

Comparing Blood Pressure Values Obtained by Two Different Protocols: National Health and Nutrition Examination Survey, 2017–2018

Data Evaluation and Methods Research



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
National Center for Health Statistics

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
National Center for Health Statistics

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Abstract

Background

Blood pressure (BP) is traditionally measured using a mercury sphygmomanometer. Given environmental concerns about mercury, clinical and survey settings are moving to automated devices with an oscillometric protocol to obtain BP. This report compares BP measurement using the mercury and oscillometric protocols.

Methods

In the 2017–2018 National Health and Nutrition Examination Survey, among participants aged 18 and over ($n = 4,477$), BP was measured using two protocols in a randomly assigned order. The auscultation protocol (AP) was administered by a physician using a mercury sphygmomanometer. The oscillometric protocol (OP) was administered by a health technician using an Omron HEM-907 XL device. Between-protocol mean systolic BP (SBP) and diastolic BP (DBP) measurements were compared. The prevalence of stage 1 high blood pressure (equal to or greater than 130/80 mmHg) was determined, and agreement between protocols was evaluated using sensitivity, specificity, and kappa statistics.

Results

Overall, mean BP difference between AP and OP was 1.5 mmHg for SBP and -1.3 mmHg for DBP ($p < 0.01$ for both). Mean differences in SBP between protocols were significantly higher using AP compared with OP for most groups except men, non-Hispanic Asian adults, and participants using large adult cuff sizes. Mean differences in DBP between protocols were significantly lower using AP compared with OP for most groups except those aged 40–59, non-Hispanic Asian and Hispanic adults, and participants using regular adult cuff sizes. Overall, stage 1 high blood pressure prevalence was 38.6% using AP and 37.3% using OP. Both protocols for stage 1 high blood pressure demonstrated a good agreement ($\kappa \geq 0.6$), and sensitivity values and positive predictive values were 70% or more for all subcategories except the 18–39 age group.

Conclusions

Although mean SBP and DBP obtained by AP and OP differed, the prevalence of stage 1 high blood pressure did not differ, suggesting that a change in protocol may not affect blood pressure prevalence estimates.

Keywords: NHANES • stage 1 high blood pressure • oscillometric protocol • auscultatory protocol

Introduction

Since 1988, standardized, protocol-guided blood pressure (BP) measurements have been obtained in the National Health and Nutrition Examination Survey (NHANES). The traditional device for measuring BP has been the mercury sphygmomanometer, an auscultatory device that involves listening for sounds in the brachial artery to determine BP (1). Due to increased environmental concerns about the disposal of mercury-contaminated medical waste

and the risk of spills from mercury sphygmomanometers, mercury devices have been phased out of clinical use (2). Alternative blood pressure devices based on oscillometric automated technology are increasingly used in clinical and epidemiological studies. Several epidemiological studies have shown that oscillometric blood pressure devices can be used to accurately measure blood pressure in research and population-based studies (3–8).

In the 2009–2010 NHANES cycle, a study was carried out comparing the Omron HEM 907–XL oscillometric

automatic BP device with the mercury sphygmomanometer device used in NHANES as the gold standard. The study, however, used only one brand of cuff, the Baum cuff, to perform all BP measurements with both the mercury sphygmomanometer and the Omron HEM-907XL. No cuffs were changed between device readings, and the Omron device was adapted to accept the Baum cuffs. The major reason for not changing the cuffs was that at the time, BP determinations (systolic/diastolic) were performed 30 seconds apart, and the 30-second window did not allow adequate time to remove the Baum cuff and correctly fit an Omron cuff. Further information on this study can be found elsewhere (9). The importance of the BP cuff as part of the automatic device algorithm is also documented in another report (10).

During the 2017–2018 NHANES, both protocols were used to again determine comparability between the two methods, this time with the ability to adjust cuff size. BP was obtained with a stethoscope and a mercury sphygmomanometer device (Baumanometer) following an auscultation protocol (AP) in addition to an Omron HEM-907XL device using an oscillometric protocol (OP). Both protocols were used for each NHANES adult participant, but the order of administration was randomly assigned. This provided a unique opportunity to compare the BP estimates obtained with AP and OP and better understand the differences and similarities in BP values obtained by the two methods.

Specifically, this study had two objectives: a) to compare mean BP (systolic and diastolic) from two protocols overall and by sex, age group, race and Hispanic origin, and cuff size; and b) to compare agreement in stage 1 high blood pressure prevalence from two protocols' values, overall and by sex, age, and race and Hispanic origin.

Methods

Study Population

NHANES is a cross-sectional national health and nutrition survey of the civilian, noninstitutionalized U.S. population that is conducted by the National Center for Health Statistics (NCHS). The survey operates continuously, and data are released in 2-year cycles. Descriptions of the NHANES sample design and data collection methods are available on the survey website (11). Survey participants were interviewed in their homes and then examined in the NHANES mobile examination center (MEC). This methodology study was conducted as part of the NHANES MEC data collection in 2017–2018, and it was approved by the NCHS Research Ethics Review Board.

Sample Selection and Response Rate

During the NHANES 2017–2018 cycle, from among 11,027 eligible participants aged 18 and over from screened households, 5,856 (response rate = 52%) were interviewed, and 5,533 (response rate = 49%) were examined in the MEC. This methodology study excluded pregnant women ($n = 55$) and 17 participants with complete BP measures who missed the BP examination on their scheduled MEC appointment and returned on a second day to the MEC to complete the BP examination. This resulted in 5,461 participants eligible for inclusion.

Study Design

Each participant was randomly assigned the order of protocol administration. BP protocols were not done consecutively; instead, they were separated by other examination components in the MEC. Of the 5,461 participants eligible to participate in the study, 164 were missing BP data obtained with both protocols, 542 had only complete AP values, 245 had only complete OP values, and 33 had less than three BP readings for either protocol. These exclusions ($n = 984$) resulted in a final analytic sample of 4,477, reflecting 82% of the 5,461 eligible participants.

Equipment

The Omron HEM-907XL is a digital upper-arm electronic BP measurement device that is designed to be used in clinical settings (9). The Omron device is validated by both the Association for the Advancement of Medical Instrumentation and the International Protocol of the European Society of Hypertension for taking BP measurements in populations aged 13 years and over (12–14). The device can accommodate a range of cuff sizes, including child, adult, large adult, and extra-large adult. The device has several notable functions, including: an automatic setting feature for a “wait period” (e.g., 5 minutes); the ability to obtain three BP determinations of each type (systolic and diastolic), each 1 minute apart; and a “hide” mode designed to mask the collected BP values from both the examiner and participant. Once measurements are collected, the display can be switched to present the readings to be recorded.

The clinical wall-mounted mercury gravity sphygmomanometer (Baumanometer) was used as the reference comparison device to the Omron HEM-907XL (9). Like the Omron device, the mercury device accommodated a range of cuff sizes including child, adult, large adult, and extra-large adult. Each device was used with its corresponding set of cuffs (Table A).

Table A. Baumanometer and Omron HEM-907XL mid-arm circumference ranges, by cuff size

Cuff size	Mid-arm circumference range		Bladder width by length	
	Baum cuff	Omron cuff	Baum cuff	Omron cuff
Adult ¹	22.0–29.9	22.0–31.9	12 by 23	12.5 by 23.5
Large adult	30.0–37.9	32.0–41.9	15 by 33	15 by 31
Extra-large adult	38.0–48.0	42.0–50.0	18 by 36	18 by 38

¹Child/small-adult cuff category is combined with the adult-size cuff category (22.0–29.9 cm) because of the small number of participants requiring this cuff size (*n* = 24).

NOTES: All measurements are in centimeters. The Baum cuff is the reference.

SOURCE: National Center for Health Statistics, National Health and Nutrition Examination Survey, 2017–2018.

BP Measurement

All BP measurements were obtained during a single MEC examination. Participants were seated in a chair with back support, with both feet resting comfortably on the floor and both forearms supported on a level surface at heart level. The appropriate BP cuff size was selected according to the direct measurement of the participant’s mid-arm circumference (15). AP was conducted solely by physicians; after 3 minutes of rest, the physician manually obtained the maximum inflation level and radial pulse, and then obtained three consecutive BP measurements, waiting 30 seconds between measurements. The OP was conducted solely by health technicians; after 5 minutes of rest, the device automatically obtained three consecutive BP measurements of each type (systolic and diastolic) 60 seconds apart using “smart inflate” (Intellisense) technology. For more detailed information, see the respective procedure manuals for AP (16) and OP (17). The increase in time interval between the three BP measurements in OP (i.e., 60-second time interval) and in AP (i.e., 30-second time interval) followed the 2017 American College of Cardiology/American Heart Association (ACC/AHA) recommendations on how to accurately obtain standardized BP values (18).

Quality Assurance and Quality Control

To follow AP accurately and reliably, MEC physicians underwent a 2-day training and certification in manual blood pressure measurement using a training program provided by an independent expert consultant. This certification was completed after successful completion of instructional presentations, video presentations that included listening to and recording Korotkoff sounds, and practice listening to the blood pressure of volunteers with a certified instructor (19). Health technicians also underwent a 4-hour training and certification in automatic BP pressure measurement. For both protocols, recertifications were maintained by quarterly on-site monitoring.

Because the Omron device is unable to download the data electronically, the health technicians entered the results twice (i.e., double-keying) to prevent data entry errors from either the incorrect reading of a measurement or incorrect manual data input. If the data from the first entry did not match that of the second entry, technicians were asked to key in the data a third time (17). In contrast with the technicians, physicians manually entered the values after each BP determination (systolic and diastolic) but did not double-key the results (16).

Outcome Variables

Regardless of protocol, the mean of three brachial systolic BP (SBP) and diastolic BP (DBP) readings was used as the participants’ SBP and DBP values. This report uses the 2017 ACC/AHA guidelines for high blood pressure by stages (20). Stage 1 high blood pressure is defined as SBP at or above 130 mmHg or DBP at or above 80 mmHg (21).

Covariates

The following independent variables are used in the analysis: sex, age, race and Hispanic origin (non-Hispanic white, non-Hispanic black, non-Hispanic Asian, and Hispanic), and cuff size. Age is categorized in groups as 18–39, 40–59, and 60 and over.

Cuff Size

Cuff size is determined based on mid-arm circumference (cm), which is measured using a standardized procedure (15). Given that AP was the reference protocol in this study, the AP mid-arm circumference cuffing dimensions (adult 22.0–29.9 cm, large adult 30.0–37.9 cm, and extra-large adult 38.0–48.0 cm) were used to determine cuff size for all study participants. A similar approach was taken in a previous cuff comparison study (10). As [Table A](#) shows, AP and OP cuff sizes vary in their mid-arm circumference ranges. For example, participants with a mid-arm circumference of 39 cm required an extra-large cuff for AP but a large cuff for OP.

Twenty-four participants required a child/small-adult cuff for mid-arm circumference of 17.0–21.9 cm. Because of the small number requiring this cuff size, the child/small-adult cuff category was combined with the regular adult-size cuff category (22.0–29.9 cm) for analysis.

Differences Between Study Participants and Those Excluded

Weighted data analyses demonstrated some statistically significant differences between those included ($n = 4,477$) and excluded ($n = 984$) among the 5,461 eligible participants (Appendix Table I). A greater percentage of women were excluded from the analyses (16.7%) compared with men (13.6%) (Wald F test, $p < 0.05$). Among race and Hispanic-origin categories, a lower percentage of non-Hispanic white adults (12.1%) did not participate in the study compared with non-Hispanic Asian (21.1%) and Hispanic (23.0%) adults ($p < 0.01$ based on t statistic from orthogonal linear contrast). However, no differences were found between participants included and excluded from the study by age group (Wald F test, $p = 0.21$). For more details, see Appendix Table I.

Statistical Analysis

To calculate nationally representative estimates, examination sample weights that account for the differential probabilities of selection, nonresponse, and noncoverage were used in the estimation process. All variance estimates accounted for the complex survey design by using Taylor series linearization. Statistical analyses were conducted using the SAS System for Windows (Release 9.4, SAS Institute Inc., Cary, N.C.) and SUDAAN (Release 11.1, RTI International, Research Triangle Park, N.C.). Statistical significance was set at a p value less than 0.05.

Randomization Order

A Wald F test was used to compare participant characteristics by randomization order, that is, AP first or OP first. Weighted multivariable regression models that included sex, age group, race and Hispanic origin, and cuff size were used to calculate adjusted least square mean estimates and assess the significant association between randomization order and mean SBP AP, mean SBP OP, mean DBP AP, and mean DBP OP.

Mean Systolic and Diastolic Protocol Comparisons

Weighted means of the three SBP and DBP readings for each protocol were estimated overall and by sex, age group, race and Hispanic origin, and cuff size. Estimates for the race and Hispanic-origin groups were adjusted for age and cuff size, using least square mean estimates from a linear regression model, due to differences in these characteristics across race and Hispanic-origin groups (22). SUDAAN 11, Proc VARGEN (which computes point estimates and their associated design-based variances) was used to test the difference between the means of the two protocols by sex, age group, and cuff size based on a paired t test statistic. Analyses were also conducted without survey sample weights (unweighted analysis) for comparison, considering that the weights used

in the analysis may not be applicable to a study comparing biomedical devices.

Scatterplots, which display mean SBP and DBP among individuals separately, were overlaid with a regression line showing the overall trend as well as a line of unity ($x = y$, as in AP value = OP value). In general, when the regression line is above the unity line, it suggests that the data values are overestimated compared with what would be predicted; if under the unity line, the values are underestimated. To compare the distribution of values for each protocol, selected percentiles (1%, 10%, 25%, 50%, 75%, 90%, 95%, and 99%) were calculated. Bland–Altman scatterplots were obtained, describing the quantitative agreement between the two protocols by plotting the differences (OP – AP values) compared with the corresponding means of the measures from the two protocols $([OP + AP]/2)$ (23). The Bland–Altman plots were overlaid with a regression line to assess any proportional bias, which indicates unequal agreement across the range of values (24).

Protocol Agreement for Stage 1 High Blood Pressure

Weighted stage 1 high blood pressure prevalence estimates by OP and AP were computed overall and by sex, age group, and race and Hispanic origin. For each of the above prevalence estimates, a ratio was computed with AP as the reference (denominator) and OP as the numerator (OP%/AP%). Ratios with a 95% confidence interval (CI) not including unity were considered statistically significant. Weighted individual-level agreement was determined using sensitivity, specificity, positive predictive values, negative predictive values, and kappa statistics. A kappa statistic between 60% and 80% was considered a good agreement (25). AP, established as the legacy protocol, was the reference protocol and considered the gold standard.

Results

Randomization

Of the final analytic sample, 49% had BP measurements obtained using OP first, and 51% had BP measurements using AP first (Table B). The average time between OP and AP for those with OP first was 47 minutes (range: 7–269 minutes), while the average time between protocols with AP first was 58 minutes (range: 10–202 minutes). The weighted distribution of sex, age (18–39, 40–59, and 60 and over), self-reported race and Hispanic origin, and distribution of cuff size showed no statistically significant differences within the randomization scheme, although the percentages of adult and large adult cuff sizes were not equally distributed by protocol (Table B). Using OP first tended to result in a higher percentage using the adult cuff, whereas using AP first had a higher percentage using the large adult cuff. Weighted multivariable regression

Table B. Participant characteristics and blood pressure, by oscillometric compared with auscultation protocol

Characteristic	Randomization order		<i>p</i> value ¹
	Oscillometric first (<i>n</i> = 2,181)	Auscultation first (<i>n</i> = 2,296)	
	Percent (95% confidence interval)		
Total	49.4 (47.7–51.1)	50.6 (48.9–52.3)	...
Sex	0.35
Men	48.6 (46.6–50.7)	51.4 (49.3–53.4)	...
Women	50.2 (47.4–52.9)	49.8 (47.1–52.6)	...
Age group	0.19
18–39	51.2 (48.3–54.0)	48.8 (46.0–51.7)	...
40–59	49.6 (45.9–53.3)	50.4 (46.7–54.1)	...
60 and over	46.9 (43.2–50.7)	53.1 (49.3–56.8)	...
Race and Hispanic origin ²	0.62
Non-Hispanic white	49.9 (47.1–52.7)	50.1 (47.3–52.9)	...
Non-Hispanic black	48.3 (44.9–51.8)	51.7 (48.2–55.1)	...
Non-Hispanic Asian	50.3 (46.7–53.8)	49.7 (46.2–53.3)	...
Hispanic	49.5 (45.0–54.0)	50.5 (46.0–55.0)	...
Cuff size	0.06
Adult ³	54.4 (49.6–59.2)	45.6 (40.8–50.4)	...
Large adult	46.9 (44.0–49.7)	53.1 (50.3–56.0)	...
Extra-large adult	50.1 (46.2–53.9)	49.9 (46.1–53.8)	...
	Mean (95% confidence interval)		
Blood pressure measurement ⁴			
Auscultation protocol systolic	122.7 (121.2–124.3)	123.6 (122.4–124.8)	0.36
Oscillometric protocol systolic	121.2 (120.0–122.4)	122.2 (121.0–123.5)	0.22
Auscultation protocol diastolic	72.7 (71.5–73.9)	72.7 (71.4–74.0)	0.92
Oscillometric protocol diastolic	73.7 (73.0–74.4)	74.2 (73.3–75.2)	0.27

... Category not applicable.

¹Derived from Wald *F* test statistic from linear regression procedure in SUDAAN.

²Results for the category “Other race and Hispanic origin” are included in overall analyses but not reported separately.

³Includes child/small-adult cuff category (*n* = 24).

⁴Estimates and *p* values are adjusted for sex, age, race and Hispanic origin, and cuff size using least square means from a linear regression model.

NOTES: Among participants, 49% had blood pressure (BP) measurements obtained using OP protocol first, and 51% had BP measurements obtained using AP protocol first. The average time between OP and AP measurements for those with OP first was 47 minutes (range: 7–269 minutes), and the average time between protocols for those with AP first was 58 minutes (range: 10–202 minutes).

SOURCE: National Center for Health Statistics, National Health and Nutrition Examination Survey, 2017–2018.

models adjusted for sex, age group, race and Hispanic origin, and cuff sizes also showed no significant differences (*p* > 0.22) in between-protocol order (AP first or OP first) for mean SBP and DBP.

Between-protocol Differences

Tables C and D describe the differences in weighted mean SBP and DBP between protocols. The results are shown by sex, age group, race and Hispanic origin, and cuff size. Overall, mean AP SBP was 123.3 mmHg, while OP SBP was 121.8 mmHg (difference between protocols, 1.5 mmHg, *p* < 0.001). For SBP, all differences were significant (*p* < 0.05) except for men (*p* = 0.87), non-Hispanic Asian adults (*p* = 0.27), and the large adult cuff category (*p* = 0.27), and mean SBP was higher in AP compared with OP for all other groups. The differences in mean SBP between AP and OP ranged from –0.1 mmHg (men) to 4.6 mmHg (extra-large cuff).

Overall, mean DBP was 72.7 mmHg for AP and 74.0 mmHg for OP (between-protocol difference, –1.3 mmHg [*p* < 0.01]).

For DBP, all differences were significant (*p* < 0.05) except for participants aged 40–59 (*p* = 0.18), non-Hispanic Asian (*p* = 0.18) and Hispanic (*p* = 0.22) adults, and the regular adult cuff category (*p* = 0.72). Mean DBP was lower in AP compared with OP for all other groups. The DBP mean differences ranged from 0.2 mmHg (adult cuff) to –2.8 mmHg (extra-large adult cuff). AP values for SBP and DBP were also compared between those who participated in the study and had both AP and OP and nonparticipants who had three BP determinations in the AP condition only and no OP measurements (*n* = 526), using weighted analysis. No statistically significant differences were found for AP mean SBP readings (participants = 123.3 mmHg and nonparticipants = 123.5 mmHg, *p* = 0.84). Similarly, no statistically significant differences were found for AP mean DBP readings (participants = 72.7 mmHg and nonparticipants = 72.2 mmHg, *p* = 0.62).

Appendix Tables II and III describe the unweighted mean differences between protocols for SBP and DBP. The weighted and unweighted mean estimates and patterns by characteristics between protocols for SBP and DBP

Table C. Weighted mean and standard error of systolic blood pressure values in auscultation and oscillometric protocols and difference, overall and by characteristic

Characteristic	<i>n</i>	Auscultation systolic blood pressure (SE)	Oscillometric systolic blood pressure (SE)	Difference (SE)	<i>p</i> value ¹
Overall	4,477	123.3 (0.50)	121.8 (0.41)	1.5 (0.31)	Less than 0.001
Sex					
Men	2,249	124.4 (0.53)	124.5 (0.47)	-0.1 (0.33)	0.87
Women	2,228	122.1 (0.77)	119.1 (0.79)	3.0 (0.38)	Less than 0.001
Age group					
18–39	1,458	115.5 (0.56)	114.3 (0.44)	1.2 (0.37)	Less than 0.01
40–59	1,377	123.8 (0.70)	122.7 (0.66)	1.1 (0.44)	Less than 0.05
60 and over	1,642	132.5 (0.82)	130.3 (0.66)	2.2 (0.42)	Less than 0.001
Race and Hispanic origin ^{2,3}					
Non-Hispanic white	1,618	123.3 (0.61)	120.8 (0.63)	1.5 (0.44)	Less than 0.01
Non-Hispanic black	1,037	128.4 (0.53)	126.6 (0.52)	1.8 (0.56)	Less than 0.01
Non-Hispanic Asian	625	124.2 (1.04)	123.6 (0.91)	0.6 (0.54)	0.27
Hispanic	957	123.3 (0.65)	122.1 (0.58)	1.2 (0.43)	Less than 0.05
Cuff size ⁴					
Adult	1,179	121.4 (0.97)	120.2 (1.00)	1.2 (0.46)	Less than 0.05
Large adult	2,403	122.9 (0.64)	122.5 (0.53)	0.4 (0.34)	0.27
Extra-large adult	825	126.2 (0.29)	121.6 (0.65)	4.6 (0.61)	Less than 0.001

¹*p* values for age, sex, and cuff size are derived from Student's *t* test from orthogonal linear contrast.

²Results for the category "Other race and Hispanic origin" are included in overall analyses but not reported separately.

³Systolic blood pressure mean values are adjusted for age and cuff size using least square means and *p* value derived from Wald *F* test statistic in a linear regression model.

⁴Baum cuff sizes used. Adult category includes child/small-adult cuff category (*n* = 24).

NOTES: SE is standard error. Blood pressure measurements are in mmHg.

SOURCE: National Center for Health Statistics, National Health and Nutrition Examination Survey, 2017–2018.

Table D. Weighted mean and standard error of diastolic blood pressure values in auscultation and oscillometric protocols and difference, overall and by characteristic

Characteristic	<i>n</i>	Auscultation diastolic blood pressure (SE)	Oscillometric diastolic blood pressure (SE)	Difference (SE)	<i>p</i> value ¹
Overall	4,477	72.7 (0.56)	74.0 (0.35)	-1.3 (0.42)	Less than 0.01
Sex					
Men	2,249	74.3 (0.74)	75.4 (0.52)	-1.1 (0.39)	Less than 0.05
Women	2,228	71.1 (0.45)	72.6 (0.45)	-1.5 (0.55)	Less than 0.05
Age group					
18–39	1,458	70.7 (0.72)	72.1 (0.47)	-1.4 (0.45)	Less than 0.01
40–59	1,377	76.6 (0.61)	77.3 (0.50)	-0.7 (0.50)	0.18
60 and over	1,642	70.6 (0.51)	72.5 (0.32)	-1.9 (0.51)	Less than 0.01
Race and Hispanic origin ^{2,3}					
Non-Hispanic white	1,618	72.3 (0.66)	73.6 (0.45)	-1.4 (0.55)	Less than 0.05
Non-Hispanic black	1,037	74.2 (0.79)	76.2 (0.36)	-2.0 (0.53)	Less than 0.01
Non-Hispanic Asian	625	74.8 (0.40)	75.5 (0.51)	-0.7 (0.48)	0.18
Hispanic	957	72.4 (0.58)	73.1 (0.35)	-0.7 (0.51)	0.22
Cuff size ⁴					
Adult	1,179	70.2 (0.67)	70.0 (0.60)	0.2 (0.59)	0.72
Large adult	2,403	73.1 (0.60)	74.5 (0.36)	-1.4 (0.44)	Less than 0.01
Extra-large adult	825	74.7 (0.57)	77.6 (0.58)	-2.8 (0.52)	Less than 0.001

¹*p* values for age, sex, and cuff size are derived from Student's *t* test from orthogonal linear contrast.

²Results for the category "Other race and Hispanic origin" are included in overall analyses but not reported separately.

³Diastolic blood pressure mean values are adjusted for age and cuff size using least square means and *p* value derived from Wald *F* test statistic in a linear regression model.

⁴Baum cuff sizes used. Adult category includes child/small-adult cuff category (*n* = 24).

NOTES: SE is standard error. Blood pressure measurements are in mmHg.

SOURCE: National Center for Health Statistics, National Health and Nutrition Examination Survey, 2017–2018.

Figure 1. Mean systolic blood pressure measured by oscillometric protocol compared with auscultation protocol

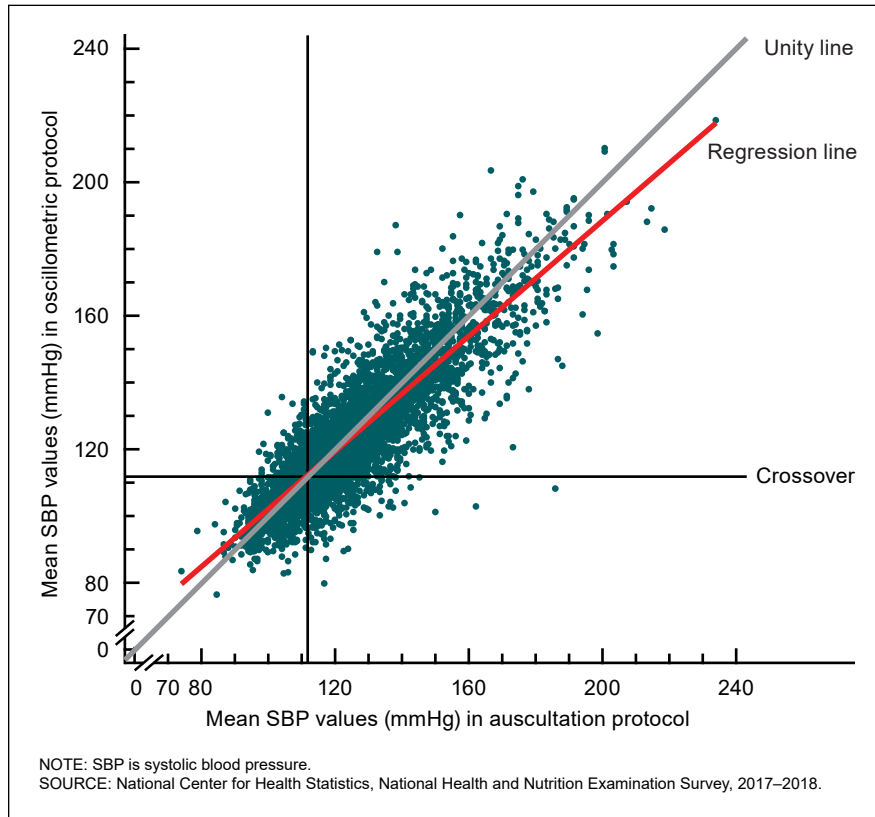
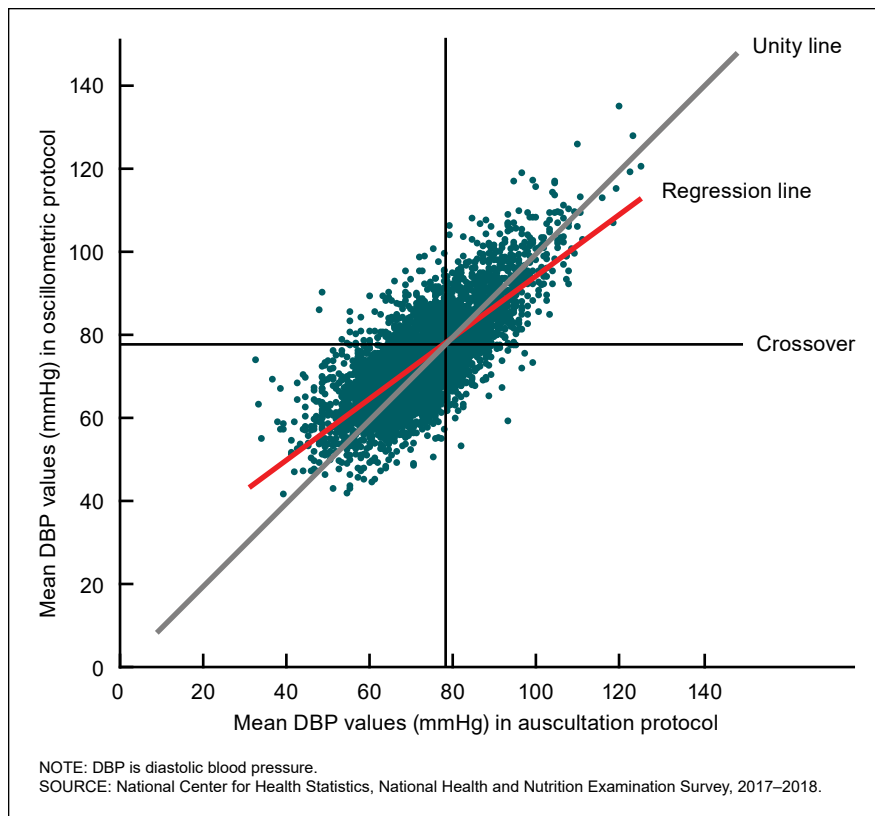


Figure 2. Mean diastolic blood pressure measured by oscillometric protocol compared with auscultation protocol



were similar across the categories except among non-Hispanic Asian and Hispanic adults, and adults aged 40–59. Among Hispanic adults and adults aged 40–59, a difference was observed between protocols for DBP in the unweighted analysis ($p < 0.001$), but not in the weighted analysis ($p = 0.22$). Among non-Hispanic Asian adults, the unweighted differences between protocols for both SBP and DBP, adjusted for age group and cuff size, were significant ($p < 0.05$, both SBP and DBP). By contrast, the weighted differences were not significant (SBP, $p = 0.27$; DBP, $p = 0.18$), and the size of the difference for DBP was somewhat reduced in the unweighted results.

Figures 1 and 2 show the unweighted scatterplots and weighted regression lines of AP and OP mean BP readings (SBP $R^2 = 0.73$ and 0.74 , DBP $R^2 = 0.56$ and 0.57 , $p < 0.001$ for both weighted and unweighted results, respectively). For SBP, the regression line was slightly above the unity line, crossing over at 111.8 mmHg to below the unity line, suggesting that OP slightly overestimated SBP compared with AP when SBP was less than 111.8, and then underestimated the mean of SBP compared with AP when SBP was greater than 111.8. For DBP, the regression line was above the unity line, crossing over at 77.7 mmHg to below the unity line, suggesting that OP overestimated the mean of DBP at DBP less than 77.7 mmHg, and underestimated the mean of DBP at DBP greater than 77.7 mmHg. Table E illustrates differences in the distribution of values between the protocols across key percentiles. For SBP, AP read higher than OP, particularly in the 1%–5% range. For DBP, in contrast, OP read higher than AP and, as with systolic differences, more so at the 1%–5% range.

Figures 3 and 4 display the Bland–Altman plots of between-protocol differences in SBP and DBP against the corresponding BP readings averaged over both protocols. The slope of the regression line for SBP was not significantly different from zero ($p = 0.82$), suggesting no proportional

Table E. Blood pressure across selected weighted percentiles, by protocol

Blood pressure	Auscultation protocol	Oscillometric protocol	Difference
Systolic percentage			
1	94.0	90.5	3.6
5	99.9	97.9	2.0
10	103.7	102.4	1.3
25	110.6	109.4	1.2
50	120.5	119.1	1.3
75	131.9	130.9	1.0
90	146.3	144.4	1.9
95	156.0	154.7	1.3
99	176.5	176.2	0.4
Diastolic percentage			
1	47.6	50.9	-3.3
5	54.8	57.4	-2.7
10	58.6	60.8	-2.2
25	65.2	66.2	-1.0
50	72.3	72.9	-0.6
75	79.0	80.6	-1.7
90	86.3	87.9	-1.6
95	90.8	92.5	-1.6
99	100.8	103.0	-2.1

NOTE: Difference is auscultation protocol minus oscillometric protocol.

SOURCE: National Center for Health Statistics, National Health and Nutrition Examination Survey, 2017–2018.

bias. The between-protocol DBP difference (OP – AP) was associated with the DBP levels, with 1 mmHg increase in the mean of DBP values (OP + AP) associated with a 0.02 mmHg decrease in between-protocol DBP difference (OP – AP) ($p = 0.05$).

Between-protocol Agreement for Stage 1 High Blood Pressure

Figures 5–7 show the weighted prevalence of stage 1 high blood pressure by each protocol overall, and by sex, age group, and race and Hispanic origin. None of the prevalence ratios (OP%/AP%) for stage 1 high blood pressure were significantly different from 1, overall (ratio = 1.01, 95% CI = 0.99–1.02), or among men (ratio = 1.02, 95% CI = 1.00–1.04), women (ratio = 1.00, 95% CI = 0.98–1.02), and age groups 18–39 (ratio = 0.99, 95% CI = 0.97–1.02), 40–59 (ratio = 1.01, 95% CI = 0.98–1.05), and 60 and over (ratio = 1.02, 95% CI = 0.99–1.05). Likewise, no race and Hispanic origin-specific prevalence ratios were significantly different from 1, as in non-Hispanic white (ratio = 1.01, 95% CI = 0.99–1.04), non-Hispanic black (ratio = 1.00, 95% CI = 0.98–1.02), non-Hispanic Asian (ratio = 1.02, 95% CI = 0.99–1.06), and Hispanic (ratio = 1.01, 95% CI = 0.99–1.03) adults.

Weighted analyses of agreement on stage 1 high blood pressure prevalence between OP and AP, with AP as the reference, are shown in Table F. Sensitivity values ranged

Figure 3. Bland–Altman plot comparing systolic blood pressure between oscillometric and auscultation protocols

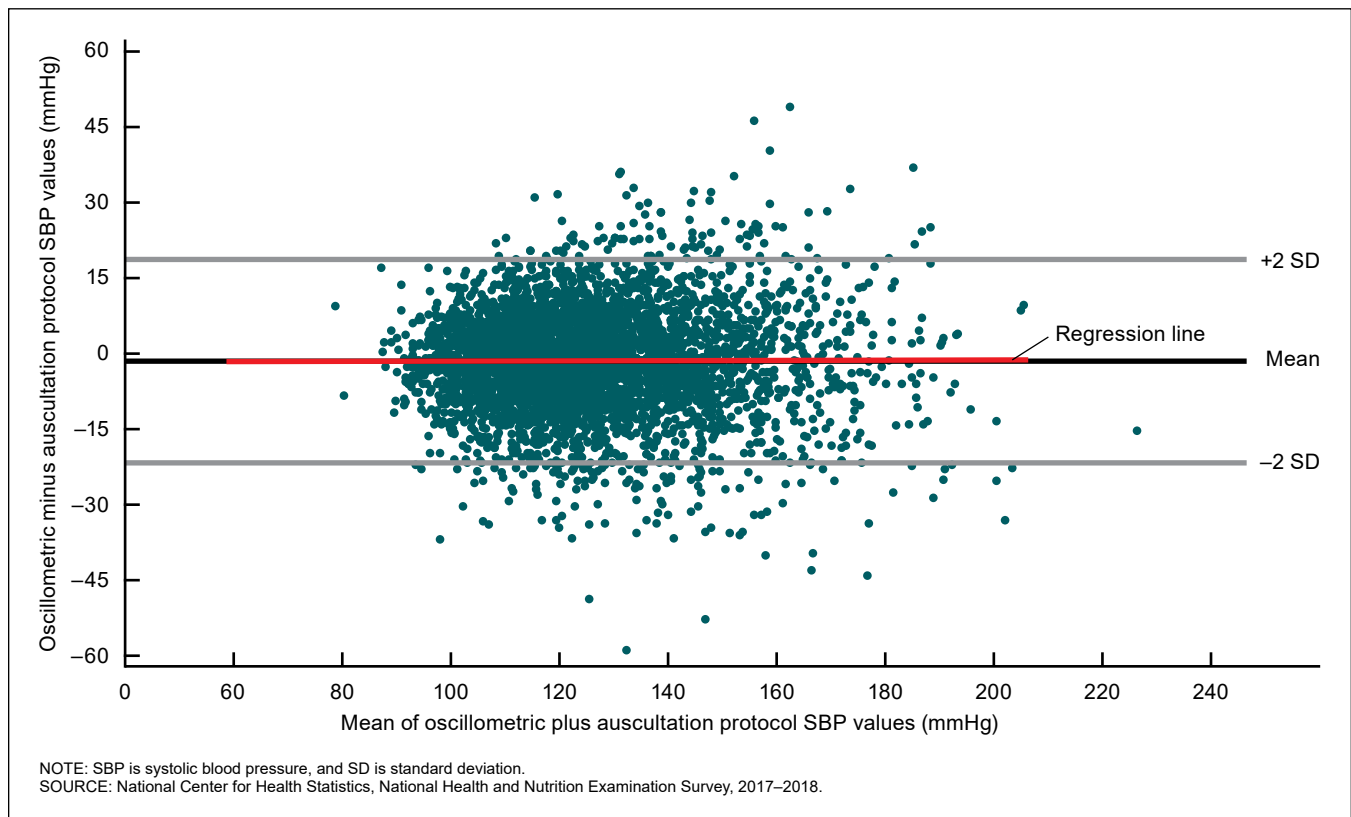


Figure 4. Bland–Altman plot comparing diastolic blood pressure between oscillometric and auscultation protocols

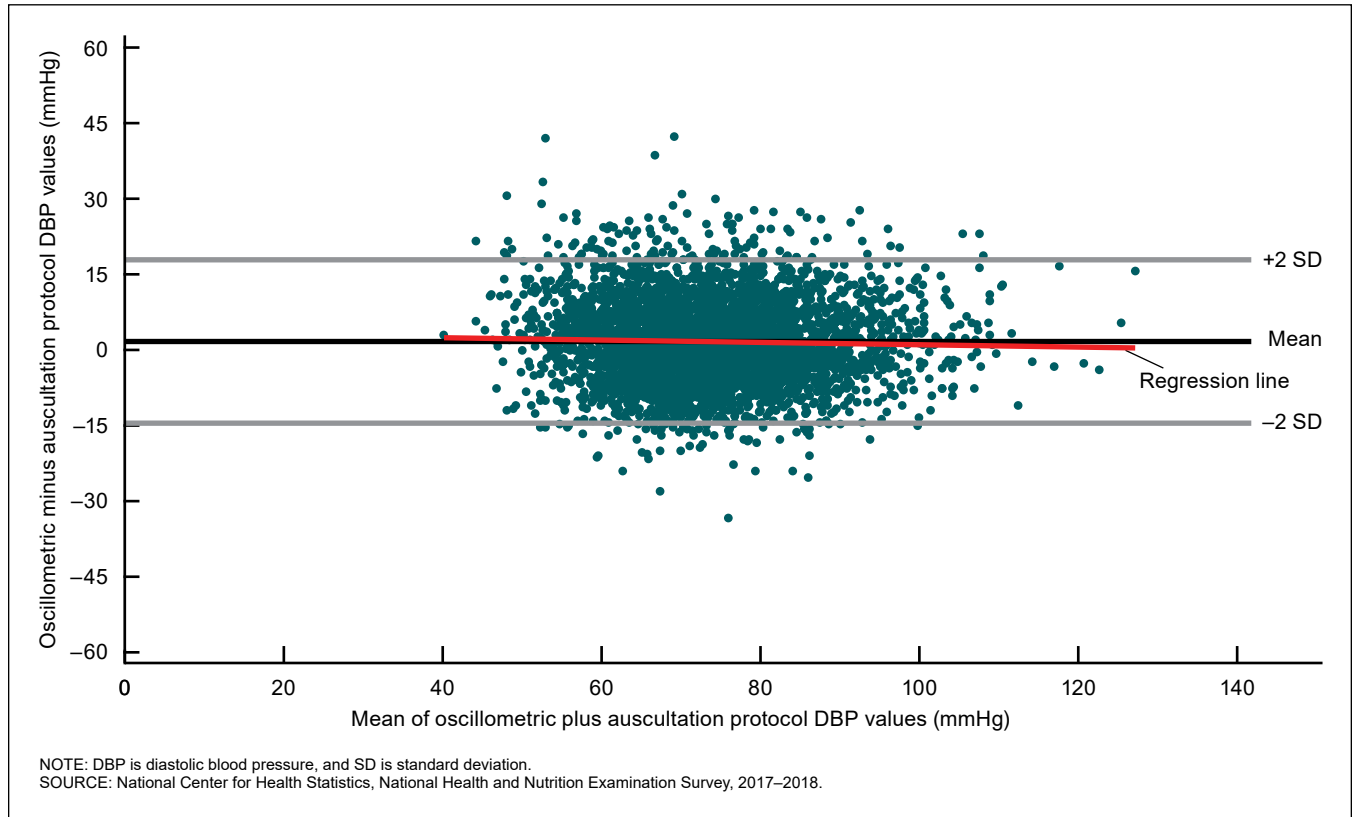


Figure 5. Weighted prevalence of stage 1 high blood pressure among adults aged 18 and over, by protocol and sex

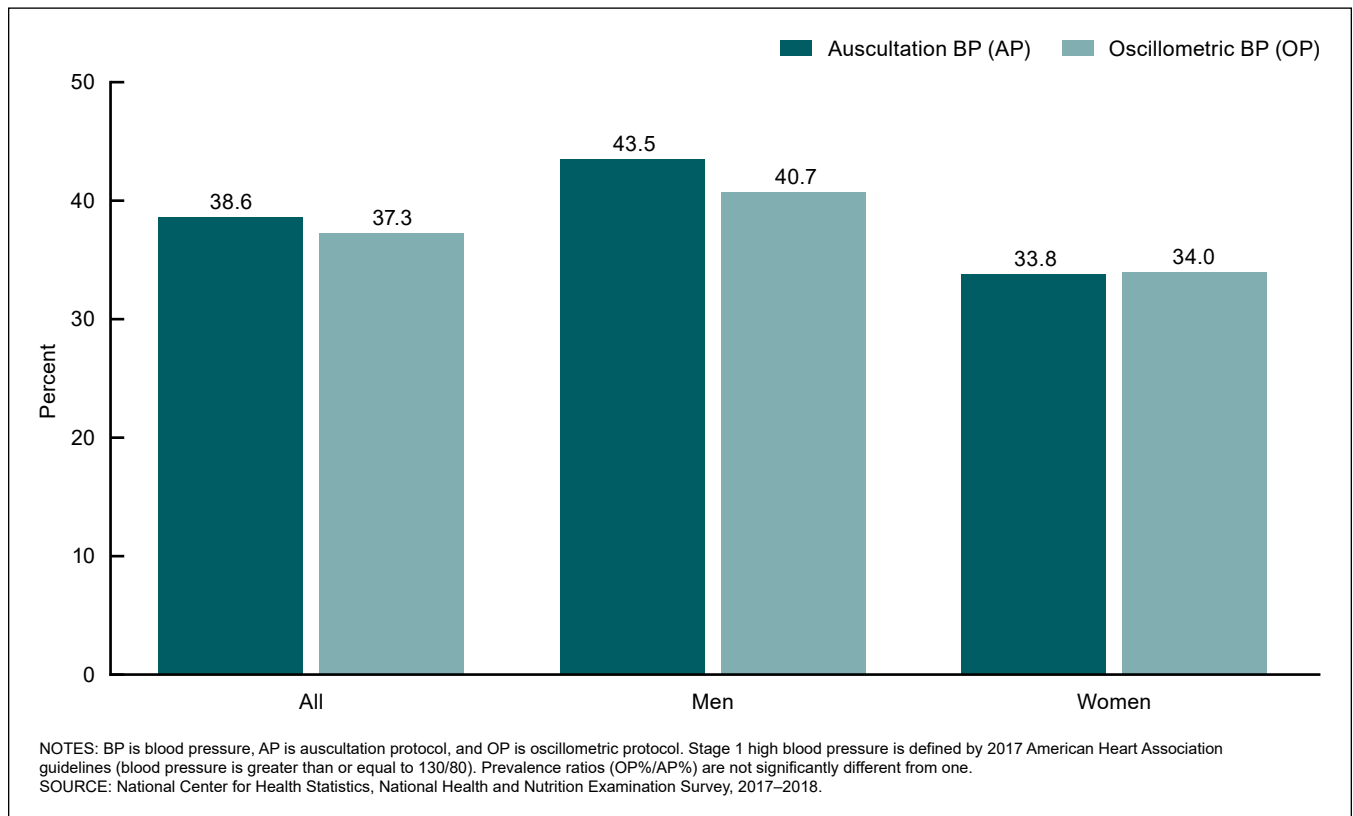


Figure 6. Weighted prevalence of stage 1 high blood pressure among adults aged 18 and over, by protocol and age group

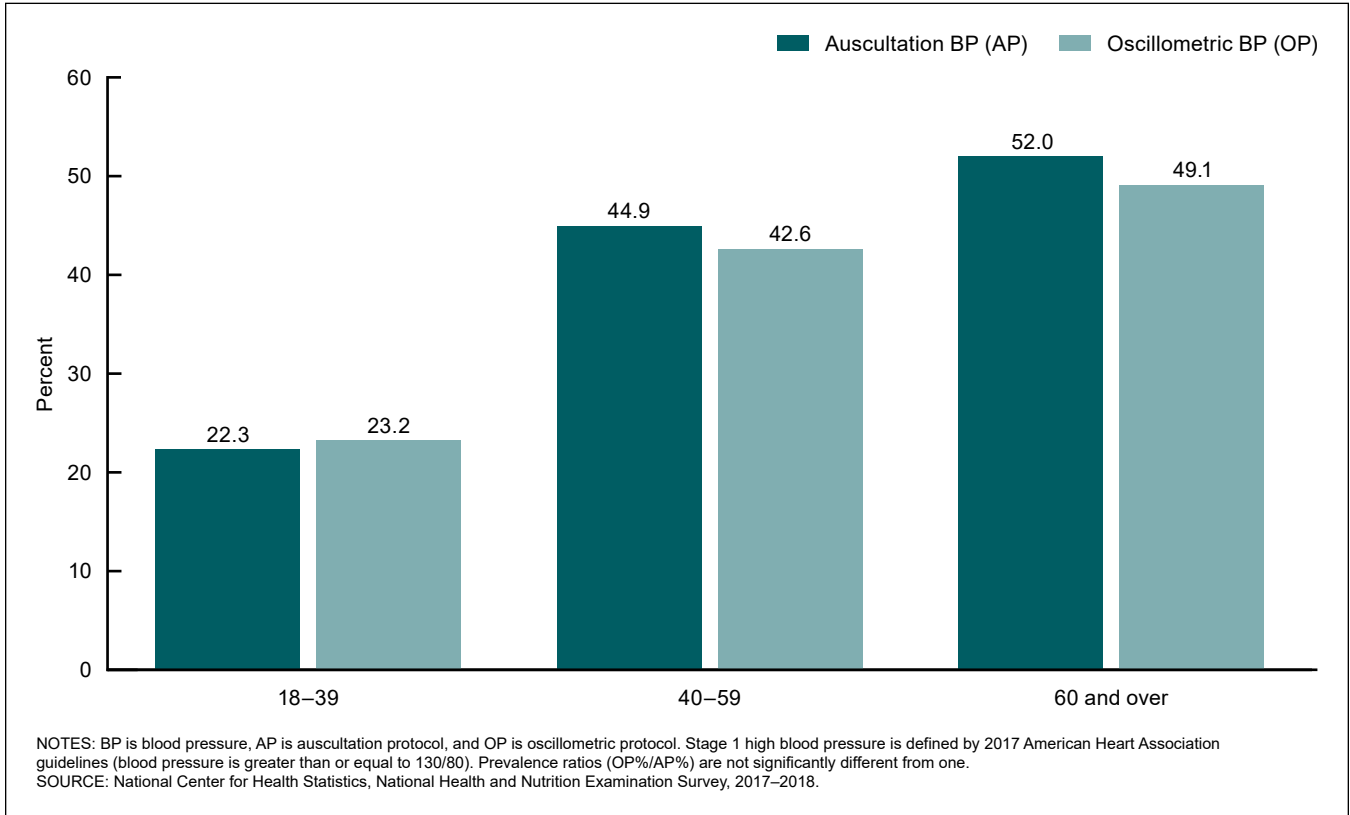


Figure 7. Weighted prevalence of stage 1 high blood pressure among adults aged 18 and over, by protocol and race and Hispanic origin

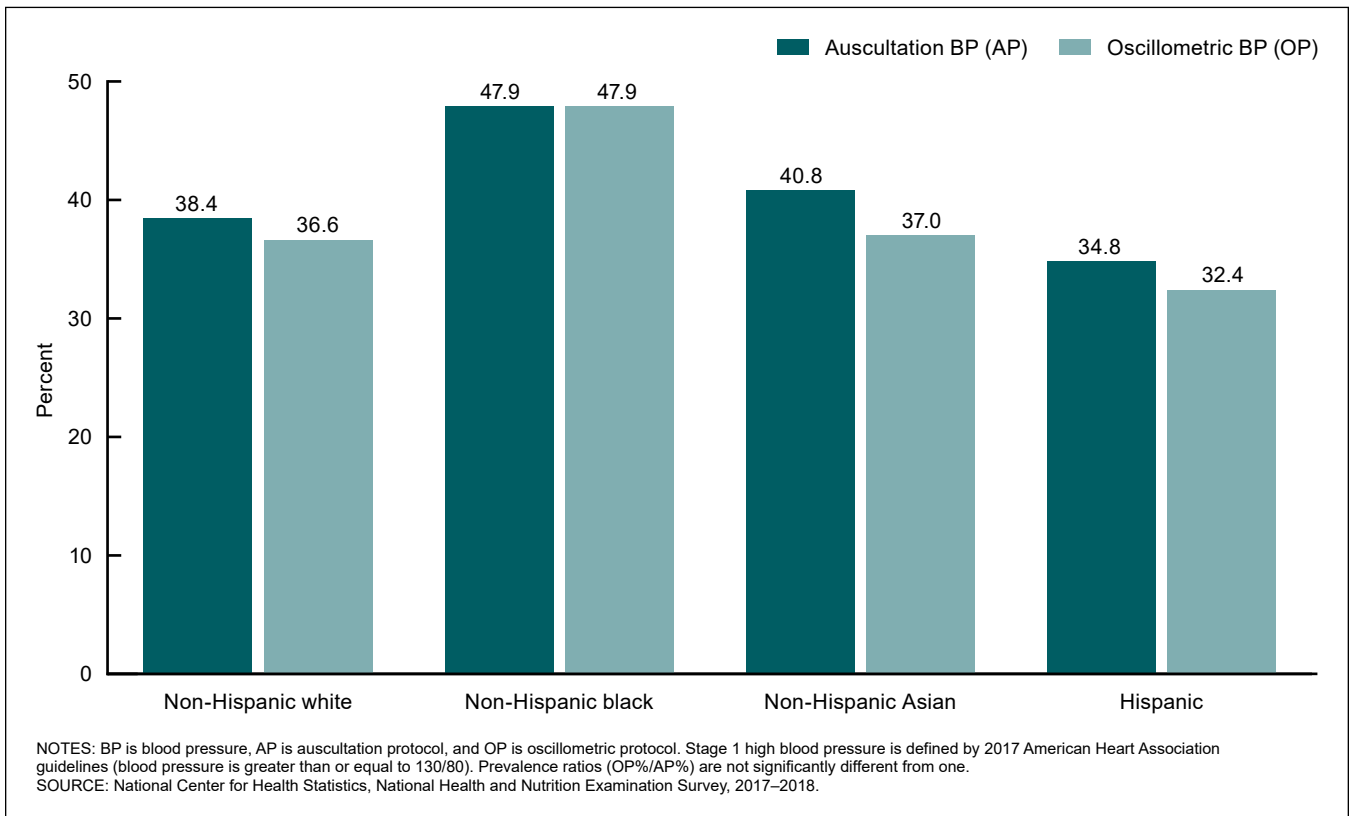


Table F. Weighted individual-level agreement on stage 1 high blood pressure between auscultation and oscillometric protocols

Characteristic	Sensitivity	Specificity	Positive predictive value	Negative predictive value	Kappa (95% CI)
Overall	76.0	87.0	78.6	85.2	0.63 (0.60–0.67)
Sex					
Men	74.5	85.3	79.5	81.3	0.60 (0.55–0.65)
Women	77.9	88.4	77.5	88.7	0.66 (0.61–0.72)
Age group					
18–39	68.6	89.8	65.8	90.9	0.58 (0.51–0.64)
40–59	75.9	84.6	80.1	81.2	0.61 (0.56–0.66)
60 and over	80.0	84.4	84.7	79.6	0.64 (0.60–0.69)
Race and Hispanic origin ¹					
Non-Hispanic white	75.1	87.3	78.6	84.9	0.63 (0.58–0.68)
Non-Hispanic black	83.8	85.0	83.7	85.1	0.69 (0.64–0.74)
Non-Hispanic Asian	72.8	87.6	80.1	82.4	0.61 (0.55–0.67)
Hispanic	73.8	89.6	79.1	86.5	0.64 (0.55–0.74)

¹Results for the category “Other race and Hispanic origin” are included in overall analyses but not reported separately.

NOTES: Stage 1 high blood pressure is defined by 2017 American Heart Association guidelines (blood pressure is greater than or equal to 130/80). Sensitivity is the probability of being classified as having stage 1 high blood pressure in the oscillometry protocol among persons who have stage 1 high blood pressure in the auscultation protocol. Specificity is the probability of being classified as normotensive in the oscillometry protocol among persons classified as normotensive in the auscultation protocol. Positive predictive value is the probability that a person who is hypertensive in the auscultation protocol is truly hypertensive. Negative predictive value is the probability that a person who is normotensive in the auscultation protocol is truly normotensive. A kappa between 60% and 80% is considered good agreement. CI is confidence interval.

SOURCE: National Center for Health Statistics, National Health and Nutrition Examination Survey, 2017–2018.

from 68.6% (age group 18–39) to 83.8% (non-Hispanic black adults). Positive predictive values ranged from 65.8% (age group 18–39) to 84.7% (age group 60 and over). Agreement statistics (κ) ranged from 0.58 (age group 18–39) to 0.69 (non-Hispanic black adults).

Discussion

This study compares two protocols for BP determination—a manual protocol that served as the standard NHANES BP measurement until 2019, and an automated protocol (AP and OP) in adults aged 18 and over in NHANES 2017–2018 who had BP values available with both AP and OP. Mean differences were found between protocols (AP – OP) of 1.5 mmHg for SBP and –1.3 mmHg for DBP. Both the scatterplot and percentile variations showed some between-protocol differences at all values. For both SBP and DBP measurements, the regression line was close to the line of unity, suggesting that OP closely approximated AP measurements. For values above the 75th percentile, which includes stage 1 high blood pressure (equal to or greater than 130/80 mmHg), the mean difference between protocols for SBP and DBP were at or less than 2.1 mmHg. Lastly, the Bland–Altman plots show that the between-protocol differences for SBP were random, while the results for DBP suggest a proportional bias and lack of equal agreement for DBP across the range of BP values.

The largest between-protocol difference reported was for the extra-large adult cuff size (mean SBP 4.6 mmHg and mean DBP –2.8 mmHg). The differences found among those

with the extra-large cuff size may be explained by occasional mismatches in measurements of the participants’ mid-arm circumference, especially for the large and extra-large cuff sizes. These differences led to 531 participants (12%) being assigned to a mercury extra-large cuff and then to an Omron large cuff, or conversely to an Omron large cuff and then to a mercury extra-large cuff. Each cuff system is unique, and the BP cuffs’ dimensions and architecture are part of the oscillometric BP device manufacturer’s internal algorithm for calculating BP (26). In addition, due to the extra-large cuff’s architecture (e.g., shape of the outside cuff and internal bladder), international validation standards consider this cuff size a special category when validating automated oscillometric devices (26).

The smallest between-protocol difference reported for mean SBP was among men (–0.1 mmHg), those with large cuff size (0.4 mmHg), and non-Hispanic Asian adults (0.6 mmHg); and for mean DBP, among both non-Hispanic Asian and Hispanic adults (each –0.7 mmHg). The possibility of a confounding effect of age and cuff size on race and Hispanic-origin categories was addressed by calculating least square means adjusting SBP and DBP for these covariates in each protocol. Anatomical differences in the upper arm may be a possible mediating factor. NHANES stopped collecting triceps skinfold measurements in survey year 2010, and the data collection years used for this analysis contain no information about upper-arm subcutaneous fat and muscle variation across race and Hispanic-origin categories. However, NHANES collects mid-arm circumference (MAC)

and upper-arm length (UAL), allowing a MAC/UAL ratio to be calculated that can help describe anatomical variations in the upper arm. This ratio was compared across race and Hispanic origin by computing weighted pairwise *t* tests. The results indicated that non-Hispanic Asian adults had a significantly smaller mean ratio of MAC/UAL (0.86, 95% CI = 0.85–0.88) when compared with non-Hispanic white (0.88, 95% CI = 0.87–0.90, *p* < 0.05), non-Hispanic black (0.91, 95% CI = 0.90–0.92, *p* < 0.001), and Hispanic adults (0.92, 95% CI = 0.91–0.93, *p* < 0.001). These results suggest that the smaller MAC/UAL ratio observed among non-Hispanic Asian adults may translate anatomically into a less conical structure of the upper arm, resulting in a better BP cuff fit. In oscillometry, several transducers are used to make the SBP and DBP determination, while in auscultation, the even distribution of pressure in the BP cuff enhances the accuracy of the BP readings (25).

Notwithstanding the protocol differences between mean SBP and DBP, the prevalence of stage 1 high blood pressure was not significantly different by sex, age group, and race and Hispanic origin. All protocol agreements (OP and AP) for stage 1 high blood pressure demonstrated a good agreement ($\kappa \geq 0.6$), and sensitivity values and positive predictive values were equal to or greater than 70% for all subcategories except the 18–39 age group. One explanation for the exclusion of this age group is the low prevalence of stage 1 high blood pressure (22.3%). This age group also had the highest negative predictive values (91%). Both prevalence of stage 1 high blood pressure and sensitivity increased with the increasing age of age groups.

OP followed the new guidelines to obtain standardized BP readings (18) and varied from the reference AP. An important difference between the protocols is the 5-minute wait period. In AP, the 5-minute wait period was interrupted when the physician interacted with the participant to position the stethoscope over the brachial artery to obtain maximum inflation level and BP measurements. In OP, by contrast, after fitting the BP cuff, no further interactions occurred with the participants. It has been shown that decreased human interaction improves the quality of BP readings (27). Other differences between the protocols included resting periods between measurements (AP called for 30 seconds, while OP called for 60 seconds). In OP, the BP determinations were not visible to either the participant or the examiner (Omron in hide mode).

A key unique strength of this study comparing two different standardized protocols to obtain BP (AP and OP) is the fact that it was conducted on a large national sample of the U.S. noninstitutionalized population aged 18 and over. These findings provide supportive data that may help understand future studies when changing BP measurement to a new protocol (OP).

This study had several limitations. First, OP BP data were collected while the device was in hide mode, masking the BP readings. In contrast, AP data were collected by trained

physicians who were aware of the BP values while collecting and keying in the data, so that the possibility of subjective bias by the physicians collecting the data cannot be ruled out (i.e., consciously or unconsciously remembering previous SBP or DBP values). Second, the OP BP data were collected by 10 different trained health technicians, and the number of measurements per technician ranged from 1% to 17%, whereas 91% of AP BP data were collected by 3 trained physicians (the remaining 9% of data were collected by equally trained backup physicians). Lastly, it is possible that BP observers of either protocol were not always adhering to standardized data collection protocol, which may have introduced systemic or random bias to their readings.

Conclusion

This unique study compared two different protocols for obtaining BP in a large national sample of the U.S. noninstitutionalized population aged 18 and over. The findings show that although mean values in BP measurements differed (by about 2 mmHg) between the two protocols, the prevalence of stage 1 high blood pressure by the two methods did not differ. BP measurement in the two protocols used for describing stage 1 high blood pressure (OP and AP) demonstrated a good agreement with moderately high sensitivity values and positive predictive values for most demographic categories. In addition to informing current and future NHANES operations, these findings may inform other clinical and epidemiologic programs in the transition to an oscillometric device.

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Appendix. Supporting Tables

Table I. Weighted data analysis comparing percentage included in study with those excluded, by characteristic: National Health and Nutrition Examination Survey, 2017–2018

Characteristic	Included (<i>n</i> = 4,477)	Excluded (<i>n</i> = 984)	<i>p</i> value ¹
Sex	Percent (95% confidence interval)		
Men	86.4 (82.4–90.3)	13.6 (9.7–17.6)	Less than 0.05
Women	83.3 (79.7–87.0)	16.7 (13.0–20.3)	Less than 0.05
Age group			
18–39	82.4 (77.5–87.4)	17.6 (12.6–22.5)	0.23
40–59	86.2 (82.9–89.6)	13.8 (10.4–17.1)	0.23
60 and over	86.3 (81.4–91.1)	13.7 (8.9–18.6)	0.23
Race and Hispanic origin ²			
Non-Hispanic white	87.9 (84.0–91.8)	12.1 (8.2–16.0)	Less than 0.05
Non-Hispanic black	81.2 (73.4–89.0)	18.8 (11.0–26.6)	Less than 0.05
Non-Hispanic Asian	78.9 (71.9–85.9)	21.1 (14.1–28.1)	Less than 0.05
Hispanic	77.0 (71.3–82.7)	23.0 (17.3–28.7)	Less than 0.05

¹Derived from Wald *F* test statistic from linear regression procedure in SUDAAN.

²Results for the category “Other race and Hispanic origin” are included in overall analyses but not reported separately.

SOURCE: National Center for Health Statistics, National Health and Nutrition Examination Survey, 2017–2018.

Table II. Unweighted mean and standard error of between-protocol device difference for systolic blood pressure values, overall and by characteristic: National Health and Nutrition Examination Survey, 2017–2018

Characteristic	<i>n</i>	Auscultation systolic BP (SE)	Oscillometric systolic BP (SE)	Mean difference (SE)	<i>p</i> value ¹
Overall	4,477	126.1 (0.3)	124.6 (0.3)	1.5 (0.2)	Less than 0.001
Sex					
Men	2,249	127.2 (0.4)	127.0 (0.4)	0.2 (0.2)	0.36
Women	2,228	124.9 (0.4)	122.2 (0.4)	2.8 (0.2)	Less than 0.001
Age group					
18–39	1,458	115.3 (0.3)	114.0 (0.3)	1.2 (0.2)	Less than 0.001
40–59	1,377	125.9 (0.5)	124.6 (0.5)	1.3 (0.3)	Less than 0.001
60 and over	1,642	135.8 (0.5)	133.9 (0.5)	1.9 (0.3)	Less than 0.001
Race and Hispanic origin ^{2,3}					
Non-Hispanic white	1,618	124.3 (0.4)	122.9 (0.4)	1.4 (0.2)	Less than 0.001
Non-Hispanic black	1,037	129.8 (0.6)	128.0 (0.6)	1.8 (0.3)	Less than 0.001
Non-Hispanic Asian	625	125.2 (0.7)	124.3 (0.7)	0.9 (0.4)	Less than 0.05
Hispanic	957	125.1 (0.6)	123.4 (0.6)	1.7 (0.3)	Less than 0.001
Cuff size ⁴					
Adult	1,179	125.0 (0.6)	123.6 (0.6)	1.3 (0.3)	Less than 0.001
Large adult	2,403	125.5 (0.4)	125.2 (0.4)	0.4 (0.2)	0.07
Extra-large adult	825	128.3 (0.6)	123.4 (0.6)	4.9 (0.4)	Less than 0.001

¹*p* values for age, sex, and cuff size are derived from Student's *t* test from orthogonal linear contrast.

²Results for the category “Other race and Hispanic origin” are included in overall analyses but not reported separately.

³Systolic BP mean values are adjusted for age and cuff size using least square means and *p* value derived from Wald *F* test statistic in a linear regression model.

⁴Baum cuff sizes used. Adult category includes child/small-adult cuff category (*n* = 24).

NOTE: BP is blood pressure, and SE is standard error.

SOURCE: National Center for Health Statistics, National Health and Nutrition Examination Survey, 2017–2018.

Table III. Unweighted mean and standard error of between-protocol device difference for diastolic blood pressure values, overall and by characteristic: National Health and Nutrition Examination Survey, 2017–2018

Characteristic	<i>n</i>	Auscultation diastolic BP (SE)	Oscillometric diastolic BP (SE)	Mean difference (SE)	<i>p</i> value ¹
Overall	4,477	72.8 (0.2)	74.5 (0.2)	-1.7 (0.1)	Less than 0.001
Sex					
Men	2,249	74.2 (0.2)	75.4 (0.2)	-1.2 (0.2)	Less than 0.001
Women	2,228	71.4 (0.2)	73.6 (0.2)	-2.1 (0.2)	Less than 0.001
Age group					
18–39	1,458	70.3 (0.3)	71.9 (0.3)	-1.6 (0.2)	Less than 0.001
40–59	1,377	77.3 (0.3)	78.4 (0.3)	-1.2 (0.2)	Less than 0.001
60 and over	1,642	71.4 (0.3)	73.6 (0.3)	-2.1 (0.2)	Less than 0.001
Race and Hispanic origin ^{2,3}					
Non-Hispanic white	1,618	71.5 (0.3)	73.6 (0.3)	-2.1 (0.2)	Less than 0.001
Non-Hispanic black	1,037	74.5 (0.4)	76.5 (0.4)	-1.9 (0.3)	Less than 0.001
Non-Hispanic Asian	625	74.5 (0.4)	75.3 (0.4)	-0.8 (0.3)	Less than 0.05
Hispanic	957	72.3 (0.4)	73.3 (0.3)	-1.1 (0.3)	Less than 0.001
Cuff size ⁴					
Adult	1,179	71.0 (0.3)	71.0 (0.3)	0.0 (0.2)	0.94
Large adult	2,403	73.1 (0.2)	75.0 (0.2)	-2.0 (0.2)	Less than 0.001
Extra-large adult	825	75.1 (0.4)	78.1 (0.4)	-3.0 (0.3)	Less than 0.001

0.0 Quantity more than zero but less than 0.05.

¹*p* values for age, sex, and cuff size are derived from Student's *t* test from orthogonal linear contrast.

²Results for the category "Other race and Hispanic origin" are included in overall analyses but not reported separately.

³Diastolic BP mean values are adjusted for age and cuff size using least square means and *p* value derived from Wald *F* test statistic in a linear regression model.

⁴Baum cuff sizes used. Adult category includes child/small-adult cuff category (*n* = 24).

NOTE: BP is blood pressure, and SE is standard error.

SOURCE: National Center for Health Statistics, National Health and Nutrition Examination Survey, 2017–2018.

Vital and Health Statistics Series Descriptions

Active Series

- Series 1. Programs and Collection Procedures**
Reports describe the programs and data systems of the National Center for Health Statistics, and the data collection and survey methods used. Series 1 reports also include definitions, survey design, estimation, and other material necessary for understanding and analyzing the data.
- Series 2. Data Evaluation and Methods Research**
Reports present new statistical methodology including experimental tests of new survey methods, studies of vital and health statistics collection methods, new analytical techniques, objective evaluations of reliability of collected data, and contributions to statistical theory. Reports also include comparison of U.S. methodology with those of other countries.
- Series 3. Analytical and Epidemiological Studies**
Reports present data analyses, epidemiological studies, and descriptive statistics based on national surveys and data systems. As of 2015, Series 3 includes reports that would have previously been published in Series 5, 10–15, and 20–23.

Discontinued Series

- Series 4. Documents and Committee Reports**
Reports contain findings of major committees concerned with vital and health statistics and documents. The last Series 4 report was published in 2002; these are now included in Series 2 or another appropriate series.
- Series 5. International Vital and Health Statistics Reports**
Reports present analytical and descriptive comparisons of U.S. vital and health statistics with those of other countries. The last Series 5 report was published in 2003; these are now included in Series 3 or another appropriate series.
- Series 6. Cognition and Survey Measurement**
Reports use methods of cognitive science to design, evaluate, and test survey instruments. The last Series 6 report was published in 1999; these are now included in Series 2.
- Series 10. Data From the National Health Interview Survey**
Reports present statistics on illness; accidental injuries; disability; use of hospital, medical, dental, and other services; and other health-related topics. As of 2015, these are included in Series 3.
- Series 11. Data From the National Health Examination Survey, the National Health and Nutrition Examination Surveys, and the Hispanic Health and Nutrition Examination Survey**
Reports present 1) estimates of the medically defined prevalence of specific diseases in the United States and the distribution of the population with respect to physical, physiological, and psychological characteristics and 2) analysis of relationships among the various measurements. As of 2015, these are included in Series 3.
- Series 12. Data From the Institutionalized Population Surveys**
The last Series 12 report was published in 1974; these reports were included in Series 13, and as of 2015 are in Series 3.
- Series 13. Data From the National Health Care Survey**
Reports present statistics on health resources and use of health care resources based on data collected from health care providers and provider records. As of 2015, these reports are included in Series 3.

- Series 14. Data on Health Resources: Manpower and Facilities**
The last Series 14 report was published in 1989; these reports were included in Series 13, and are now included in Series 3.
- Series 15. Data From Special Surveys**
Reports contain statistics on health and health-related topics from surveys that are not a part of the continuing data systems of the National Center for Health Statistics. The last Series 15 report was published in 2002; these reports are now included in Series 3.
- Series 16. Compilations of Advance Data From Vital and Health Statistics**
The last Series 16 report was published in 1996. All reports are available online; compilations are no longer needed.
- Series 20. Data on Mortality**
Reports include analyses by cause of death and demographic variables, and geographic and trend analyses. The last Series 20 report was published in 2007; these reports are now included in Series 3.
- Series 21. Data on Natality, Marriage, and Divorce**
Reports include analyses by health and demographic variables, and geographic and trend analyses. The last Series 21 report was published in 2006; these reports are now included in Series 3.
- Series 22. Data From the National Mortality and Natality Surveys**
The last Series 22 report was published in 1973. Reports from sample surveys of vital records were included in Series 20 or 21, and are now included in Series 3.
- Series 23. Data From the National Survey of Family Growth**
Reports contain statistics on factors that affect birth rates, factors affecting the formation and dissolution of families, and behavior related to the risk of HIV and other sexually transmitted diseases. The last Series 23 report was published in 2011; these reports are now included in Series 3.
- Series 24. Compilations of Data on Natality, Mortality, Marriage, and Divorce**
The last Series 24 report was published in 1996. All reports are available online; compilations are no longer needed.

For answers to questions about this report or for a list of reports published in these series, contact:

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