Introduction and Objective

Hypertension (HTN), or high blood pressure, affects one-third of the U.S. population. As an established cause of heart disease, stroke, and chronic kidney disease, HTN is a public health concern. However, addressing HTN early with pharmacologic and lifestyle interventions reduces its morbidity and mortality risk. Electronic health (E-health) devices, such as heart rate watches and BP applications, are being rapidly developed and popularized among patient populations. Such devices offer a great amount of convenience to users and have the capacity to reshape BP diagnosis and management. However, the majority of these devices remain unregulated by the FDA and may be detrimental to users’ health if inaccurate.

E-health devices that claim to measure BP without a traditional cuff are of particular interest because they hold potential to be heavily utilized as at-home BP monitoring. This study evaluates the accuracy of two popular, novel BP monitors: the Bodimetrics Performance Monitor and the Everlast TR10 watch.

Methods

A sample of 127 ambulatory patients (>18yrs) were recruited from the Thomas Jefferson University Hospital Preadmission Testing Center. This protocol was adopted from the international ANSI/AAMI/ISO standard for non-invasive sphygmomanometers.

Research staff were trained to measure BP with both of the experimental devices and a validated, standard automated sphygmomanometer (Cardiocap 5, Datex-Ohmeda, Madison, WI) according to their manufacturers’ guidelines. The Everlast TR10 provides both systolic BP (SBP) and diastolic BP (DBP), while the Bodimetrics device only provides SBP. After five minutes of quiet sitting, an initial calibration measurement was taken following manufacturer guidelines for the Bodimetrics performance monitor. This required a measurement with the validated sphygmomanometer followed by a calibration reading from the Bodimetrics device with sixty seconds in between readings. Following calibration, four standard and three investigational BP measurements were taken with sixty seconds in between each measurement (Figure 1). Each investigational measurement was therefore bounded by two standard measurements. The reference BP value for the standard device used for analysis was calculated as the mean between two subsequent readings that had an investigational reading. This yielded three reference-investigational comparison pairs for each device. We calculated the mean (SD) of the absolute difference between the respective investigational devices and the reference for SBP and DBP.

Results

Data from study participants was excluded if any consecutive reference measurements differed by more than 12 mmHg for SBP or by more than 8 mmHg for DBP. 85 of the 127 subjects met inclusion criteria. Of these 85, 36 (42%) were female. The mean (SD) age was 53 (21) and body mass index was 28 (7) kg/m². 32 (38%) participants self-reported hypertension – 97% of which reported taking antihypertensive medications.

- The Bodimetrics Performance Monitor SBP measurements correlated well with the reference SBP measurements (p = 0.88, P < 0.01, Figure 2A), whereas the Everlast TR10 fitness watch did not (SBP: p = 0.19, P > 0.01; DBP: p = 0.01, P < 0.01; Figure 2B).
- The mean (SD) absolute difference between the Bodimetrics performance monitor and the reference measurement was 5.3 (4.7) mmHg for SBP (Figure 3A).
- The mean absolute differences between the Everlast watch and the reference measurements were 22.7 (27.4) mmHg for SBP and 6.9 (6.2) mmHg for DBP (Figure 3B).
- The absolute differences between the Everlast watch and reference measurements were dependent on the SBP value. Higher SBPs were estimated lower and lower SBPs were estimated higher (p = 0.45, P < 0.01, Figure 3B).
- The Bodimetrics performance monitor reported a hypertensive BP (≥140 mm Hg) for 80% of the hypertensive reference SBP measurements, whereas the Everlast watch measured no hypertensive BP values for any of the hypertensive reference SBP or DBP measurements (Figure 2).

Figure 2. Scatterplots of (A) SBP of the Bodimetrics, (B) SBP of the Everlast Watch, and (C) DBP of the Everlast Watch compared to the standard device. The solid lines represent the line of identity. The dashed lines represent the cutoff points for stage 2 hypertension (140/90 mmHg). Neither Bodimetrics performance monitor residuals nor Everlast watch residuals were normally distributed (Shapiro-Wilk test). Spearman correlation showed a correlation between Bodimetrics SBP measurements and reference measurements, whereas Everlast SBP and DBP measurements were not correlated with reference measurements. SBP = systolic blood pressure, DBP = diastolic blood pressure.

Figure 3. Bland-Altman plots for examining (A) SBP of the Bodimetrics, (B) SBP of the Everlast Watch, and (C) DBP of the Everlast Watch compared to the standard device. The dotted lines represent the mean relative differences (investigational minus standard), the dashed lines represent ±1.96 SDs for the mean absolute difference. The difference between the Everlast SBP measurement and reference SBP measurement was dependent on the blood pressure value, such that lower SBPs were estimated higher and higher SBPs were estimated lower. SBP = systolic blood pressure, DBP = diastolic blood pressure.

Conclusions

According to the results and ANSI/AAMI/ISO guidelines, the Everlast fitness watch and Bodimetrics handheld device were not considered accurate BP measurement devices. Although both devices were considered invalid, the Bodimetrics Performance Monitor was considerably more accurate than the Everlast TR10 was. Widespread use of this technology could result in the misclassification of a patient’s blood pressure status—potentially resulting in delayed diagnosis of hypertension or incorrect self-titration of medication. Neither of the devices included in the study was approved by the FDA. There are currently at least a dozen similar devices for sale through major US retailers such as Walmart, Amazon, and eBay. The continued sales of these devices without the required validation is a public health concern that should be addressed by regulatory bodies, physicians, and patient organizations in order to avoid serious consequences that inaccurate BP measurements can have on patients.

Some limitations of this study need to be considered. First, the measurements between the standard and investigational devices could not have been obtained simultaneously due to the nature of the devices. While the exclusion criteria prevents large variations in BP from skewing results, there was still some potential for variation in the one-minute timeframe between measurements. Averaging the bound standard measurements to compare with each investigational measurement likely diminished this potential issue. Additionally, while the cuff-based device utilized in this study was validated, the accuracy of cuff-based devices in general has been called under question. Utilizing intra-arterial BP measurements may provide additional insights regarding device accuracy, however this is a more costly and invasive methodology.

References