Collection Protocol

We measure blood pressure simultaneously using an HeartGuide™ and an upper arm blood pressure monitor HEM-1022. All devices were made available in participants' homes. Participants were instructed to use both devices correctly.

The HeartGuide™ wristwatch is worn on the left wrist, while the upper arm blood pressure monitor is used on the right arm. Participants were asked

Fig. 1. An Omron wearable blood pressure monitor HeartGuide™. Left: blood pressure and heart rate readings on the display. Right: the wristband contains a cuff that will be inflated during a measurement.

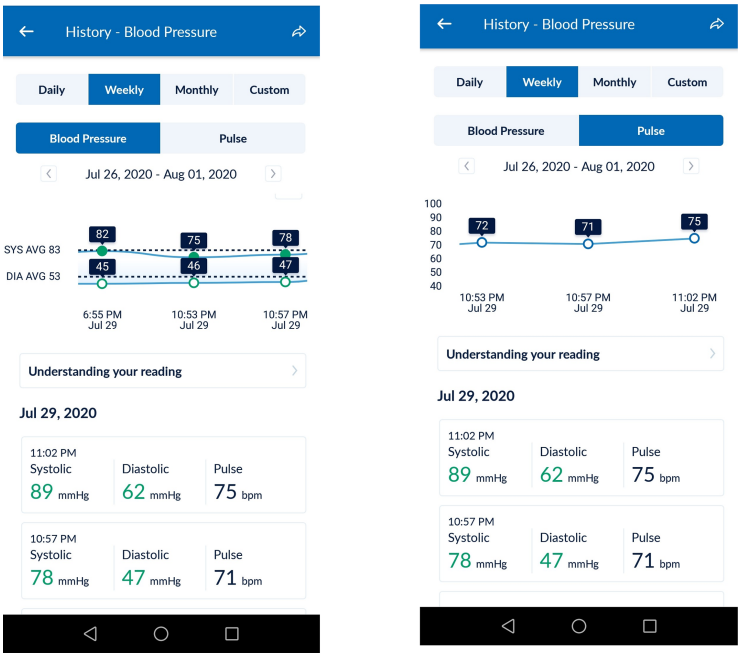

Fig. 2. Screenshots of the HeartAdviser smartphone app. Left: a weekly history of blood pressure. Right: a weekly history of heart rate.

to press the start button of the upper arm monitor first. Immediately following that, they were asked to press the start button of the HeartGuide™. They were required to sit still until both devices finish measuring, since HeartGuide™ takes more time than the upper arm monitor. In case either device requires re-measurement, participants were asked to adjust their postures before doing another round of measurement using both devices. Blood pressure was measured four times a day: right after waking up, before lunch, before dinner and before bedtime. Participants just follow their daily routine, and no intervention task was given.

To explore what factors may be associated to device accuracy, we also collected data on the list of factors summarized in Table 1. These factors include physiological metrics (i.e., salivary cortisol, blood glucose, systolic pressure, diastolic pressure, heart rate, and body temperature) and ambient conditions (i.e., ambient temperature, ambient humidity, and air pressure). Salivary cortisol was a reliable indicator of stress level. In this study, salivary cortisol was measured using the real-time SOMA cortisol test kit that only requires 10 min of room temperature incubation before obtaining measurement readings. Blood glucose was measured using FreeStyle Libre continuous glucose sensors. The readings of the upper arm blood monitor HEM-1022 were considered as the ground truth of systolic pressure, diastolic pressure and heart rate. Body temperature was measured using a digital body temperature thermometer. Ambience temperature, humidity and air pressure were measured using a multi-functional barometer.

Table 1. Potential association factors and their measurement methods

Factors	Measurement method
Salivary cortisol	SOMA cortisol test kit[a]
Blood glucose	FreeStyle Libre continous glucose sensor[b]
Systolic pressure	Upper arm continuous pressure monitor HEM-1022
Diastolic pressure	The same as above
Heart rate	The same as above
Body temperature	Digital body temperature thermometer
Ambient temperature	Multi-functional barometer
Ambient humidity	The same as above
Air pressure	The same as above

[a] http://somabioscience.com/.
[b] https://www.freestylelibre.us/.

3.3 Performance Measures

We compared the readings obtained using an HeartGuide™ with the those obtained using an upper arm blood pressure monitor HEM-1022. The metrics of our interest include systolic pressure, diastolic pressure and heart rate.

We adopted the following performance measures to quantify the agreement between the two devices.

- *Paired sample t-test* [29]. This test was used to determine if the means of the readings from two devices are significantly different from each other.
- *Scatter plots and the Pearson's correlation coefficient* [30]. The scatter plot visualizes the relationship between the two devices. The Pearson's correlation coefficient quantifies the linear relationship between the two devices.
- *Bland-Altman plots and mean differences* (95% confidence interval) [27]. The Bland-Altman plot visualizes the level off agreement between the two devices. In clinical settings, if the bias between two devices are not clinically important, then the two devices will be considered as equivalent and interchangeable [28].

We also investigate the associations between the Absolute Percent Error (APE) and a list of factors summarized in Table 1. The APE of the i-th pair of measurements is calculated using the equation below, where $\hat{x}_i$ and x_i denote the reading of the HeartGuide^{TM} and the upper arm blood pressure monitor respectively. Pairwise Pearson's correlation coefficient was calculated between APE and each factor.

$$APE_i = \frac{|\hat{x}_i - x_i|}{x_i} \tag{1}$$

4 Results

A total of 210 pairs of readings were obtained using both devices. Compared to the upper arm monitor, HeartGuide^{TM} showed lower value for systolic pressure (HeartGuide^{TM}: 87 ± 11 mmHg; upper arm monitor: 104 ± 12 mmHg; $t = 14.83$, $p < 0.001$), diastolic pressure (HeartGuide^{TM}: 54 ± 9 mmHg; upper arm monitor: 61 ± 8 mmHg; $t = 7.80$, $p < 0.001$).

Figure 3 shows the Bland-Altman plot and scatter plot on the readings of systolic pressure from two devices. The HeartGuide underestimated systolic pressure compared to HEM-1022 by an average of 16 mmHg (95% CI = [15, 18]). The scatter plot demonstrates positive strong correlation between the readings of two devices ($r = 0.70$, $p < 0.001$). Figure 4 shows the Bland-Altman plot and scatter plot on the readings of diastolic pressure from two devices. The HeartGuide underestimated diastolic pressure compared to HEM-1022 by an average of 6 mmHg (95% CI = [5, 7]). The Bland-Altman plot for also demonstrated a trend in device difference as a function of the diastolic pressure: the difference between the two devices diminishes as the diastolic pressure increases. The scatter plot demonstrates positive strong correlation between the readings of two devices ($r = 0.69$, $p < 0.001$). Figure 5 shows the Bland-Altman plot and scatter plot on the readings of heart rate from two devices. The Bland-Altman plot indicates good agreement between two devices. The scatter plot demonstrates positive strong correlation between the readings of two devices ($r = 0.85$, $p < 0.001$).

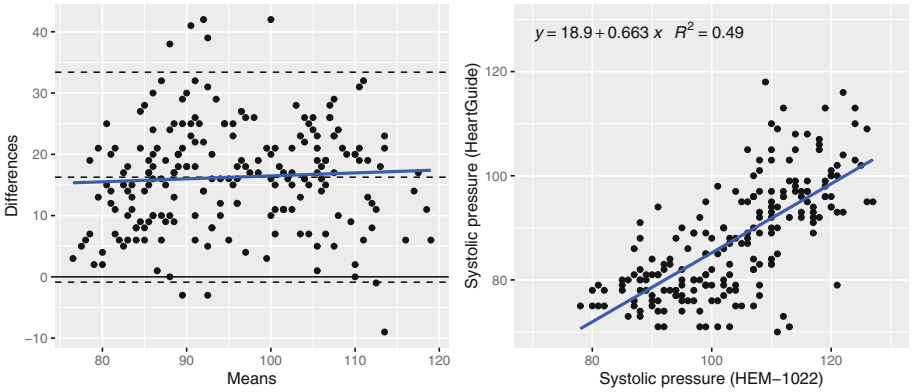

Fig. 3. Comparison between HeartGuide^{TM} and digital upper arm blood pressure monitor on systolic pressure. Left: Bland-Altman plot demonstrates a systematic bias of 16 mmHg (95% CI = [15, 18]). Right: scatter plot shows a correlation coefficient of 0.70 ($p < 0.001$).

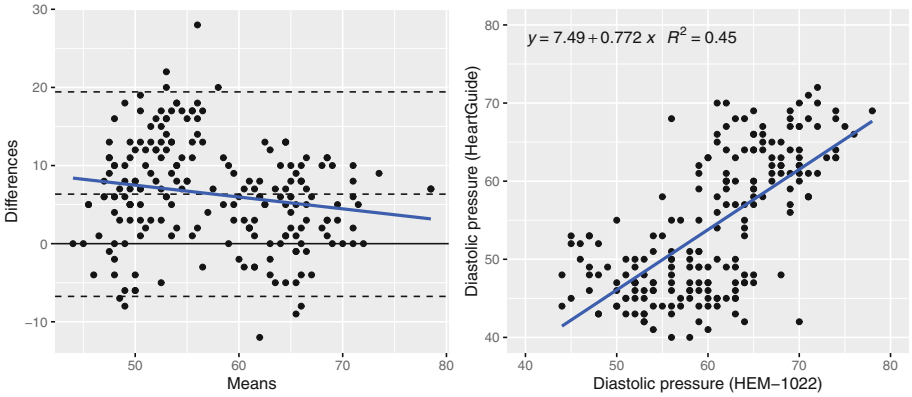

Fig. 4. Comparison between HeartGuide^{TM} and digital upper arm blood pressure monitor on diastolic pressure. Left: Bland-Altman plot demonstrates a systematic bias of 6 mmHg (95% CI = [5, 7]), and the level of agreement between two devices increases with diastolic pressure. Right: scatter plot shows a correlation coefficient of 0.69 ($p < 0.001$).

Table 2 gives a summary of the Pearson correlation analysis between the APE of HeartGuide^{TM} and the association factors. First, the APE of systolic pressure is weakly and positively correlated to the true systolic pressure, and weakly and negatively correlated to the heart rate and ambient temperature. Second, the APE of the diastolic pressure is weakly and negatively correlated to the systolic pressure, body temperature, and ambient temperature, and is

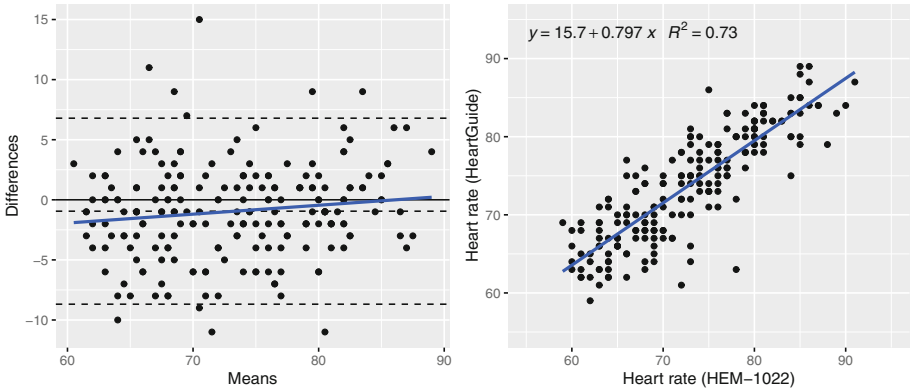

Fig. 5. Comparison between HeartGuide^{TM} and digital upper arm blood pressure monitor on heart rate. Left: Bland-Altman plot demonstrates good agreement between two devices on heart rate readings. Right: scatter plot shows a correlation coefficient of 0.85 ($p < 0.001$).

moderately and negatively correlated to the true heart rate. Last but not the least, the APE of heart rate is weakly and positively correlated to blood glucose level, and is weakly and negatively correlated to the heart rate.

5 Discussion

This study has shown a quantitative comparison between the first consumer wearable blood pressure monitor HeartGuide^{TM} and a medical-grade upper arm blood pressure monitor. We found that the HeartGuide^{TM} systematically underestimated both systolic pressure and diastolic pressure when compared to the upper arm blood pressure monitor HEM-1022, but both devices agreed well on heart rate readings. Moreover, the difference between HeartGuide^{TM} and the upper arm monitor on diastolic pressure diminishes as the diastolic pressure increased.

In clinical settings, two blood pressure monitoring methods are considered interchangable if their difference is within 5 mmHg [31]. Based on this criterion, the HeartGuide^{TM} and HEM-1022 can be considered identical in measuring diastolic pressure and heart rate. The deviation of HeartGuide^{TM} on systolic pressure should not be overlooked. Nevertheless, the mean difference of the two devices on systolic pressure is comparable to inter-observer differences among specialists using sphygmomanometer [32]. To this end, the HeartGuide^{TM} is a plausible alternative to sphygmomanometer and upper arm cuff for ubiquitous blood pressure monitoring.

There are several factors that may play a role in the measurement accuracy of the HeartGuide^{TM}. The absolute percent error (APE) of systolic pressure slightly increases as the true systolic pressure increases, but slightly decreases as the true heart rate and ambient temperature increases. The APE of the diastolic

Table 2. Correlation analysis between absolute percent error (APE) and association factors.

Factors	APE_{SP}[a]	APE_{DP}[b]	APE_{HR}[c]
Salivary cortisol	0.09	0.13	0.17
Blood glucose	−0.10	−0.14	**0.28***[d]
SP	**0.28*****[e]	**−0.23*****	−0.15*
DP	−0.02	0.00	−0.14*
HR	**−0.21****	**−0.32*****	**−0.25*****
Body temperature	−0.02	**−0.27*****	−0.12
Ambient temperature	**−0.21****	**−0.21****	−0.14*
Ambient humidity	−0.05	−0.09	−0.02
Air pressure	0.16*	0.16*	0.16*

[a]Systolic pressure.
[b]Diastolic pressure.
[c]Heart rate.
[d]Significance level: *:$p < 0.05$; **:$p < 0.01$; ***:$p < 0.001$.
[e]Bold font highlights the absolute value of the Pearson's correlation coefficient $r > 0.20$ (indicating at least weak correlation).

pressure slightly decreases as the true systolic pressure, the true heart rate, body temperature or ambient temperature goes up. The APE of heart rate slightly increases as blood glucose increases or heart rate decreases. We also observed that device placement and arm position during measurement could all affect measurement accuracy. In contrast, salivary cortisol, the true diastolic pressure, ambient humidity and air pressure were not related to device accuracy. One possible way to improve the accuracy of the HeartGuide^{TM} is to consider these association factors in designing correction algorithms.

6 Conclusion

Compared to the upper arm blood pressure monitor HEM-1022, the HeartGuide^{TM} significantly underestimated systolic pressure and diastolic pressure by an average of 16 mmHg and 6 mmHg respectively. In addition, lower discrepancy between two devices was observed when diastolic pressure increased. The HeartGuide^{TM} agreed well to HEM-1022 in measuring heart rate. We also found weak but statistically significant correlations between measurement errors and physiological or ambient conditions. High systolic pressure, low heart rate and low ambient temperature were associated to greater measurement errors on systolic pressure. Low systolic pressure, low body temperature, low ambient temperature and low heart rate were associated to greater measurement errors on diastolic pressure. High blood glucose and low heart rate were associated to greater measurement errors on heart rate. These factors should be taken into consideration to design algorithms for wearable blood pressure monitors in the future.

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