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Comparisons of an automated oscillometric device with a hybrid manual auscultatory device for the Korea National Health and Nutrition Examination Survey

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Abstract

This study evaluated an oscillometric device (OD), Microlife WatchBP Office AFIB, and a hybrid manual auscultatory device (AD), Greenlight 300TM, to determine a suitable blood pressure (BP) measurement device for the Korea National Health and Nutrition Examination Survey in a mercury-free context. Adhering to the 2018 Universal Standard's suggested consensus, the study involved 800 subjects (mean age 51.2 ± 17.5 years; 44.3% male), who underwent triplicate BP measurements following 5 min of rest in a randomized order (OD-first: 398 participants; AD-first: 402 participants). BP difference was calculated as OD value minus AD value, with results stratified by measurement sequence. The overall BP difference and tolerable error probability were -1.1 ± 6.5/-2.6 ± 4.9 mmHg and 89.2%/92.5% for systolic/diastolic BP (SBP/DBP), respectively. Lin's concordance correlation coefficient was 0.907/0.844 for SBP/DBP

Yu-Mi Kim and Sang Hyeon Park contributed equally to this work.

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(OD-first/AD-first: 0.925/0.892 for SBP, 0.842/0.845 for DBP). The overall agreement for hypertension (BP ≥ 140 and/or 90 mmHg) was 0.71 ($p < 0.0001$), and the OD underestimated the overall hypertension prevalence by 5.1%. Analysis of the AD-first data revealed a lower level of agreement compared to the OD-first data; however, the observed blood pressure difference adhered to Criterion 1 of the 2018 Universal Standard. Microlife met the Criterion 1 of 2018 Universal Standard but underestimated the prevalence of hypertension. The BP discrepancy increased with higher BP levels, male sex, and smaller AC. With increasing age, the discrepancy decreased for SBP and increased for DBP.

KEYWORDS
agreement, blood pressure determination, health survey, hypertension, sphygmomanometers

1 | BACKGROUNDS

Hypertension is a major risk factor for cardiovascular disease affecting over 12.0 million people in Republic of Korea.[1] Accurate blood pressure (BP) measurement is essential for the early detection and management of hypertension. For many years, the mercury sphygmomanometer (MS) was considered the gold standard device for BP measurements; however, it is no longer used in clinical practice and national health surveys (NHS) in Republic of Korea because of concerns about mercury toxicity.[2] Two alternative devices are currently used for BP measurements: a hybrid manual auscultatory device (AD; aneroid or electronic), and an automated oscillometric device (OD).[3] ODs are commonly used for BP measurements in clinical practice[4] and NHS[5] because they are easy and safe to use and have minimal observer bias. However, the main limitation of ODs is that they may be inaccurate in some populations, including older adults, diabetes, pregnant women, children, and patients with obesity, arrhythmias, or stiffened arteries.[6] Therefore, to adopt an OD to NHS, the device needs to clarify the compatibility of a population with a wide range of ages, arm circumferences (ACs), and BP levels.

The Korea National Health and Nutrition Examination Survey (KNHANES), a nationally representative cross-sectional health survey,[7] has determined that an OD could be used for adult BP measurements in future surveys because of banning of MS in Republic of Korea.[8,9] Previously, the possibility of using an OD as a replacement for MS was investigated; however, those studies with A&D UA-767 PC[9] and Omron HEM-907 provided similar systolic BP (SBP) readings, but significantly lower diastolic BP (DBP) readings compared with the MS in KNHANES participants.[10] Thus, the prevalence of hypertension may have been significantly underestimated. Microlife WatchBP Office AFIB (Microlife; Microlife AG Swiss Corporation, Switzerland) is an internationally validated OD[11–13] that could be measured BP in individuals with a wide range of ages and ACs in clinical practice.[14] Additionally, during BP measurement, it can accurately detect asymptomatic atrial fibrillation,[15,16] a disease more commonly seen in older adults and a common cause of stroke in Republic of Korea.[17] However, there are limited data to evaluate the agreement of Microlife as a replacement of MS and effect of its use on the prevalence of hypertension in NHS. Recently, Kim et al reported that Greenlight 300 (Greenlight; Accoson Essex, United Kingdom), an internationally validated AD,[18] can be used as a new reference device to replace the MS in KNHANES.[19]

The aims of this study were to compare (1) the Microlife (OD) against Greenlight (AD) to clarify the compatibility of Microlife as a replacement of MS using the Criterion 1 of the 2018 Universal Standard; (2) the influence of systematic errors in BP measurements and; (3) the effect of the adoption of Microlife on the prevalence of hypertension in the KNHANES.

2 | METHODS

2.1 | Study participants

From June to August 2020, we enrolled 800 consecutive participants aged over 19 years, who underwent BP measurements using both Microlife (OD, test device) and Greenlight (AD, reference device) at the four mobile examination centers for the KNHANES. The participants provided informed consent to participate in this study. No exclusion criteria were applied unless a participant refused to undergo triplicate BP measurements per device. The study protocol was approved by the Institutional Review Board of the Korea Disease Control and Prevention Agency (KDCA, 2018-01-03-3C-A).

2.2 | Device calibration before and after use

Microlife[11] and Greenlight[18] have been validated according to the 2002 European Society of Hypertension-International Protocol. Four Microlifes and four Greenlights were calibrated to ensure pressure accuracy of devices and to exclude inter-device differences before and after use as follows[8]; three devices [non-invasive BP analyzer[20] (NIBP; Rigel BP-SiM, Rigel Medical, USA) and two Microlifes] were connected in parallel; the pressure accuracy was calculated as

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pressure difference between Microlife and NIBP over a range of pressures from 280 to 60 mmHg (10 calls per deflation, 20 reading per device); inter-device difference was calculated as pressure difference of each Microlife pressure values in each data point (40 readings per device). After the completion of the study, the calibration procedure was repeated. As criteria for pressure accuracy, at least 95% reference and test measurement pairs and inter-device pressure differences must be within ± 3 mmHg of each other.[8,21] All devices fulfilled the pressure accuracy criteria before-and after-use calibration without exhibiting malfunction during use.

2.3 | BP measurement with Microlife (OD) and Greenlight (AD)

BP was measured by four trained nurses who collected the data at the four mobile examination centers for the KNHANES. The standardized protocol for BP measurements, as per the guidelines of the Korea Disease Control and Prevention Agency (KDCA), is comprehensively delineated in separate methodology papers.[7,8] The participants were seated on a chair with back support, and BP measurements were obtained with their forearm supported on a table. The cuff was selected according to the mid-AC and was wrapped around the upper arm with the center of the bladder placed over the brachial artery at the midsternal level. The selection of proper cuff size was based on the KDCA protocols. BP was measured three times at least 30 s apart following 5 min of rest, and pulse rate was examined using radial artery palpation for 30 s in participants with a regular pulse and for 60 s in those with an irregular pulse. The first and fifth Korotkoff sounds for Greenlight were recorded for the SBP and DBP, respectively. The deflation speed and other quality control issues were as previously described.[8]

Greenlight and Microlife were alternately used to record each triplicate BP measurements per participant. All measurements were obtained from the same arm, in the same posture, and wearing an appropriate-sized cuff. The first measurement was randomly assigned to either Greenlight or Microlife to reduce measurement bias. To facilitate interpretation, the observer was not blinded to the Microlife readings.

2.4 | Definitions of BP differences and absolute errors, and BP classification for hypertension prevalence

Based on the KDCA protocol, the first BP reading was discarded, and the average of the 2nd and 3rd BP readings was used for representative BP values. Thus, the SBP difference (D-SBP) was defined as the average of the 2nd and 3rd SBP reading obtained using Microlife minus the average of the 2nd and 3rd SBP reading obtained using Greenlight. The DBP difference (D-DBP) was defined, as the average of the 2nd and 3rd DBP reading obtained using Microlife minus the average of the 2nd and 3rd DBP reading obtained using Greenlight. Absolute error was defined as the absolute value of the BP difference in SBP (A-SBP) and DBP (A-DBP).

On the basis of the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7),[22] BP status was categorized as normal, prehypertension, or hypertension without considering the participants' antihypertensive medication use.

2.5 | The 2018 Universal Standard Protocol for BP device validation

The criterion 1 and suggested consensus from the 2018 Universal Standard.[23]were used to compare and clarify the compatibility of Microlife against Greenlight. Microlife was deemed acceptable when met the criteria 1 (the mean BP difference ± standard deviation between Microlife and Greenlight did not exceed 5 ± 8 mm Hg) and a consensus (when at least 85% of the measurements were within the tolerable error of ≤10 mmHg).[23] This consensus was incorporated into the ESH International Protocol.[24]

2.6 | Statistical analyses

The characteristics of the study participants were summarized using descriptive statistics. Because OD-first measurements could affect the reading of the AD readings, the results were presented separately according to the order of device use. The agreement between OD-measured BP and AD-measured BP was evaluated using Lin's concordance correlation coefficient (CCC) and the Bland-Altman's limits of agreement (LOA). For assessing the overall level of agreement in BP classifications, weighted kappa values were estimated, and Bowker's symmetry test was performed. To assess the factors affecting BP differences, multiple linear regression analysis was applied, and the following covariates were considered: Model 1 including BP level; Model 2 including Model 1+ age and AC; Model 3 including Model 2 + sex and pulse rate/minute. All analyses were performed using SAS version 9.4 (SAS Institute, Cary, NC, USA).

3 | RESULTS

3.1 | General characteristics of the study participants

The 800 total participants were categorized into two groups according to the order of use of the BP devices: OD-first (n = 398) and AD-first (n = 402). The mean age was 51.2 ± 17.5 years, and 44.3% were men. The general characteristics were similar between the two groups (Table 1).

3.2 | Comparison of the OD (Microlife) and AD (Greenlight) BP values

The overall mean BP difference was −1.1 ± 6.53/−2.6 ± 4.93 mmHg for SBP/DBP (Table 2). These values met the Universal Standard Criteria 1. However, the BP differences were higher in the AD-first group

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TABLE 1 General characteristics of the study participants.

	Total $N = 800$	OD-first $N = 398$	AD-first $N = 402$	*p*-value
Sex, *n* (%)				
Male	354 (44.3%)	184 (46.2%)	170 (42.3%)	0.2616
Female	446 (55.8%)	214 (53.8%)	232 (57.7%)	
Age (years)				
Mean ± Std.	51.2 ± 17.5	51.4 ± 17.1	51.0 ± 17.9	0.6925
Median [min, max]	51.0 [19.0, 93.0]	52.0 [19.0, 85.0]	51.0 [19.0, 93.0]	
Age group, *n* (%)				
<45 years	280 (35.0%)	135 (33.9%)	145 (36.1%)	0.6571
45–64 years	321 (40.1%)	166 (41.7%)	155 (38.6%)	
65+ years	199 (24.9%)	97 (24.4%)	102 (25.4%)	
Height (cm)				
Mean ± Std.	163.4 ± 9.3	163.7 ± 9.6	163.0 ± 9.1	0.3021
Median [min, max]	162.8 [139.0, 190.0]	163.3 [141.0, 189.0]	162.2 [139.0, 190.0]	
Weight (kg)				
Mean ± Std.	64.6 ± 12.8	64.9 ± 13.0	64.4 ± 12.7	0.5935
Median [min, max]	63.2 [37.0, 140.0]	63.5 [37.0, 107.0]	63.1 [37.0, 140.0]	
BMI (kg/m^2)				
Mean ± Std.	24.1 ± 3.6	24.0 ± 3.6	24.1 ± 3.6	0.8842
Median [min, max]	23.7 [15.4, 47.8]	23.8 [17.1, 38.2]	23.7 [15.4, 47.8]	
Waist (cm)				
Mean ± Std.	84.1 ± 10.3	84.1 ± 10.1	84.2 ± 10.4	0.9187
Median [min, max]	84.4 [59.0, 130.0]	84.3 [60.0, 116.0]	84.5 [59.0, 130.0]	
Arm circumference (cm)				
Mean ± Std.	26.8 ± 3.12	26.9 ± 3.18	26.7 ± 3.06	0.3875
Median [min, max]	26.6 [19.7, 39.0]	26.7 [19.7, 39.0]	26.5 [20.0, 38.9]	
Antihypertensive medication use, *n* (%)				
No	608 (76.0%)	310 (77.9%)	298 (74.1%)	0.2131
Yes	192 (24.0%)	88 (22.1%)	104 (25.9%)	

Note: *p*-value from an independent *t*-test for continuous variables and the chi-square test for categorical variables.
Abbreviations: AD, blood pressure measurements recorded using the Greenlight device; BMI, body mass index; Greenlight, Accoson Greenlight 300; Microlife, Microlife WatchBP Office AFIB; OD, blood pressure measurements recorded using the Microlife device; *N* and *n*, number; Std, standard deviation.

than in the OD-first group (SBP OD-AD, 0.3 ± 5.61/−2.1 ± 4.92 mmHg $p < 0.0001$; DBP OD-AD, −2.1 ± 4.92/−3.1 ± 4.91 mmHg in OD-first/AD-first, $p = 0.0033$) Only 80 participants exhibited an irregular rhythm on pulse palpation. The SBP differences in these participants were higher than that in participants with a regular rhythm, whereas the DBP difference did not differ according to rhythm [SBP difference (−2.52/−0.92 mmHg) and DBP difference (−2.63/−2.39 mmHg) in participants with an irregular/regular rhythm].

3.3 | Agreement between OD and AD BP values

OD-SBP was highly correlated with AD-SBP (overall CCC, 0.907), whereas OD-DBP was moderately correlated with AD-DBP (overall CCC, 0.844). The CCC was higher in women than in men. Additionally, the CCC was higher in the OD-first group than in the AD-first group for SBP but was similar between the two groups for DBP (OD-first/AD-first, 0.925/0.892 for SBP and 0.842/0.845 for DBP) (Figure 1). The Bland–Altman LOA was separately plotted against the corresponding averages of the OD and AD measurements of SBP and DBP. The LOA for SBP was widely scattered in the AD-first group compared with that in the OD-first group; the LOA for DBP was similarly scattered between the two groups (Figure 2). The overall tolerable error probability was 89.2% for SBP and 92.5% for DBP. These values met the Universal Standard Criteria 1. However, the tolerable error probability was higher in the OD-first group than in the AD-first group for both SBP and DBP (tolerable error probability for SBP/DBP, 92.7/94.8% in the OD-first group and 85.6%/90.1% in the AD-first group) (Figure 3).

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TABLE 2 Distribution of blood pressure values measured using OD (Microlife) and AD (Greenlight).

	Total $N = 800$	OD-first $N = 398$	AD-first $N = 402$	*p*-value
Pulse rate per minute				
Mean ± Std.	70.3 ± 10.1	70.0 ± 10.0	70.5 ± 10.2	0.9013
Median [min, max]	68.0 [39.0, 116.0]	68.0 [47.0, 116.0]	68.0 [39.0, 108.0]	
OD-SBP, mmHg[a]				
Mean ± Std.	117.1 ± 14.60	117.5 ± 14.11	116.7 ± 15.1	0.4428
Median [min, max]	116.5 [85, 187]	116.5 [88, 163]	116.3 [85.0, 187.0]	
AD-SBP, mmHg[b]				
Mean ± Std.	118.1 ± 16.00	117.1 ± 14.95	119.1 ± 16.9	0.0785
Median [min, max]	117.0 [86, 184]	117.0 [87, 158]	118.0 [86.0, 184.0]	
SBP OD−AD, mmHg [c]				
Mean ± Std.	−1.1 ± 6.53	0.3 ± 5.61	−2.5 ± 7.07	<0.0001
Median [min, max]	−0.5 [−28.5, 22.5]	0.5 [−16.5, 19.0]	−2.0 [−28.5, 22.5]	
|SBP OD−AD|, mmHg [d]				
Mean ± Std.	5.0 ± 4.29	4.4 ± 3.46	5.7 ± 4.90	<0.0001
Median [min, max]	4.0 [0.0, 28.5]	3.5 [0.0, 19.0]	4.5 [0.0, 28.5]	
OD-DBP, mmHg[a]				
Mean ± Std.	72.7 ± 9.65	73.2 ± 9.27	72.2 ± 10.00	0.1693
Median [min, max]	72.0 [48, 108]	72.5 [51, 104]	71.5 [48, 108]	
AD-DBP, mmHg[b]				
Mean ± Std.	75.3 ± 9.98	75.2 ± 9.55	75.3 ± 10.41	0.9019
Median [min, max]	75.0 [47, 107]	75.0 [48, 105]	75.0 [47, 107]	
DBP OD−AD, mmHg[c]				
Mean ± Std.	−2.6 ± 4.94	−2.1 ± 4.92	−3.1 ± 4.91	0.0033
Median [min, max]	−2.5 [−17.5, 24.0]	−2.5 [−16.5, 24.0]	−2.8 [−17.5, 23.5]	
|DBP OD−AD|, mmHg[d]				
Mean ± Std.	4.3 ± 3.50	4.2 ± 3.27	4.5 ± 3.72	0.3527
Median [min, max]	3.5 [0.0, 24.0]	3.5 [0.0, 24.0]	3.5 [0.0, 23.5]	

Note: *p*-value from an independent *t*-test.

Abbreviations: AD, blood pressure measurements recorded using the Greenlight device; OD, blood pressure measurements recorded using the Microlife device; *N* and *n*, number; Std, standard deviation.

[a]Average of the second and third measurements from OD.

[b]Average of the second and third measurements from AD.

[c]Difference in blood pressure: average of the 2nd and 3rd measurements from OD minus average of the 2nd and 3rd measurements from AD.

[d]Absolute error = absolute value of the blood pressure difference.

The percentage of absolute errors within ≤2 mmHg for SBP/DBP was only 28.0%/33.9%.

3.4 | Agreement of BP classification (according to JNC 7 guidelines) between OD and AD measurements

The percentages of BP measurements categorized as normal, prehypertension, and hypertension were 55.6%, 34.9%, and 9.5% for the OD and 47.1%, 38.3%, and 14.6% for the AD, respectively. The prevalence of hypertension was underestimated by 5.1% by the OD compared with the AD estimation of hypertension prevalence (9.5% vs. 14.6%). The difference in hypertension prevalence was higher in the AD-first group than in the OD-first group (6.5% vs. 3.8%). The overall agreement for hypertension (BP ≥140 and/or 90 mmHg) was 0.71 (symmetry test < 0.0001, kappa = 0.73/0.69 in OD-first/AD-first) (Table 3).

3.5 | Multivariate regression analysis for risk factors for BP differences

In the multivariable analysis to identify the risk factors for BP differences, OD-BP and male sex were positively associated, whereas

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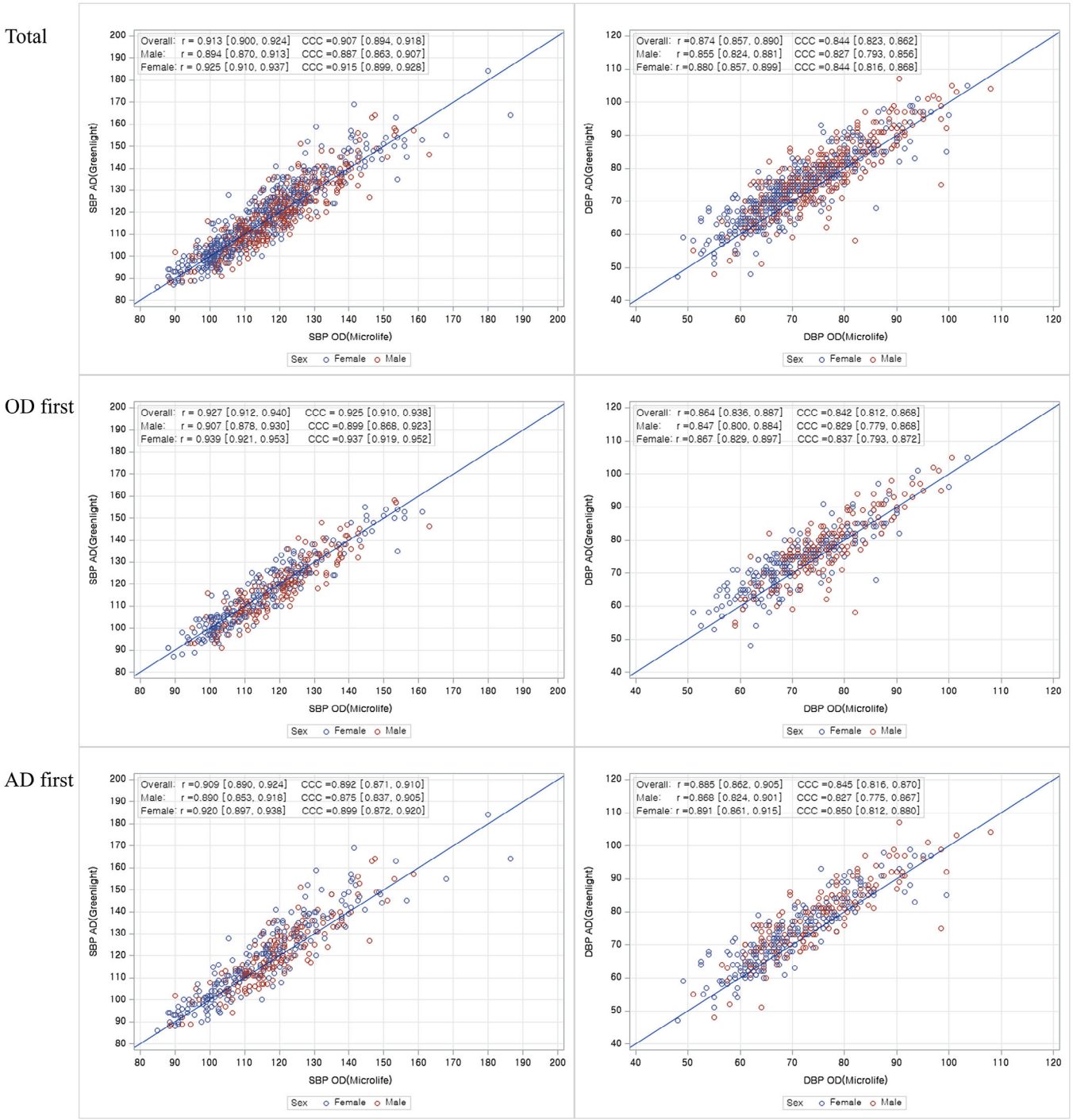


FIGURE 1 Scatter plots and correlations between OD (Microlife) and AD (Greenlight). *r*: Pearson's correlation coefficient, CCC: Lin's concordance correlation coefficient. SBP, systolic blood pressure; DBP, diastolic blood pressure; OD, blood pressure measurements recorded using the Microlife device; AD, blood pressure measurements recorded using the Greenlight device.

AC was negatively associated with BP differences. Age was negatively associated with SBP differences but positively associated with DBP differences. Pulse rate was positively associated with DBP differences (Table 4). However, regardless of the predictive model type, the adjusted R^2 values for OD measurements were low overall ($R^2 = 0.0965$ and 0.2031 for SBP and DBP differences in model 3).

4 | DISCUSSION

Microlife is an internationally validated OD for use in clinical practice[11–13]; however, to our knowledge, no previous study has evaluated the validity of this device for use in NHS. Limited data[19] are available on the suitability of an OD for use in NHSs in the

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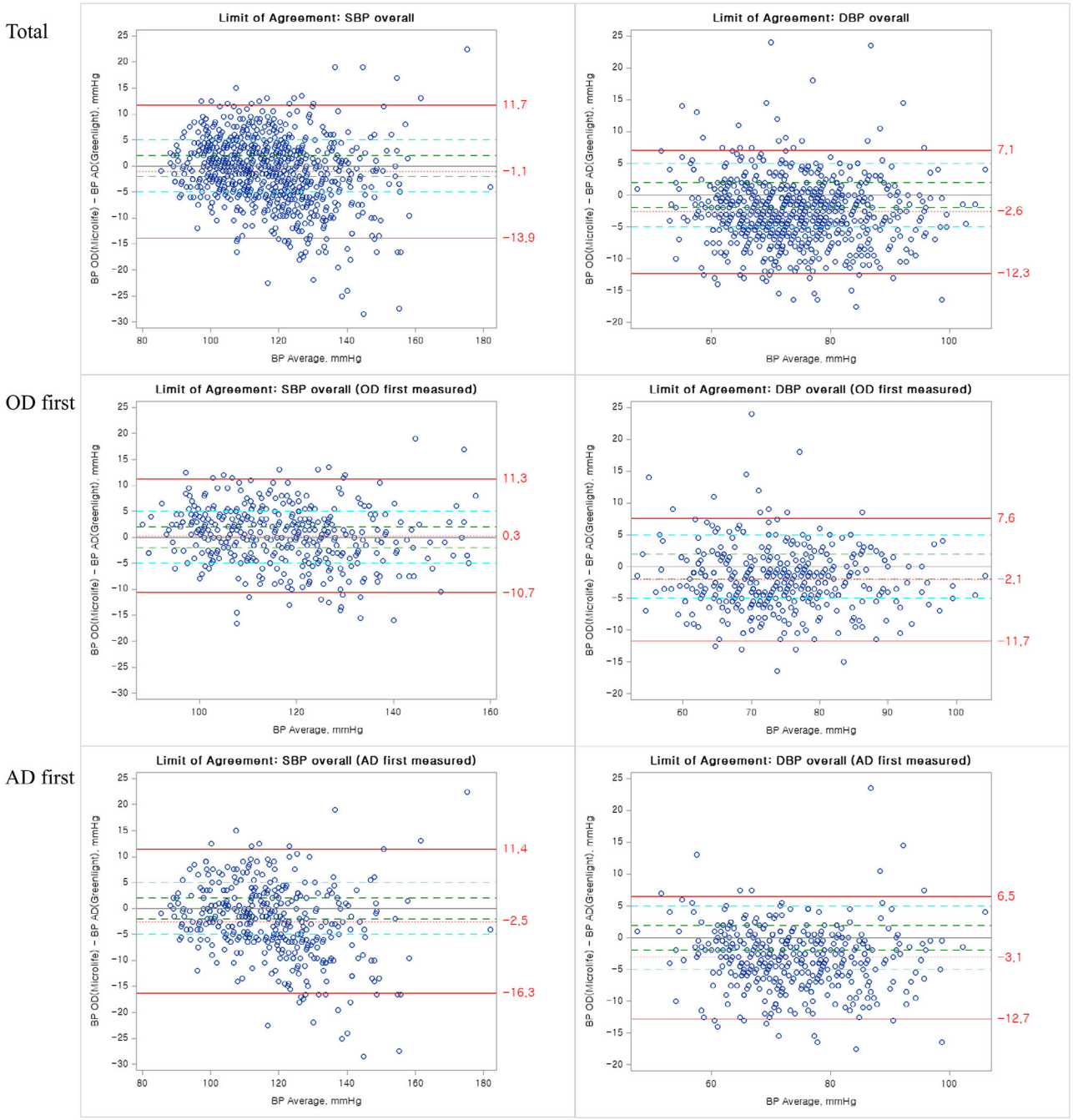


FIGURE 2 Bland–Altman plots and limits of agreement between OD and AD. SBP, systolic blood pressure; DBP, diastolic blood pressure; OD, blood pressure measurements recorded using the Microlife device; AD, blood pressure measurements recorded using the Greenlight device.

mercury-free era, compared with an AD as a reference device, based on the 2018 Universal Standard (Criterion 1: ≤5 ± 8 mmHg, tolerable error < 85%). Previously, our study group showed that HEM-907 (OD) met the accuracy requirements of the Universal Standard for SBP but not for DBP because the DBP readings of HEM-907 in the KNHANES were significantly lower than those of an AD (D-SBP/D-DBP, 2.6 ± 6.2/−5.1 ± 5.6 mmHg).[19] In this study, Microlife met the accuracy requirements of the Universal Standard Criteria 1 for both SBP and DBP, although the agreement was better for SBP (D-SBP/D-DBP, −1.1 ± 6.53/−2.6 ± 4.94 mmHg). Moreover, the probability of tolerable errors was 89.2%/92.5% for SBP/DBP in our study and 88.1%/81.3% for SBP/DBP in the HEM-907 study.[19] These findings suggest that Microlife may be more accurate than HEM-907 in terms of DBP measurements. Previously, Choi et al.[10] reported that memory bias might be acceptable in an indirect comparison study (OD vs. MS, AD vs. MS). However, in our study, the BP differences were larger in the AD-first group than in the OD-first group for SBP but were similar between groups for DBP (−2.52/−0.92 mmHg in AD-first/OD-first). Moreover, the agreement was higher in the OD-first group than in the AD-first group for SBP but was not

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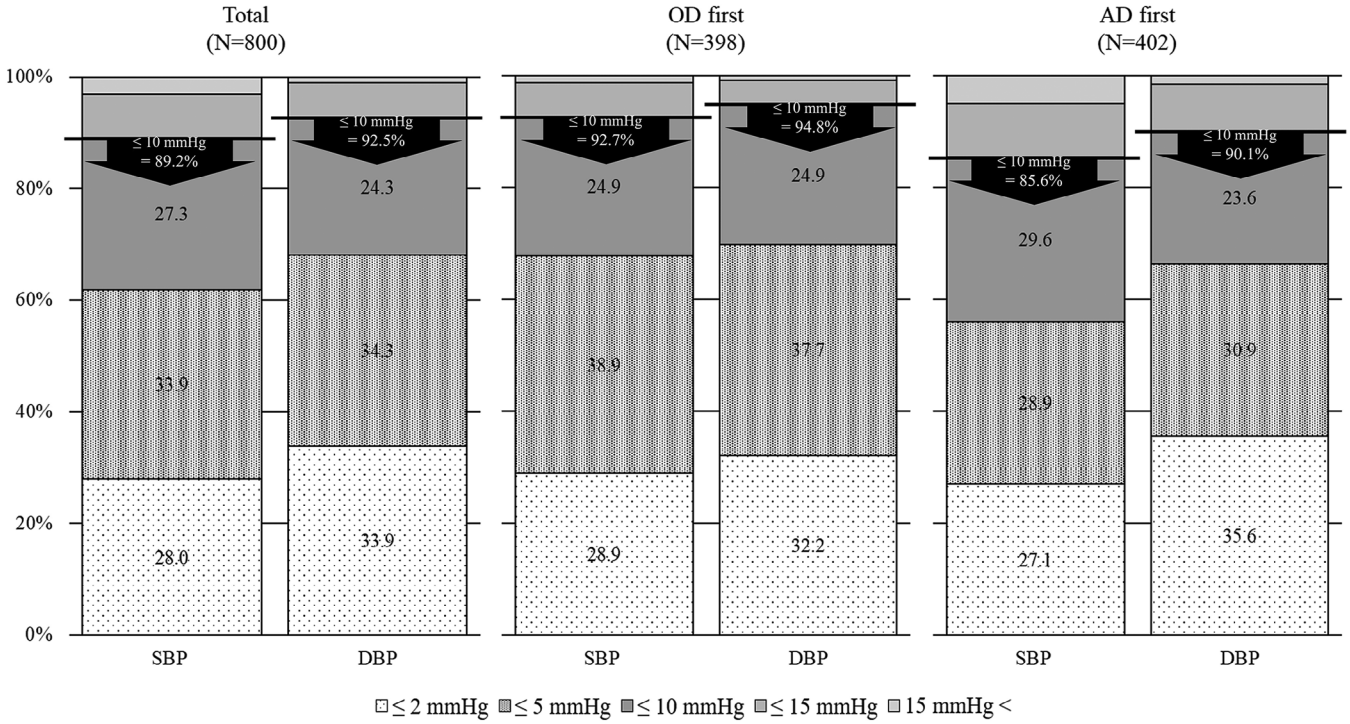


FIGURE 3 Distribution of absolute errors between OD and AD according to range. SBP, systolic blood pressure; DBP, diastolic blood pressure; OD, blood pressure measurements recorded using the Microlife device; AD, blood pressure measurements recorded using the Greenlight device.

TABLE 3 Agreement of hypertension diagnosis based on blood pressure measurements from OD vs. AD.

	OD|AD	Normal	Pre-HTN	HTN	All	% Agreement	Weighted kappa	Symmetry test
Total	Normal	357	87	1	445 (55.6%)	79.5%	0.71	<0.0001
	Pre-HTN	20	211	48	279 (34.9%)		[95% CI: 0.67, 0.75]	
	HTN	0	8	68	76 (9.5%)			
	All	377 (47.1%)	306 (38.3%)	117 (14.6%)	800		0.74	
OD-first	Normal	181	37	0	218 (54.8%)	81.4%	0.73	0.0002
	Pre-HTN	14	112	19	145 (36.4%)		[95% CI: 0.68, 0.79]	
	HTN	0	4	31	35 (8.8%)			
	All	195 (49.0%)	153 (38.4%)	50 (12.6%)	398			
AD-first	Normal	176	50	1	227 (56.5%)	77.6%	0.69	<0.0001
	Pre-HTN	6	99	29	134 (33.3%)		[95% CI: 0.64, 0.75]	
	HTN	0	4	37	41 (10.2%)			
	All	182 (45.3%)	153 (38.1%)	67 (16.7%)	402			

Abbreviations: AD, blood pressure measurements recorded using the Greenlight device; HTN, hypertension; OD, blood pressure measurements recorded using the Microlife device.

different between the groups for DBP. These findings suggest that the observers might have remembered the BP values first measured using the OD (Microlife), and this might have affected their subsequent reading of the SBP using the AD (Greenlight). Thus, the order of use of the BP devices may have resulted in a memory bias in our study.

Commonly, an OD may not be accurate in the presence of arrhythmia because the BP fluctuations due to the beat-to-beat variability of stroke volume affect the beat-to-beat oscillations of the arterial wall. However, Lakhal et al. reported that arrhythmia did not cause flawed automated brachial cuff measurements with an Intellivue MP70 monitor (OD) compared to intra-arterial measurements.[25] Microlife can detect asymptomatic atrial fibrillation during BP measurements with high accuracy.[15,16] In our study, the observers examined the participants' cardiac rhythm through radial artery pulse palpation, and D-SBP was higher in participants with an irregular rhythm. This suggests that using Microlife might result in a higher BP difference in individuals with arrhythmia. To date, no data are available to assess the BP difference

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TABLE 4 Factors associated with the blood pressure difference between OD and AD using a multiple regression model.

			Model 1: BP level (mmHg)		Model 2: Model 1 + age, AC		Model 3: Model 2 + sex, PR	
			β	*p*-value	*β*	*p*-value	*β*	*p*-value
Total	SBP	OD SBP (mmHg)	0.0002	0.9922	0.0451	0.0056	0.0422	0.0134
		Age (year)			−0.1095	<0.0001	−0.1131	<0.0001
		Male					2.0031	<0.0001
		AC (cm)					−0.1711	0.0343
		PR (beats/min)					0.0068	0.7631
		R^2	0.0000		0.0758		0.0965	
	DBP	OD DBP (mmHg)	0.0956	<0.0001	0.0785	<0.0001	0.0892	<0.0001
		Age (year)			0.0989	<.0001	0.0912	<0.0001
		Male					0.8319	0.0155
		AC (cm)					−0.3289	<0.0001
		PR (beats/min)					0.0468	0.0045
		R^2	0.0349		0.1565		0.2031	
OD first	SBP	OD SBP (mmHg)	0.0178	0.3740	0.0349	0.0921	0.0339	0.1189
		Age (year)			−0.0488	0.0044	−0.0563	0.0019
		Male					1.8972	0.0014
		AC (cm)					−0.2264	0.0207
		PR (beats/min)					0.0260	0.3579
		R^2	0.0020		0.0223		0.0546	
	DBP	OD DBP (mmHg)	0.1100	<0.0001	0.1046	<0.0001	0.1150	<0.0001
		Age (year)			0.0996	<0.0001	0.0899	<0.0001
		Male					0.9760	0.0412
		AC (cm)					−0.3242	<0.0001
		PR (beats/min)					0.0537	0.0210
		R^2	0.0429		0.1628		0.2138	
AD first	SBP	OD SBP (mmHg)	−0.0200	0.3948	0.0579	0.0139	0.0564	0.0234
		Age (year)			−0.1689	<0.0001	−0.1706	<0.0001
		Male					1.7396	0.0166
		AC (cm)					−0.1094	0.3772
		PR (beats/min)					−0.0109	0.7426
		R^2	0.0018		0.1562		0.1686	
	DBP	OD DBP (mmHg)	0.0790	0.0012	0.0520	0.0236	0.0624	0.0106
		Age (year)			0.0995	<0.0001	0.0933	<0.0001
		Male					0.6216	0.2095
		AC (cm)					−0.3406	<0.0001
		PR (beats/min)					0.0443	0.0566
		R^2	0.0259		0.1540		0.2016	

Abbreviations: AC, arm circumference; AD, blood pressure measurements recorded using the Greenlight device; BP, blood pressure; DBP, diastolic blood pressure; OD, blood pressure measurements recorded using the Microlife device; PR, pulse rate per minute; SBP, systolic blood pressure.

between individuals with a normal rhythm and those with an abnormal rhythm when ODs are used in NHSs. Moreover, electrocardiography was not performed on each participant in our study. Thus, further studies are needed to evaluate how arrhythmia affects the validity of ODs for use in NHSs.

In this study, the main determinants of BP differences were BP level, male sex, AC, and age. BP discrepancy between OD and AD increased with increasing BP levels for both SBP and DBP. Ni et al. reported that the Dinamap device (OD) tended to overestimate the SBP in participants with stage I–III hypertension.[26] This suggests that

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Microlife may misclassify participants with higher BP levels as having hypertension owing to BP overestimation. Theoretically, the point of maximal oscillation corresponds to the mean arterial pressure; thus, an OD can only indirectly estimate SBP and DBP using a presumed algorithm.[27] An increase in the BP difference occurs with increasing BP levels with almost all ODs; however, the degree of difference varies between each OD. Our study showed that the BP differences were higher in men than in women. However, previous studies on BP differences by sex have shown inconsistent findings.[5,11,19,28] Therefore, further studies are needed to clarify the influence of sex on BP measurements because the overall prevalence of hypertension is higher in men than in women in Republic of Korea.[29] This study showed that AC was negatively correlated with BP differences. Therefore, the BP differences were the largest in participants in the smallest AC quartiles, similar to the finding of a previous study.[19] This indicates that the probability of inaccurate BP measurements in participants with thin arms is higher with Microlife than that with Greenlight, regardless of the proper cuff size. However, our data showed that the R^2 values for Microlife measurements were low overall. Thus, further studies are needed to identify the determinants of differences in oscillometric BP readings in NHSs. The relatively low *R*-squared values observed in this study could suggest the absence of significant determinants influencing the discrepancies in measurement methods. This implies that the observed variances are likely to occur indiscriminately across all instances, rather than being predominantly evident in particular scenarios. This study showed that with increasing age, BP discrepancy decreased for SBP and increased for DBP, which is similar to the result of our previous study.[19] Picone et al. reported that cuff SBP was progressively underestimated, whereas cuff DBP was progressively overestimated compared with intra-arterial SBP and DBP in participants with increasing age.[30] In older adults, a DBP of $\leq$ 60 mmHg is associated with reduced survival, independent of large artery stiffness.[31] Thus, caution should be taken when using Microlife in NHSs, as it has a greater chance of inaccurate DBP measurements in older adults.

In this study, Microlife underestimated the overall prevalence of hypertension by 5.1%, although it satisfied the accuracy requirement of the Universal Standard Criteria 1 (overall prevalence of hypertension with Microlife vs. Greenlight, 9.5% vs. 14.6%). The difference in hypertension prevalence was higher in the AD-first group than in the OD-first group (6.5% vs. 3.8%). Moreover, the overall prevalence was significantly lower for both systolic hypertension (2.9%) and diastolic hypertension (3.2%) in Microlife measurements than those in Greenlight measurements. These results suggest that the potential misclassification of hypertension as normotension should be considered when adopting Microlife for use in the KNHANES. This makes early detection of hypertension difficult. BP levels are strongly and directly related to vascular mortality in individuals with hypertension, and the annual absolute differences in risk are greater in older adults.[32] Therefore, a correction formula adjusting for the hypertension prevalence may be required to overcome the underestimation problem with Microlife before it can be used in future NHSs.

This study had some limitations. First, we did not consider the BP differences according to the observers, although BP was measured at four different mobile examination centers. Second, this study compared BP differences and errors between Microlife (OD) and Greenlight (AD); however, the degree of difference varies between each OD model because different models use different predetermined algorithms. Thus, the findings of this study cannot be generalized to all individuals or to different OD models. Third, given the potential influence of measurement order on blood pressure readings, the incorporation of blinding is a critical consideration for future studies. While memory bias was not observed in our previous studies,[9,10] the AD-first data in current study revealed a reduced agreement compared to the OD-first data; indicating a possible memory bias. However, t is noteworthy that the results for AD-first subjects aligned with the overall study findings and confirmed the criterion 1 of the 2018 Universal Standard.

In conclusion, while Microlife met the criterion 1 and a consensus based on the 2018 Universal Standard, there remains a potential for underestimation of hypertension prevalence, necessitating the development of a correction formula to address this issue. The BP discrepancy increased with higher BP levels, male, and smaller ACs. With increasing age, the discrepancy decreased for SBP and increased for DBP. Given these findings, cautious interpretation is advised, and further research using standardized validation methods is essential to confirm the accuracy of these observations.

AUTHOR CONTRIBUTIONS

Yu-Mi Kim, Sang Hyeon Park, and Eun Mi Lee drafted the manuscript and prepared figures and tables. Jinho Shin, Ki-Chul Sung, Sang-Hyun Ihm, Seong Heon Kim, Dae-Hee Kim, Sang Min Park, In Jeong Cho, Kyung Won Oh, and Eun Mi Lee contributed to the conception of the study and the interpretation of the results. All authors reviewed the original draft and approved the final manuscript.

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CONFLICT OF INTEREST STATEMENT

The authors declare that they have no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data used came from Blood Pressure Quality Assurance and Control Project for the Korea National Health and Nutrition Examination Survey restrictions apply to the availability of these data. However, data might be available from the corresponding author upon reasonable request and with permission of the Korea Disease Control and Prevention Agency.

PATIENT CONSENT STATEMENT

Each subject provided written informed consent.

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