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# Direct comparison of an automated oscillometric device with an electronic auscultatory device for epidemiologic survey to evaluate the prevalence of hypertension

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**Abstract**

Mercury-free sphygmomanometers are gradually replacing the traditional sphygmomanometers in clinical settings and epidemiological surveys for measuring blood pressure (BP) due to mercury toxicity. No direct comparative studies have evaluated BP differences and statistical errors of automated oscillometric devices (ODs) against electronic auscultatory devices (ADs) for epidemiologic surveys. Herein, we evaluated the validity of ODs for the Korea National Health and Nutrition Examination Survey (KNHANES) using the Universal Standard for BP device validation through a direct comparison with ADs as the reference standard. Four trained observers performed validation on 278 volunteers aged ≥ 19 years with a standardized BP measurement protocol. Agreement between the BP measurements recorded with an OD against those recorded with an AD was assessed by Lin's concordance correlation coefficient (CCC) and Bland–Altman's limits of agreement. To evaluate the agreement for BP classification, weighted kappa values were estimated. To explore the factors associated with BP measurement differences between the 2 devices, multiple linear regression analysis was performed. The average BP differences (OD-AD) were 2.6 ± 6.2 mm Hg for systolic BP (SBP) and −5.1 ± 5.6 mm Hg for diastolic BP (DBP). Lin's CCCs were 0.927 and 0.768 for the overall SBP and DBP, respectively. The cumulative percentage of absolute errors ≤10 mm Hg was 88.1% for SBP and 81.3% for DBP. The weighted kappa value for the Joint National Committee 7 BP classification was 0.75 (95% confidence interval: 0.68–0.81). An OD overestimated the prevalence of SBP (0.3%, $P = .0222$) and underestimated the prevalence of DBP (1.8%, $P < .0001$). Multivariate analysis to identify the risk factors for BP difference revealed the arm circumference (AC) to be negatively associated with BP difference. Male sex was positively associated, while age was negatively associated with SBP difference. OD-DBP was positively associated with DBP difference and negatively associated for DBP absolute error. ODs met the accuracy requirements of the Universal Standard criteria against ADs for SBP but not for DBP. Thus, the DBP values may be underestimated by ODs in the KNHANES.

**Abbreviations:** AC = arm circumference, BP = blood pressure, AD = electronic auscultatory device, CCC = Lin's concordance correlation coefficient, DBP = diastolic blood pressure, KNHANES = Korea National Health and Nutrition Examination Survey, MS = mercury sphygmomanometer, OD = automated oscillometric device, SBP = systolic blood pressure.

**Keywords:** blood pressure determination, sphygmomanometers, health survey, hypertension, validation

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*The authors have no conflicts of interest to disclose.*

*The data that support the findings of this study are available from a third party, but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are available from the authors upon reasonable request and with permission of the third party.*

*The data that support the findings of this study are available from the Korea Disease Control and Prevention Agency (KDCA), although restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. The KDCA provides information that is devoid of personal and/or private information.*

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## 1. Introduction

Hypertension is an important risk factor for mortality and morbidity associated with cardiovascular diseases.[1] Therefore, accurate blood pressure (BP) measurement is essential for reliable diagnosis and proper treatment of hypertension. Traditionally, mercury sphygmomanometers (MSs) were used as a gold standard for BP measurement; however, mercury-free sphygmomanometers are gradually replacing traditional MS in clinical settings and epidemiological surveys for hypertension due to environmental concerns of mercury toxicity.[2] These alternative devices include electronic auscultatory devices (ADs), requiring a trained observer,[3] and automated oscillometric devices (ODs).

Among these devices, ODs have been widely used in clinical settings[4] because they are safe, easy to use, and free of observer bias.[2] However, for a population-based epidemiological survey, the traditional BP device might be able to measure BP more accurately in a wide range of age, sex, and arm circumference (AC). Specifically, accurate BP measurements is more challenging in the older age group because of the increased arterial stiffness with advancing age.[5] Although a BP difference of < 5 mm Hg between the test and reference devices is usually acceptable for clinical use, a difference of < 2 mm Hg is usually accepted for epidemiologic surveys.[3,6] However, some studies suggested that BP differences of an OD compared with those of an MS could be influenced by increased BP, arrhythmias,[7] and arterial stiffness due to atherosclerosis.[8] Thus, a validated and accurate BP device for accurate assessment of hypertension prevalence in an epidemiological survey is required.

Omron HEM-907 (HEM, Omron, Kyoto, Japan) is an internationally validated BP measuring OD[9] and can be recommended for clinical use to measure BP in the elderly population without arrhythmias.[10] Accoson Greenlight 300™ (Greenlight, Accoson, Essex, United Kingdom) is an internationally validated AD.[11] Previously, Shin et al indirectly compared HEM and Greenlight against an MS in the Korea National Health and Nutrition Examination Survey (KNHANES), a nationwide cross-sectional health survey performed in the Republic of Korea.[12] Although MSs had been used as the reference device for measuring BP in the KNHANES since 1998, it is time to consider alternatives owing to the trend of banning mercury use. Therefore, the KNHANES has decided that a mercury-free device must be used as an alternative to an MS for BP measurement in future surveys.[13]

Recently, the Universal Standard recommended that an AD can also be used as another reference standard for device validation if the device fulfills the requirement for accuracy (maximum permissible error between the test and reference device should be within ± 1 mm Hg).[14] Accordingly, the KNHANES may also change to Greenlight as the reference standard for replacing MSs in future validation studies. Although the previous study reported that Greenlight was comparable to an MS in both SBP and DBP measurements, SBP values were comparable to those of an MS; however, various measurement errors in DBP occurred when HEM was compared against an MS. Hence the prevalence of hypertension might have been significantly underestimated.[11] Meanwhile, it is necessary to establish a validated alternative device to be used as the reference standard after replacing MSs for BP measurement in the KNHANES.

However, to the best of our knowledge, there are no direct comparative studies evaluating the BP differences and statistical errors of an OD (HEM) against an AD (Greenlight) as the reference standard and how these results affected the prevalence of hypertension in the KNHANES. Thus, this study aimed to evaluate the validity of an OD for the KNHANES using the Universal Standard criteria for BP device validation through a direct comparison with an AD as the reference standard. Furthermore, we analyzed how these results affected the prevalence of hypertension when an OD is adopted for the KNHANES.

## 2. Methods

### 2.1. Study participants

Among the 363 participants of the KNHANES conducted in January 2020, we enrolled 278 volunteers aged ≥ 19 years into 4 mobile examination units who met the inclusion criteria and agreed to participate in this validation study. The inclusion criteria included participants whose BP was recorded using both an AD and OD, who had a regular pulse rate during the 30-s examination, and whose AC was between 19.5 and 39.8 cm. There were no exclusion criteria unless the participant refused to give their BP measurements 3 times per device. This study was conducted in accordance with the Declaration of Helsinki. The study protocol was approved by the institutional review board of the Korea Center for Disease Control and Prevention (KCDC) (2018-01-03-3C-A). Written informed consent was obtained from all subjects.

### 2.2. Before-use and after-use device calibration

ADs and ODs have been internationally validated based on the European Society of Hypertension-International Protocol, 2002.[15] To ensure the pressure accuracy before use, we tested 4 ODs compared with MSs over a range of pressures on a 280-60 mm Hg scale (30 calls per deflation), per the British Hypertension Society protocol for the evaluation of BP measuring device.[16] We obtained 30 readings per device and calculated the BP difference by subtracting the OD-BP value from the MS-BP value for each data point. The average BP difference before-use calibration was 0.4 mm Hg, 0.8 mm Hg, 0.5 mm Hg, and 0.5 mm Hg for devices 1 to 4, respectively. To exclude inter-device differences, each of the 3 devices (1 MS and 2 ODs) was connected in parallel and 30 readings were obtained per device by 3 observers and the BP differences were calculated with multiple comparisons. For 1 month after use, the calibration procedure was repeated. The average BP difference after-use calibration variability was 0.4 mm Hg, 0.8 mm Hg, 0.6 mm Hg, and 1 mm Hg for devices 1 to 4, respectively. The validation criteria were defined as at least 28 of 30 controls and test measurement pairs being within 3 mm Hg of each other. All devices fulfilled the validation criteria in before-use and after-use calibrations and did not malfunction during use.

### 2.3. BP measurements

***2.3.1. Accoson greenlight 300™ (AD, accoson, essex, united kingdom).*** An AD, a mercury-free AD with an electronic digital display, was used as the reference standard device that fulfills the requirement for accuracy. BP was measured by 4 trained nurses who collected the data for the KNHANES. We previously described our standardized protocol of the Korea Disease Control and Prevention Agency protocol for BP measurement for the KNHANES.[12,13] Briefly, BP was measured in a quiet room under 65 dB with an ambient temperature between 20℃ and 25℃. Participants were seated in a chair with back support with both feet flat on the floor, and the right forearm was used for measuring BP with the arm resting on a table. After measuring the participant's mid-AC, an appropriate cuff was selected, and the cuff was wrapped around the upper arm with the center of the bladder placed over the brachial artery. The first and the fifth Korotkoff sounds were recorded for SBP and DBP, respectively. Deflation speed and other quality control issues were described in a previous study.[12] BP was measured 3 times at least 30 sec apart following a minimum of 5-minutes rest.

***2.3.2. Omron HEM-907 (OD, Kyoto, Japan).*** An OD, a digital upper-arm electronic BP measurement device, was internationally validated[9,10] and has been used in clinical settings[6] and

epidemiologic surveys.[17,18] OD and AD were alternately used to record each triplicate BP measurement per participant, with the same arm, posture, and appropriate-sized cuffs following the Korea Disease Control and Prevention Agency protocol for BP measurement. The first measurement was randomly assigned to either an AD or OD to reduce measurement bias. To facilitate interpretation, the observer was not blinded to OD readings (HIDE mode off feature). However, an observer asked the participants not to stare at the OD monitor before recording BP measurements to reduce the effect of alarm reaction. The cuff size selection was based on the manufacturer's guidelines for each device. BP was measured 3 times per device with a 30-seconds interval following a 5-minutes rest.

### 2.4. Definitions of BP differences and absolute errors

Based on the recommendation of the Korea Disease Control and Prevention protocol, the first reading was discarded, and the average value of the second and third measurements was used for the analysis. Thus, the SBP difference (D-SBP, subtracting AD-SBP from OD-SBP) was defined as the value minus the average of the second and third SBP readings recorded with the AD from the average of the second and third SBP readings recorded with the OD. In contrast, the DBP difference (D-DBP) was the value minus the average of the second and third DBP readings recorded with the AD from the average of the second and third DBP readings recorded with the OD. An absolute error was defined as the absolute value of the BP difference in SBP (A-SBP) and DBP (A-DBP).

### 2.5. Universal standard 2018 for OD validation[14]

BP readings obtained using the OD were compared with those obtained using the AD with reference to the Universal Standard 2018 for device validation (Association for the Advancement of Medical Instrumentation/European Society of Hypertension/International Organization for Standardization Collaboration Statement). A device is acceptable when the cumulative percentage of the absolute error is below 10 mm Hg in at least 85% of the measurements, and the BP difference does not exceed 5 ± 8 mm Hg.

### 2.6. BP classification for hypertension prevalence

Based on the Joint National Committee 7 (JNC 7),[19] BP was classified as normal (SBP, <120 mm Hg and DBP, <80 mm Hg), prehypertension (SBP, 120 mm Hg to <140 mm Hg and/or DBP, ≤80 mm Hg to <90 mm Hg), and hypertension (SBP ≥ 140 mm Hg and/or DBP, ≥90 mm Hg). Hypertension based on the JNC 7 guidelines was classified according to the obtained BP values without considering the usage of antihypertensive medication.

### 2.7. Statistical analyses

The participants' characteristics, including age, sex, pulse rate, and AC, were summarized using descriptive statistics. Agreement between BP measurements recorded with the OD against those recorded with the AD was evaluated using Lin's concordance correlation coefficient (CCC) and Bland-Altman's limits of agreement, the limits where 95% of the measurement differences exist. For assessing the overall level of agreement in BP classifications, weighted kappa values were estimated, and Bowker's symmetry test was performed.

To explore the factors associated with BP measurement differences between the 2 devices, multiple linear regression analysis was performed, and the following clinically important factors were considered: OD-BP readings, male sex, age, AC, and pulse rate. All analyses were performed using SAS version 9.3 (SAS Institute, Cary, NC). A $P$ value < .05 was considered statistically significant.

## 3. Results

### 3.1. Baseline characteristics of the study population

Of 278 participants, 122 (43.9%) were men, and the mean age was 50.1 ± 17.1 years (range, 19–88 years; Table 1). The average AC was 26.7 ± 3.2 cm. The OD pulse pressure and AD pulse pressure was 49.8 ± 12.2 mm Hg and 42.2 ± 13.0 mm Hg, respectively (Table 1). Compared with those by the AD, BP values by the OD were higher for SBP and lower for DBP (SBP of OD vs AD, 120.9 ± 17.4 mm Hg vs 118.3 ± 17.3 mm Hg; DBP of OD vs AD, 76.2 ± 9.9 mm Hg vs 71.1 ± 11.1 mm Hg). D-SBP (OD-AD) was 2.6 ± 6.2 mm Hg, whereas D-DBP was −5.1 ± 5.6 mm Hg. A-SBP and A-DBP were 5.3 ± 4.0 mm Hg and 6.2 ± 4.4 mm Hg, respectively.

### 3.2. Agreement between AD- and OD-BP values

AD-SBP and OD-SBP values were highly correlated and were near the diagonal line, and the corresponding CCC was high (overall, 0.927 [95% confidence interval [CI]: 0.909–0.942]; men: 0.901 [95% CI: 0.863–0.929]; women: 0.939 [95% CI: 0.91–0.955]; Fig. 1A). AD-DBP and OD-DBP values showed a moderate correlation and were below the diagonal line, implying that OD-DBP values were lower than the AD-DBP values (overall CCC, 0.768 [95% CI: 0.723–0.807]; men, 0.808 [95% CI: 0.747–0.856]; women, 0.704 [95% CI: 0.629–0.767]; Fig. 1B). The relationship between the OD- and AD-BP differences and BP levels is shown in Figures 1C–H. Bland-Altman's limits of agreement was plotted against the corresponding averages of the 2 device readings for SBP and DBP measurements separately and found that the values did not differ by sex (SBP: −8.4 to 15.3

**Table 1**

**Baseline characteristics of the study population.**

| Variables | N = 278 |
|---|---|
| Age, yrs | 50.1 ± 17.1 |
| <40 | 89 (32.0%) |
| 40–49 | 41 (14.7%) |
| 50–64 | 83 (29.9%) |
| ≥65 | 65 (23.4%) |
| Male sex, n (%) | 122 (43.9%) |
| Height, cm | 164.4 ± 8.9 |
| Weight, kg | 64.9 ± 13.6 |
| Body mass index, kg/m$^2$ | 23.8 ± 3.7 |
| Right Arm measured, n (%) | 275 (98.9%) |
| Arm circumference, cm | 26.7 ± 3.2 |
| Pulse rate, per min | 74.8 ± 17.8 |
| SBP, mm Hg | |
| OD SBP, mm Hg† | 120.9 ± 17.4 |
| AD SBP, mm Hg‡ | 118.3 ± 17.3 |
| Difference, mm Hg* | 2.6 ± 6.2 |
| Absolute error, mm Hg | 5.3 ± 4.0 |
| DBP, mm Hg | |
| OD DBP, mm Hg† | 71.1 ± 11.1 |
| AD DBP, mm Hg‡ | 76.2 ± 9.9 |
| Difference, mm Hg* | −5.1 ± 5.6 |
| Absolute error, mm Hg | 6.2 ± 4.4 |
| Pulse pressure, mm Hg# | |
| OD pulse pressure, mm Hg | 49.8 ± 12.2 |
| AD pulse pressure, mm Hg | 42.2 ± 13.0 |

Data are presented as means ± standard deviations. N and n, number; SBP, systolic blood pressure; DBP, diastolic blood pressure; OD, BP measurements recorded with the HEM device; AD, BP measurements recorded with the Greenlight device.

† Average of the second and third measurements in OD-BP.

‡ Average of the second and third measurements in AD-BP.

* Difference in BP: the average of the second and third measurements in OD-BP minus the average of the second and third measurements in AD-BP. An absolute error is the absolute value of the BP difference.

# Difference between systolic and diastolic blood pressure.

for men and −10.2 to 13.9 for women; DBP: −15.2 to 5.5 for men and −16.7 to 6.1 for women). Figure 2 is a bar graph that shows the percent distribution of the absolute errors between the 2 device measurements. Absolute errors with ≤2, ≤5, ≤10, ≤15, and ≥16 mm Hg was 25.5%, 30.9%, 31.7%, 9.7%, and 2.2% for SBP and 20.9%, 28.4%, 32%, 14%, and 4.7% for DBP, respectively. Thus, the cumulative percentage of absolute error below 10 mm Hg was 88.1% for SBP and 81.3% for DBP. The distribution of absolute errors for SBP did not differ by sex; However, the proportion of men who had absolute errors for DBP within 2 mm Hg was higher than the respective proportion of women (25.4% vs 17.3%).

### 3.3. BP differences according to age and AC

BP differences adjusted by sex, age, and AC were presented according to the age group and AC quartiles. The adjusted SBP differences according to age group tended to be higher than zero across all age groups, and these differences were the smallest in participants aged 40 to 49 years and the biggest in participants aged 50 to 64 years. In contrast, the adjusted DBP differences were consistently lower than zero, and these differences across age groups were not significantly different (Fig. 3A–C). The adjusted SBP differences according to AC quartiles were consistently higher than zero except for the fourth quartile group, and the differences across AC groups were marginally significant. In contrast, the adjusted DBP differences were lower than zero and were not significantly different (Fig. 3D–F). The adjusted absolute differences of SBP and DBP values were not significantly different in age groups (Fig. 4A–C) and AC quartiles (Fig. 4D–F).

### 3.4. Multivariate analysis for risk factors for BP differences and absolute errors

In multivariate analysis to identify the risk factors for BP difference, OD-SBP values showed marginally positive association for SBP difference and SBP absolute error, while OD-DBP was positively associated with DBP difference and negatively associated with DBP absolute error after adjusting for age, sex, AC, pulse rate, and pulse pressure. AC was negatively associated with BP differences after adjusting for age, sex, pulse rate, and pulse pressure. Male sex was positively associated, while age was negatively associated with SBP differences. In the multivariate model, pulse pressure did not have a significant relationship with SBP and DBP differences and absolute errors (Table 2). However, regardless of the predictive model types, the adjusted $R^2$ values for the OD device were overall low ($R^2 = 0.1546$ and 0.2896 for SBP and DBP differences; $R^2 = 0.0535$ and 0.2098 for the absolute error of SBP and DBP, respectively).

### 3.5. Between-device agreement by the JNC 7 BP classification

The prevalence of normotension, prehypertension, and hypertension was 48.6%, 36.7%, and 14.7%, as obtained by the AD, and 50.7%, 35.3%, and 14.0%, as obtained by the OD, respectively (Table 3). The percentage of participants with OD-SBP under 120 mm Hg was 6.4% lower than those with AD-SBP, and the percentage of participants with OD-DBP under 80 mm Hg was 15.1% higher than those with AD-DBP. The percentage of SBP (≥140 mm Hg) and DBP (≥90 mm Hg) values was 0.3% higher for SBP and 1.8% lower for DBP with ODs than those with ADs ($P = .0222$ and $P < .001$ for SBP and DBP, respectively) (Table 3). However, the overall prevalence of hypertension defined by ODs had a 0.7% lower incidence compared with that defined by the AD; however, its difference was not statistically significant (14.0% vs 14.7%). BP classification based on the JNC 7 guidelines demonstrated an agreement in 81.3% of the values, and its weighted kappa value was 0.75 (95% CI: 0.68–0.81; $P = .745$).

## 4. Discussion

This study assessed the accuracy and systemic errors of BP measurements by an OD (HEM) for the KNHANES through a direct comparison with an AD (Greenlight) as the reference standard and evaluated the impact on hypertension prevalence following the introduction of the OD. The primary findings were (1) SBP values recorded by the OD were slightly higher, and DBP values were lower, demonstrating better agreement for SBP than DBP. (2) The absolute error was tolerable for SBP but not for DBP by the Universal Standard. (3) In multivariate analysis, AC was negatively associated with BP difference. Male sex was positively associated, while age was negatively associated with SBP difference. OD-DBP values were positively associated with DBP difference. (4) The percentage of SBP and DBP was 0.3% higher and 1.8% lower when recorded with the OD than those recorded with the AD. However, the overall prevalence of hypertension defined by the OD was not significantly lower. These results show that the OD, HEM, met the accuracy requirements of the Universal Standard (5 ± 8 mm Hg) for SBP but not for DBP. Thus, the SBP values obtained by the OD would be underestimated when used in the KNHANES. Moreover, these findings are similar to those of a previous comparative study of an OD against an MS.[12] Therefore, Greenlight, a mercury-free AD, is a suitable alternative to an MS as a reference standard for comparative studies.

HEM is an internationally validated automated OD for clinical use,[9,10] which has been used in population-based epidemiologic surveys, including the National Health and Nutritional Examination Survey (NHANES) in the United States.[17] However, to the best of our knowledge, there are no studies that evaluated the BP differences and systemic errors of an OD against those of an AD. Therefore, no study directly compared ODs with ADs to evaluate the usefulness of an AD as a reference standard despite being mercury-free. Previously, Shin et al indirectly compared BP differences between HEM versus an MS and Greenlight versus an MS in the KNHANES and concluded that Greenlight might be a viable alternative to an MS and that HEM demonstrated good accuracy in SBP measurements.[12] However, due to the measurement errors in DBP, HEM was considered inferior to Greenlight. In the current study, we directly compared the BP differences measured with HEM against those of Greenlight, which was used as a reference standard instead of an MS. In the Republic of Korea, MSs have been banned by law since 2020, and thus, they are no longer available for use, even for scientific purposes. Therefore, it is necessary to establish a valid device to be used as a reference standard for replacing an MS. Recently, the Universal Standard for BP device validation recommended that an AD can be used as the reference standard for device validation that fulfills the requirement for accuracy (BP difference between the test and reference devices must be < 1 mm Hg). A previous study on the KNHANES showed that the mean difference of Greenlight values compared with MS values (Greenlight minus Mercury) was 0.52 mm Hg and 0.78 mm Hg in SBP and DBP, respectively.[12] Therefore, based on these results, the KNHANES determined that Greenlight will be used as the reference standard for replacing the MS in future comparative studies for ODs versus ADs. Moreover, in the above study, BP difference of HEM against the MS was 0.62 ± 5.62 mm Hg for SBP and −6.23 ± 5.62 mm Hg for DBP. The current study showed that the SBP and DBP difference was 2.6 ± 6.2 mm Hg and −5.1 ± 5.6 mm Hg, respectively. Therefore, these findings showed that BP differences of HEM against Greenlight are similar to those in the comparative study of HEM against an MS.[12] Thus, our findings suggest that Greenlight might be a suitable

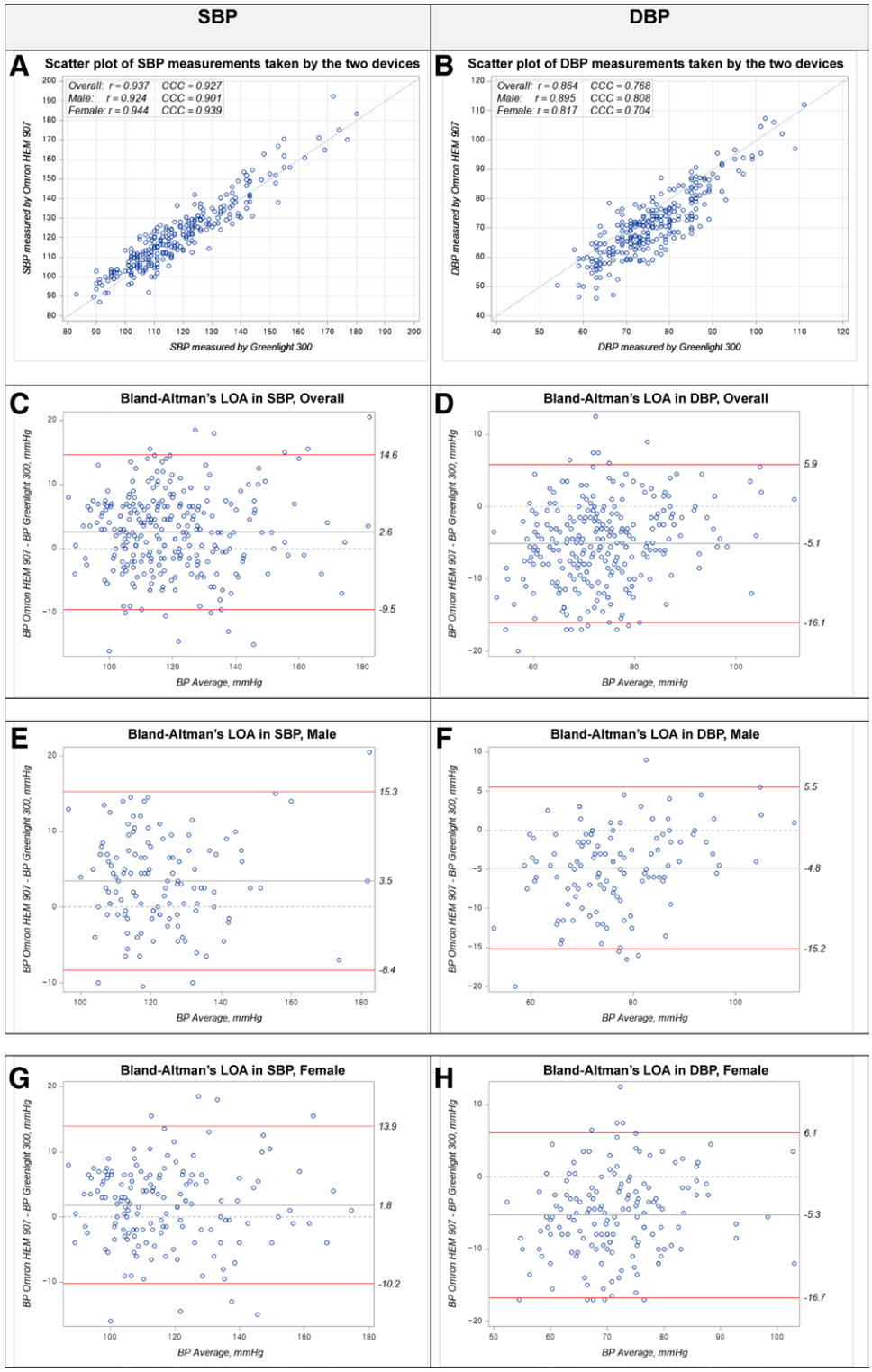


**Figure 1.** Scatterplots and Bland-Altman's LOA of BP measurements recorded with an OD and AD. SBP, systolic blood pressure; DBP, diastolic blood pressure; OD, BP measurements recorded with the HEM device; AD, BP measurements recorded with the Greenlight device; r = Pearson's correlation coefficient; CCC = Lin's concordance correlation coefficient; LOA = limits of agreements.

alternative to an MS as a reference standard in future validation studies with ODs versus ADs.

In our study, compared with the Greenlight readings, HEM readings were lower in DBP. These findings were similar to those of previous studies comparing HEM with an MS. Our study showed SBP higher readings with HEM. Previous studies on BP measurement with HEM showed inconsistent results for SBP. A few studies conducted by the NHANES in the US showed lower readings of SBP with HEM,[17,18] whereas Shin et al through the KNHANES in the Republic of Korea showed higher readings against MS.[12] However, the factors resulting in higher readings of SBP in our study are not known. However, some aspects of BP measurement techniques between the NHANES and KNHANES are different. In the NHANES, the HEM device

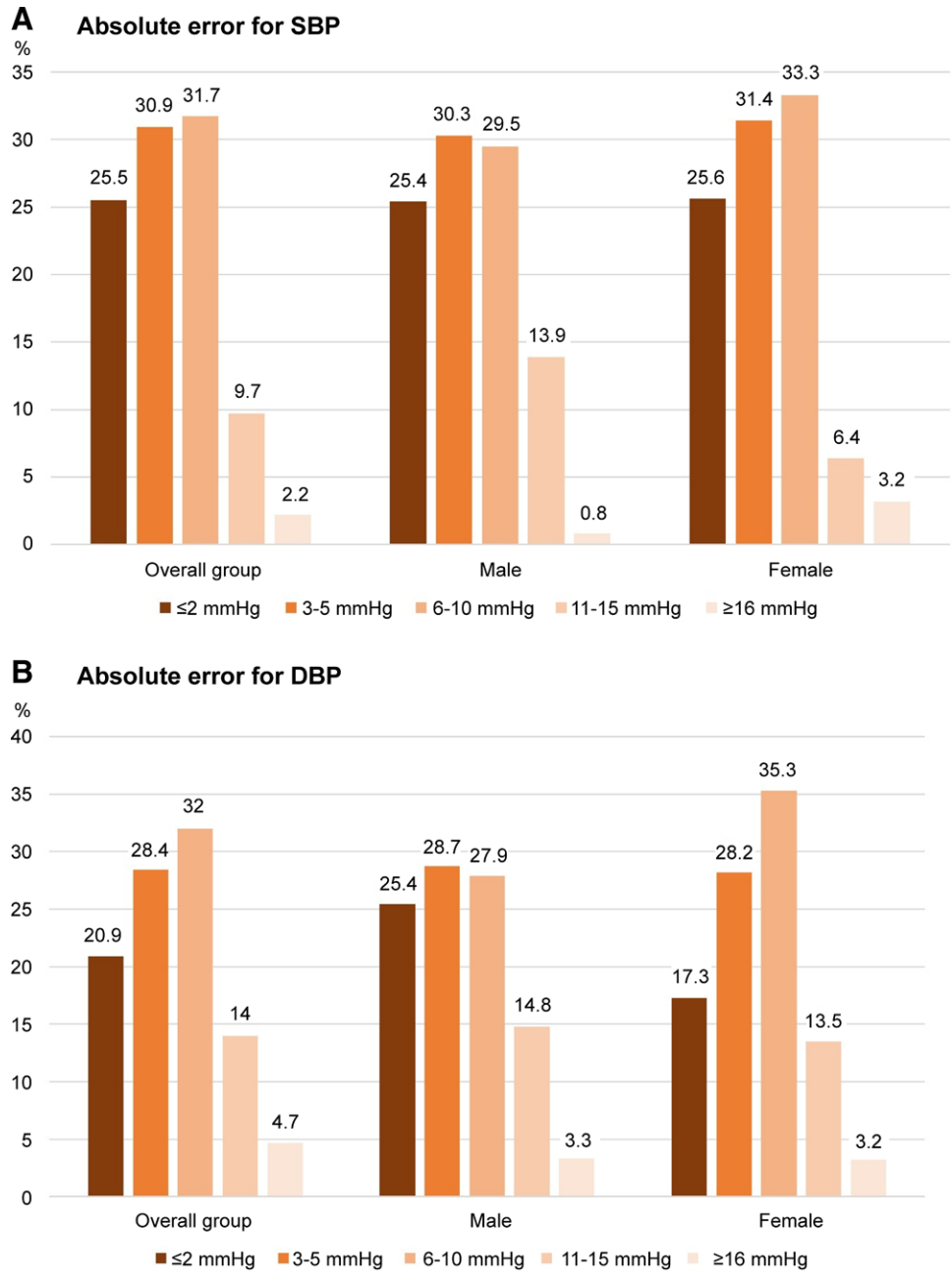


**Figure 2.** Frequency of absolute error distributions by sex for SBP and DBP. SBP, systolic blood pressure; DBP, diastolic blood pressure; OD, BP measurements recorded with the HEM device; AD, BP measurements recorded with the Greenlight device. Absolute error, the absolute value of BP difference between OD and AD. AD = electronic auscultatory device, OD = automated oscillometric device.

was in the "hide" function, and therefore, the measurements are automatically hidden when recording BP to reduce the participant's anxiety; however, in the KNHANES, it was set as hiding mode "off" feature to facilitate interpretation. Accordingly, the results might have been visible to the participants, thus causing increased SBP measurements with HEM, although the observer routinely asked the participants not to stare at the HEM monitor before recording BP measurements. Thus, not hiding the HEM monitor might have introduced the possibility of white coat hypertension in the KNHANES. Further studies are needed to clarify the possible reasons for higher SBP readings obtained with HEM in our survey. However, although SBP readings were inconsistent, our study showed better agreement for SBP than for DBP.

Our study showed that DBP discrepancy increased with increased DBP levels. Furthermore, SBP discrepancy increased with increased BP levels, but it showed statistically marginal significance. Previously, Ostchega et al reported results similar to the findings of our study.[17] In contrast, Omboni et al showed that only increased SBP values were associated with an increased discrepancy in older adults,[10] suggesting that it is necessary to consider the fact that a higher percentage of individuals are misdiagnosed with hypertension by the HEM device compared with the Greenlight device in extreme BP levels. This finding can be partly explained by the fact that BP values measured by an OD, such as the HEM device, are indirectly calculated through a presumed algorithm specific to each device. Thus, the increased discrepancy at extreme BP values occurs in virtually all ODs, although the degree of error varies according to each device.[20]

Popele et al showed that an oscillometric BP device compared with an MS overestimates SBP and DBP readings in participants with stiff arteries.[8] HEM may be validated for clinical use in

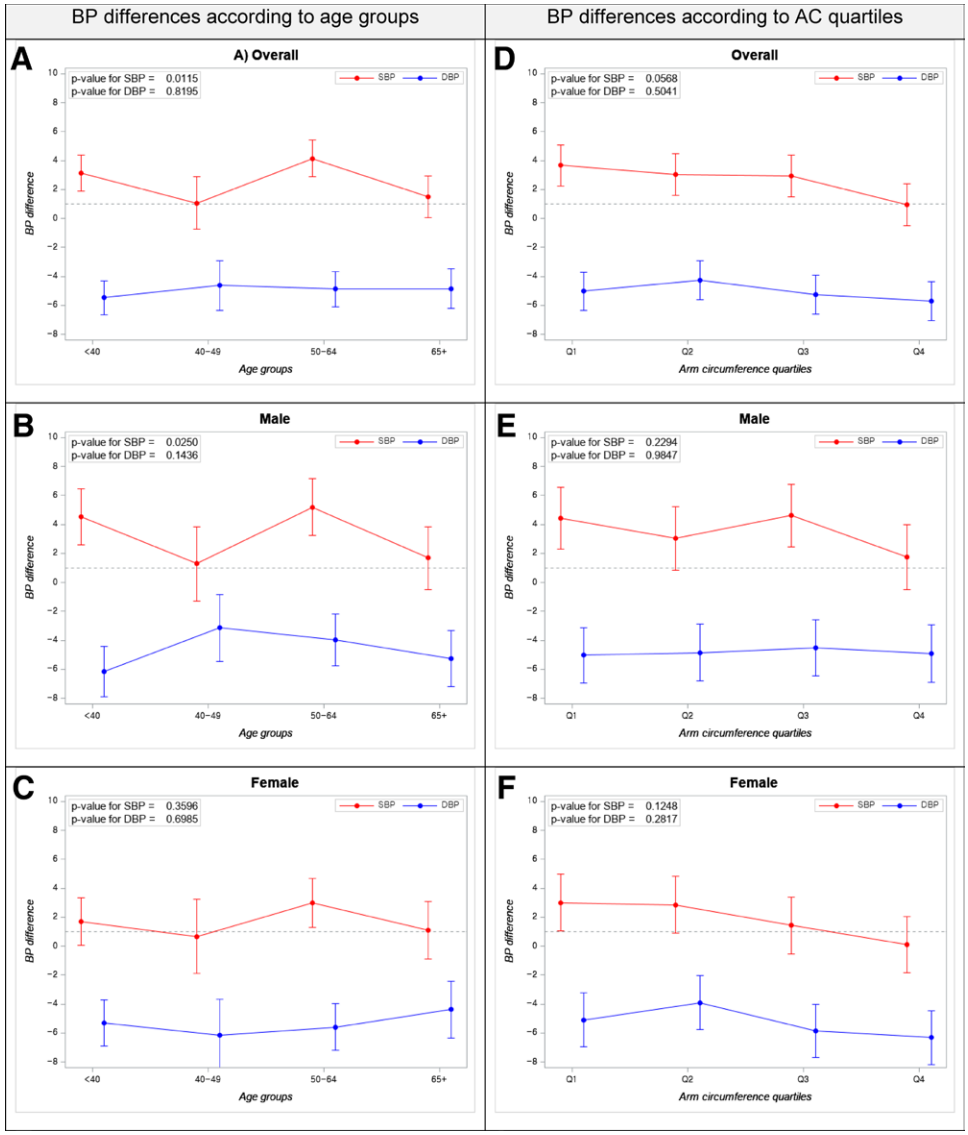


**Figure 3.** BP differences according to age groups and AC groups. The least-square means of the BP difference, adjusted for sex and arm circumference or age. A–F: SBP differences adjusted for sex and arm circumference or age were consistently higher than zero across all the age groups and arm circumference groups, whereas DBP differences were consistently lower than zero across all the groups, and those differences were not significantly different. AC = arm circumference, DBP = diastolic blood pressure, SBP = systolic blood pressure.

older individuals without atrial fibrillation or frequent ectopic beats.[10] Previously, Shin et al reported that the BP difference was rather exaggerated in younger individuals (aged < 40 years) between HEM and an MS.[12] However, in our data, adjusted SBP differences were the smallest in participants aged 40–49 years and largest in participants aged 50 to 64 years; however, in multivariate models, this relationship between age and SBP differences was negatively associated. Thus, in our study, middle-aged individuals aged 50 to 64 years might have a higher chance of being misdiagnosed as having hypertension. However, we could not explain these results exactly. Picone reported greater differences between upper-arm cuff BP and invasive BP increasing age, and this occurred irrespective of the level of BP, thus potentially exposing older persons to a greater chance for misdiagnosis of true BP level regardless of the BP levels.[21] Considering that arterial stiffness could affect the blood pressure measurements,[22] we conducted an analysis that considered pulse pressure as surrogate of arterial stiffness (Table 2). When analyzed including pulse pressure, pulse pressure did not have a significant relationship with SBP and DBP differences and absolute errors. In the multivariate model with pulse pressure, OD SBP values showed marginally significant relationship with SBP difference and SBP absolute error (Table 2). Especially, considering the increase in arterial stiffness with age, further studies need to validate the influence of arterial stiffness on blood pressure measurement.

Our study showed that AC was also negatively correlated with the BP difference between ODs and ADs. Thus, SBP and DBP differences were the smallest in participants with the largest AC quartiles. This finding was similar to that of a previous study.[12] Therefore, it might be considered that individuals with thin arms have a higher probability of obtaining inaccurate values using HEM than when using Greenlight, although the observers used an accurate cuff size. However, our data showed that the adjusted $R^2$ values for the HEM device were very low. Thus, further studies are needed to explain the influence of age and AC on oscillometric BP readings.

A device is acceptable when the cumulative percentage of the absolute error is within ≤ 10 mm Hg in at least 85% of the values according to the Universal Standard.[14] Our data showed that it was 88.1% for SBP and 81.3% for DBP. Thus, the absolute error was not tolerable in DBP when measured using HEM. An

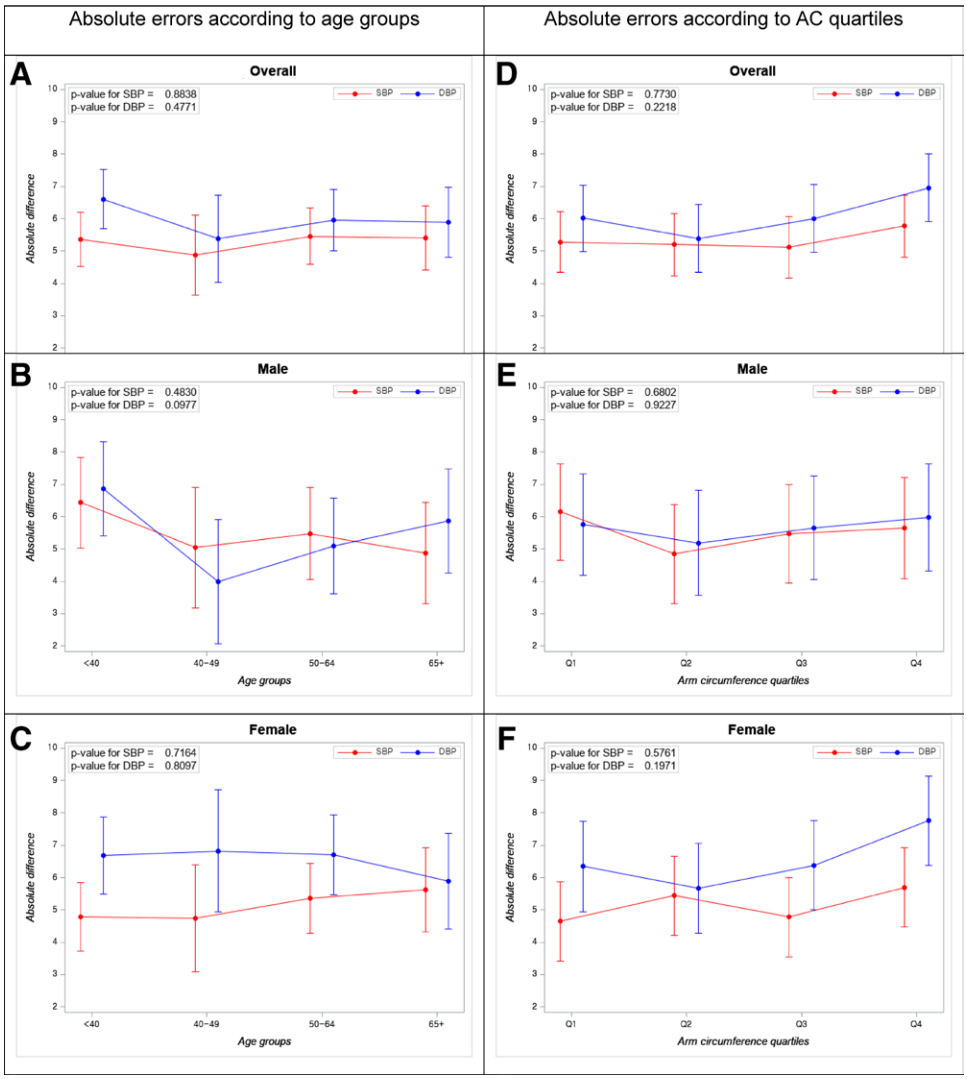


**Figure 4.** Absolute errors according to age groups and AC quartiles. The least-square means of the absolute BP difference, adjusted for arm circumference or age; the quartiles were 20.3–26.5, 26.6–28.2, 28.3–29.8, and 30.0–36.0 cm in males and 19.5–23.5, 23.6–25.2, 25.3–27.0, and 27.1–39.8 cm in females. A–F: The adjusted absolute errors in both DBP and SBP were not significantly different in age groups or arm circumference groups. AC = arm circumference, DBP = diastolic blood pressure, SBP = systolic blood pressure.

absolute agreement within 5 mm Hg is considered the acceptable threshold for between-device agreement in clinical studies, although an even more stringent threshold within 2 mm Hg is applied for the epidemiologic study.[3,6] Previously, the NHANES reported that an absolute error within 5 mm Hg between HEM and MS devices was 62.43% and 56.71% for SBP and DBP readings, respectively, and an absolute error within 2 mm Hg for HEM and MS was 31.24% and 27.72% for SBP and DBP readings, respectively.[12,18] According to our data, this frequency was overall lower than that of a previous study. (A-SBP and A-DBP within ≤ 5 mm Hg, 56.4% and 49.3%, respectively; A-SBP and A-DBP within ≤ 2 mm Hg, 25.5% and 20.9%, respectively). These findings suggest that HEM demonstrated a slightly lower validity in the KNHANES than in the NHANES.

According to our data, HEM showed an overall 0.7% lower prevalence of hypertension than Greenlight, although this difference was not statistically significant (14.0% vs 14.7%). However, HEM showed a 0.3% higher rate of SBP (≥140 mm Hg) and a 1.8% lower rate of DBP (≥90 mm Hg) than Greenlight. Moreover, our study showed that the mean HEM-DBP was approximately 5 mm Hg lower than Greenlight-DBP, suggesting that DBP might be underestimated when the HEM device is introduced in a population-based epidemiologic survey. The burden of SBP and DBP independently predicted the adverse outcomes.[23] Moreover, DBP drives the risk of coronary diseases in younger subjects,[24] which hinders early detection of hypertension and prevention of cardiovascular complications, especially in young individuals when hypertension is measured using HEM in a population-based epidemiologic survey. Therefore, when the HEM device is introduced in a population-based epidemiologic survey, it might underestimate DBP, leading to misdiagnosis.

This study has some limitations that should be considered before interpreting our findings. First, this is a small-sample comparative study in which the HEM device was compared with the Greenlight device. Second, this study compared HEM with Greenlight regarding the accuracy of BP measurements. Thus, it is impossible to conclude that similar BP differences and systemic errors could be observed in other types of ODs against other types of ADs, including aneroid devices and other electrical ADs. Therefore, these findings cannot be generalized to all individuals and different models of oscillometric BP devices.

In conclusion, this study evaluated the validity of BP differences and systemic errors of HEM against Greenlight as a reference standard instead of an MS in the KNHANES, according to the Universal Standard for device validation, and investigated the impact of these results on the prevalence of hypertension.

**Table 2**

**Multiple regression analysis for evaluating the effects of covariates included pulse pressure on BP difference and absolute BP difference.**

| | SBP | | DBP | |
|---|---|---|---|---|
| | β (se) | *P* value | β (se) | *P* value |
| **BP difference** | | | | |
| Intercept | 5.869 (4.108) | .1542 | −9.056 (3.427) | .0087 |
| OD SBP (mm Hg) | 0.055 (0.033) | .0990 | - | - |
| OD DBP (mm Hg) | - | - | 0.278 (0.028) | <.0001 |
| Male (Ref: Female) | 2.415 (0.767) | .0018 | 0.401 (0.640) | .5315 |
| Age, yrs | −0.066 (0.024) | .0077 | 0.008 (0.020) | .7061 |
| Arm circumference, cm | −0.531 (0.124) | <.001 | −0.533 (0.104) | <.0001 |
| Pulse rate, per min | 0.036 (0.020) | .0672 | −0.002 (0.016) | .8852 |
| Pulse pressure (mm Hg) | 0.075 (0.050) | .1324 | −0.039 (0.029) | .1788 |
| $R^2$ | 0.1546 | | 0.2896 | |
| **Absolute error** | | | | |
| Intercept | −2.757 (2.827) | .3302 | 8.053 (2.847) | .005 |
| OD SBP (mm Hg) | 0.039 (0.023) | .0854 | - | - |
| OD DBP (mm Hg) | - | - | −0.178 (0.023) | <.0001 |
| Male (Ref: Female) | −0.142 (0.528) | .7888 | −0.945 (0.532) | .0766 |
| Age, yrs | −0.026 (0.017) | .1240 | −0.011 (0.017) | .5237 |
| Arm circumference, cm | 0.083 (0.085) | .3312 | 0.382 (0.086) | <.0001 |
| Pulse rate, per min | 0.016 (0.014) | .2279 | 0.001 (0.014) | .9360 |
| Pulse pressure (mm Hg) | 0.025 (0.034) | .4734 | 0.028 (0.024) | .2426 |
| $R^2$ | 0.0535 | | 0.2098 | |

DBP = diastolic blood pressure, OD = BP measurements recorded with the HEM device, se = standard error, SBP = systolic blood pressure.

**Table 3**

**Diagnostic agreement in hypertension classification.**

| | OD | AD | | | | % Agreed [95% CI] | Weighted kappa [95% CI] | *P* value for symmetry test |
|---|---|---|---|---|---|---|---|---|
| **SBP, mm Hg** | | <120 | 120 to <140 | ≥140 | All | 83.1% | 0.76 | .0222 |
| | <120 | 137 | 8 | 0 | 145 (52.2%) | [78.2%–87.3%] | [0.70–0.83] | |
| | 120 to <140 | 26 | 67 | 6 | 99 (35.6%) | | | |
| | ≥140 | 0 | 7 | 27 | 34 (12.2%) | | | |
| | **All** | 163 (58.6%) | 82 (29.5%) | 33 (11.9%) | 278 | | | |
| **DBP, mm Hg** | | <80 | 80 to <90 | ≥90 | All | 80.6% | 0.62 | <.0001 |
| | <80 | 181 | 44 | 1 | 226 (81.3%) | [75.4%–85.1%] | [0.53–0.72] | |
| | 80 to <90 | 3 | 28 | 5 | 36 (12.9%) | | | |
| | ≥90 | 0 | 1 | 15 | 16 (5.8%) | | | |
| | **All** | 184 (66.2%) | 73 (26.3%) | 21 (7.6%) | 278 | | | |
| **Categorization§** | | Normal | Pre-hypertension | Hypertension | All | 81.3% | 0.75 | .7450 |
| | Normotension | 118 | 23 | 0 | 141 (50.7%) | [76.2%–85.7%] | [0.68–0.81] | |
| | Prehypertension | 17 | 74 | 7 | 98 (35.3%) | | | |
| | Hypertension | 0 | 5 | 34 | 39 (14.0%) | | | |
| | **All** | 135 (48.6%) | 102 (36.7%) | 41 (14.7%) | 278 | | | |

CI = confidence interval, DBP = diastolic blood pressure, N = number, SBP = systolic blood pressure.

OD, BP measurements recorded with the HEM device; AD, BP measurements recorded with the Greenlight device.

§Normotension: SBP < 120 mm Hg and DBP < 80 mm Hg; Prehypertension: SBP:120 to < 140 mm Hg or DBP 80 to < 90 mm Hg; Hypertension: SBP ≥ 140 and/or DBP ≥ 90 mm Hg.

These results showed that the HEM device met the accuracy requirements of the Universal Standard for SBP but not for DBP. Thus, HEM may underestimate the DBP values in the KNHANES. Moreover, these findings were similar to those of the previous comparative studies between HEM and an MS. Therefore, Greenlight, a mercury-free AD, is a suitable alternative to an MS as a reference standard in comparative studies.

## Author contribution

Conceptualization and design: J.S. and E.M.L; methodology: Y.-M.K. and E.M.L; formal analysis: Y.-M.K.: data curation: Y.K., K.O., and Y.-M.K.; writing—original draft preparation: D.W.O., Y.-M.K. and E.M.L writing—review and discussion: Y.-M.K., D.W.O., S.H.K., D.-H.K., S.M.P., I.-J.C., S.-H.I., K.-C.S., J.S., Y.K., K.O. and E.M.L. All authors have read and agreed to the published version of the manuscript.

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