An Assessment of the Accuracy of Home Blood Pressure Monitors When Used in Device Owners

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OBJECTIVE
To examine the accuracy of home blood pressure (BP) devices, on their owners, compared to auscultatory reference standard BP measurements.

METHODS
Eighty-five consecutive consenting subjects ≥18 years of age, who owned an oscillometric home BP device (wrist or upper-arm device), with BP levels between 80–220/50–120 mm Hg, and with arm circumferences between 25–43 cm were studied. Pregnancy and atrial fibrillation were exclusion criteria. Device measurements from each subject's home BP device were compared to simultaneous 2-observer auscultation using a mercury sphygmomanometer. Between-group mean comparisons were conducted using paired *t*-tests. The proportion of patients with device-to-auscultatory differences of ≥5, 10, and 15 mm Hg were tabulated and predictors of systolic and diastolic BP differences were identified using linear regression.

RESULTS
Mean age was 66.4 ± 11.0 years, mean arm circumference was 32.7 ± 3.7 cm, 54% were female and 78% had hypertension. Mean BPs were 125.7 ± 14.0/73.9 ± 10.4 mm Hg for home BP devices vs. 129.0 ± 14.7/72.9 ± 9.3 for auscultation (difference of −3.3 ± 7.3/0.9 ± 6.1; *P* values <0.0001 for systolic and 0.17 for diastolic). The proportion of devices with systolic or diastolic BP differences from auscultation of ≥5, 10, and 15 mm Hg was 69%, 29%, and 7%, respectively. Increasing arm circumference was a statistically significant predictor of higher systolic (parameter estimate 0.61 per cm increase; *P* value 0.004) and diastolic (0.38; 0.03) BP.

CONCLUSIONS
Although mean differences from 2-observer auscultation were acceptable, when tested on their owners, most home BP devices were not accurate to within 5 mm Hg. Ensuring acceptable accuracy of the device-owner pairing should be prioritized.

Keywords: auscultatory; blood pressure; blood pressure measurement; home blood pressure; hypertension; oscillometry; validation.

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Accurate measurement of blood pressure (BP) is essential to the optimal diagnosis and management of hypertensive individuals.[1] Home BP monitoring is widely used to diagnose and monitor patients with or at risk for hypertension.[2] Advantages of home BP monitoring over conventional office BP measurements include patient convenience, detection of white coat and masked phenomena, superior risk prediction, and enhancement of patient self-management and therapeutic adherence through self-monitoring.[3,4] Consequently, hypertension guidelines strongly endorse use of home BP monitoring in hypertensive patients.[5,6]

Home BP monitors measure BP primarily using the oscillometric technique, in which BP is estimated using an algorithm applied to the envelope of oscillometric waveforms generated during cuff inflation and/or deflation.[7] Many home BP devices are sold without formal validation of accuracy.[8] Even when BP monitors are determined to be valid according to contemporary standards, it is difficult to predict if the study results are generalizable to an individual patient. Patients purchasing and using these devices are likely to be older and to have cardiovascular comorbidities. These are predisposing factors for arterial stiffness and widened pulse pressure, which are thought to detrimentally affect the accuracy of oscillometry.[9] Despite these potential limitations, the accuracy of a given home BP device to measure BP in the patient who uses that device is almost never verified and this has been identified as a key limitation of current validation standards.[10,11]

The objective of this study was to compare measurements taken using an individual patient's home BP monitor to a simultaneous, 2-observer, auscultatory mercury sphygmomanometer reference standard. The primary intent was

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to identify the mean difference in systolic and diastolic BP between these 2 techniques, the variability, the proportion of patients in whom accuracy was suboptimal (defined as a device-to-reference standard difference of ≥5, 10, and 15 mm Hg), and identify predictors of inaccuracy.

METHODS

Study Population

The University of Alberta Research Ethics Board approved the protocol and informed consent was obtained from all participants. A convenience sample of 85 consecutive, consenting adults aged ≥18 years that owned and used an oscillometric home BP monitor (wrist or upper-arm device) were enrolled. Subjects were recruited using posters, newspaper advertisements, and in person at local farmer's markets and seniors' fairs. The study poster stated, "We plan to study how the accuracy of your home blood pressure monitor compares to standard blood pressure measurements." Subjects were required to have baseline BP levels between 80–220/50–120 mm Hg and upper-arm circumferences 25–43 cm. Exclusion criteria were pregnancy and atrial fibrillation.

Baseline Data Collection

Baseline data collection included age, sex, race, height, weight, and self-reported history of hypertension, coronary artery disease, cerebrovascular disease, peripheral vascular disease, obstructive sleep apnea, diabetes, and dyslipidemia. Weight was measured to the nearest 0.1 kg. Height was measured to the nearest 0.1 cm. Body mass index was calculated by dividing weight by the square of height. Arm circumference was measured by first marking the midpoint (to the nearest 0.1 cm) between the acromion and olecranon processes while standing with the arm bent at 90 degrees. The arm was then straightened at the subject's side and the circumference measured at the marked midpoint with the measuring tape parallel to the floor. Baseline office BP and heart rate were measured once in the seated position using the BpTru (Coquitlam, Canada) automated oscillometric device and the appropriate cuff size to ensure participants met the BP inclusion criteria. A rhythm strip was obtained to assess for atrial fibrillation (Schiller, Doral, FL, USA).

Home cuffs were classified by brand category (Omron vs. Miscellaneous), site (upper arm vs. wrist), validation status (listed as valid according to the Canadian Hypertension Education Program [hypertension.ca], dabl Educational Trust [dableducational.org] or Medaval [medaval.ie], and by type of cuff design (soft material vs. hard shell)). All wrist cuffs were of rigid design and were included in the hard shell category. Subject-estimated device age in years was also recorded.

DATA COLLECTION

Prior to study initiation, all study personnel attended a workshop on BP measurement taught by an expert in hypertension and BP measurement. Study procedures were based primarily upon the International Organization for Standardization (ISO 81060–2:2013) standards.[12] However, recommended sex, BP variability, and BP distribution requirements were not observed as the study was not conducted to validate a new device.

BP Measurements

Six trained study observers performed the auscultatory measurements, with 3 observers performing 71% of the BP measurements. An expert in hypertension and BP measurement acted as the supervisor, monitoring agreement between observers, and changing between the cuff used to perform auscultatory measurements and the participant's home cuff.

All BP measurements were performed according to recommended guidelines after a 5-minute rest period with the participant in the seated position, back supported, and the arm resting on a table at heart level.[6] Thirty to sixty seconds were observed between measurements. Both observers measured BP simultaneously with a double-headed stethoscope (3M Littman; St Paul, MN, USA) according to the recommended technique. Observers were blinded to each other's results. Subjects were blinded to all readings.

A Baumanometer mercury sphygmomanometer (0250NL; Copiague, NY, USA) with mercury column intact and the meniscus centered at 0 mm Hg was used. Baum cuffs were used for all auscultatory measurements (large cuff bladder size 33.5 × 16.5 cm; regular cuff bladder size 22.5 × 12.5 cm). Cuff size was selected according to arm circumference (for arms 25.0–33.0 cm, a regular adult cuff was used, for arms 33.1–43.0 cm, a large cuff was used).

Nine Pairs of BP Measurements Were Performed Sequentially in Each Subject

Measurement 1 was taken using the appropriately sized Baum cuff and mercury sphygmomanometer to introduce the subject to the procedure and familiarize the observers with the subject's Korotkoff sounds. For measurement 2, the subject's home BP monitor and cuff were used. Measurements 1 and 2 were not used in the analysis. For Measurements 3–9, we alternated between the Baum cuff/mercury sphygmomanometer (measurements 3, 5, 7, and 9) and the participant's home BP cuff/monitor (measurements 4, 6, and 8). BP results with a between-observer difference of more than 4 mm Hg were discarded and the measurement was repeated. The mean of the reference (Baum cuff/mercury sphygmomanometer) readings was used as the overall estimate of the reference measurement. The mean of the home BP cuff/monitor was similarly used as the overall estimate of the home BP measurement.

STATISTICAL ANALYSIS

Auscultatory readings were used as the reference standard. Descriptive analyses were first performed, including calculation of means, medians, and proportions. Mean differences in systolic and diastolic BP between the auscultatory and home BP measurements and corresponding SD were calculated. In categorical analyses, the proportion of patients with device-to-auscultatory differences in systolic or diastolic BP of ≥5, 10, and 15 mm Hg were tabulated.

Exploratory subgroup analyses were conducted by cuff site (upper arm vs. wrist), device brand (Omron vs. Miscellaneous), validation status (validated vs. nonvalidated), and cuff design (soft vs. hard). Linear regression models were constructed to identify statistically significant predictors of change in systolic and diastolic BP. Model covariates included age, sex, race, arm circumference, medical comorbidities, cuff site, cuff design, validation status, device age, and device brand. Age, sex, hypertensive status, and cuff site were included in each model. Additional covariates with *P* values <0.20 on univariable analysis were then included.

Two-tailed paired *t*-tests were used to compute *P* values for comparisons between home devices and auscultation. *P* values <0.05 were considered statistically significant. SAS 9.3 (Cary, NC, USA) was used for all analyses.

RESULTS

Of 87 subjects, one was excluded because of excessively high diastolic BP (>120 mm Hg) and one because between-observer auscultatory measurements were not within 4 mm Hg and this was not identified at the time of measurement, leaving 85 subjects in the final study sample. Mean auscultatory measurements taken by observer 1 were 128.9 ± 14.7/72.5 ± 9.3 mm Hg and corresponding values for observer 2 were 129.1 ± 14.7/73.5 ± 9.4, with between-observer mean differences of −0.2 ± 0.9/−1.0 ± 1.4.

Baseline Characteristics

Mean age was 66.4 ± 11.0 years, mean arm circumference was 32.7 ± 3.7 cm, 54% were female, and 78% had a past history of hypertension or were on antihypertensive medications; 59 (66%) devices were validated. Omron devices were used in 46 (54%) subjects. Thirteen other device brands comprised the "Miscellaneous" category, with Life Source and Life Brand being most common, collectively used in 20 (24%) subjects. Soft cuffs were more common (57%) than hard ones (44%) and the mean device age was 6.1 years. Seventy-nine devices used upper arm cuffs and 6 used wrist cuffs. Other baseline characteristics are summarized in Table 1.

Table 1. Baseline characteristics

Variable	Mean ± SD or No. (%)
Age (years)	66.4 ± 11.0
Female	46 (54)
Ethnicity	
Caucasian	70 (82)
Asian	10 (12)
Other	5 (6)
Weight (kg)	81.3 ± 18.0
Body mass index (kg/m^2)	29.6 ± 5.1
Arm circumference (cm)	32.7 ± 3.7
History of hypertension or taking antihypertensive medication	66 (78)
Type 2 diabetes	17 (20)
Dyslipidemia	37 (44)
Coronary artery disease	9 (11)
Cerebrovascular disease	8 (9)
Obstructive sleep apnea	13 (15)
Automated office SBP (mm Hg)	132.6 ± 18.1
Automated office DBP (mm Hg)	77.9 ± 10.4
Heart rate (beats per minute)	70.7 ± 10.5
Validated	59 (66)
Cuff Brand	
Omron	46 (54)
Miscellaneous	39 (46)
Cuff Type	
Soft	48 (57)
Hard	37 (44)
Cuff Size	
Standard	54 (64)
Large	31 (37)
Device age (years)	6.1 (6)

Abbreviations: DBP, diastolic blood pressure; SBP, systolic blood pressure.

Mean BP Comparisons

Mean BP levels were 125.7 ± 14.0/73.9 ± 10.4 mm Hg for the home BP device group and 129.0 ± 14.7/72.9 ± 9.3 mm Hg for auscultation, with a between-method difference of −3.3 ± 7.3/0.9 ± 6.1 mm Hg (*P* values <0.0001 for systolic BP and 0.17 for diastolic BP; Table 2).

Subgroup analyses are summarized in Table 2. In general, larger mean differences between methods were observed for wrist cuffs (vs. upper arm), Omron devices (vs. "Miscellaneous"), and hard cuffs (vs. soft). Validated devices exhibited slightly higher mean differences but less variability in this difference.

Categorical Analyses

The number of subjects with systolic or diastolic BP differences between the 2 methods of ≥5, ≥10, and ≥15 mm Hg are summarized in Table 3. Categorical analyses by systolic and diastolic BP and by subgroup are also summarized in Table 3. The results of the categorical analyses by subgroup were consistent with the mean differences by subgroup analyses described above. The percentage of subjects with systolic or diastolic differences of ≥5 mm Hg was greater for wrist cuffs (vs. upper arm), nonvalidated devices (vs. validated), Omron devices (vs. "Miscellaneous"), and hard cuffs (vs. soft).

Regression Models

Results of the regression models are summarized in Table 4. Male sex (parameter estimate 3.22; *P* value 0.04) and increasing arm circumference (0.61; 0.004) were significant

Table 2. Blood pressure comparisons

Variable	Home device mean ± SD	Auscultation mean ± SD	Difference mean ± SD	*P* value
All devices (*n* = 85)				
Systolic	125.7 ± 14.0	129.0 ± 14.7	−3.3 ± 7.3	<0.0001
Diastolic	73.9 ± 10.4	72.9 ± 9.3	0.9 ± 6.1	0.17
Upper-arm devices (*n* = 79)				
Systolic	125.0 ± 13.5	128.1 ± 14.2	−3.1 ± 7.3	0.0004
Diastolic	73.3 ± 10.2	72.7 ± 9.5	0.6 ± 5.8	0.34
Wrist devices (*n* = 6)				
Systolic	135.2 ± 18.6	141.1 ± 16.9	−5.9 ± 7.8	0.12
Diastolic	81.1 ± 10.9	76.3 ± 5.1	4.7 ± 8.8	0.25
Validated device (*n* = 59)				
Systolic	125.1 ± 14.7	128.7 ± 15.4	−3.6 ± 6.2	<0.001
Diastolic	73.5 ± 10.3	72.2 ± 9.3	1.3 ± 5.9	0.11
Nonvalidated device (*n* = 26)				
Systolic	127.2 ± 12.3	129.7 ± 13.4	−2.5 ± 9.5	0.19
Diastolic	74.7 ± 10.7	74.6 ± 9.0	0.1 ± 6.6	0.92
Omron device (*n* = 46)				
Systolic	127.1 ± 14.9	131.1 ± 15.6	−3.9 ± 6.7	0.0003
Diastolic	75.4 ± 10.4	73.3 ± 9.5	2.1 ± 6.5	0.03
Miscellaneous device (*n* = 39)				
Systolic	124.1 ± 12.8	126.6 ± 12.8	−2.5 ± 7.9	0.06
Diastolic	72.1 ± 10.2	72.6 ± 10.2	−0.5 ± 5.4	0.57
Soft cuff (*n* = 48)				
Systolic	123.3 ± 12.3	126.1 ± 14.4	−2.8 ± 8.4	0.02
Diastolic	72.1 ± 9.7	73.1 ± 9.0	−1.1 ± 4.9	0.13
Hard cuff (*n* = 37)				
Systolic	128.9 ± 15.5	132.8 ± 14.5	−3.8 ± 5.5	0.0002
Diastolic	76.2 ± 11.0	72.7 ± 9.7	3.5 ± 6.7	0.003

predictors of a systolic BP difference. Increasing age (0.16; 0.01), increasing arm circumference (0.38; 0.03), hard cuff design (3.81; 0.002), and increasing device age (−0.24; 0.03) were significant predictors of a diastolic BP difference.

DISCUSSION

In summary, although the mean BP differences between home BP monitors and auscultation were within 5 mm Hg, over two-thirds of devices tested exhibited a systolic or diastolic BP difference of ≥5 mm Hg, a degree of BP difference considered to be clinically important.[11,13] Several prior studies have examined the accuracy of individual patient's home BP monitors.[14–20] Of these, one study employed 2-observer auscultation with a mercury sphygmomanometer but the mean of the observer's readings was not used (rather, the closest reading to that of the device was used) and accuracy was defined as an absolute device-to-reference standard difference of ≤4 mm Hg for systolic and diastolic BP (rather than ≤5 mm Hg).[16] This study reported that 72% of the 554 devices tested (171 upper arm and 383 wrist) were not accurate, findings very similar to those of the present study. In another study, single-observer mercury-based auscultation was used and 5 measurements were taken (3 with the home device and 2 with the mercury sphygmomanometer).[20] Nearly 15% of devices were inaccurate (5 mm Hg difference from mercury-based auscultation). The proportion of home devices considered inaccurate was greater for nonvalidated devices (19%) compared to validated ones (7%).[20]

Statistically significant predictors of either a systolic or diastolic BP difference between measurement methods included older subject age, male sex, increasing arm circumference, a hard cuff design, and increasing device age. Most of these factors are known or suspected to affect oscillometric device measurement accuracy by preventing optimal limb-appropriate cuff fit, altering pulse pressure, and/or causing vascular stiffness.[9,20–22] Indeed, in an analysis of 5,070 oscillometric office device measurements taken in 755 patients, pulse pressure and arm circumference were the most consistent predictors of unreliable measurements, defined as a difference from single-observer same-arm simultaneous mercury-based sphygmomanometry of

Table 3. Proportion of subjects with absolute differences between their home device and the auscultatory method

	≥±5 mm Hg	≥±10 mm Hg	≥±15 mm Hg
Measurement parameter	**No. (%)**	**No. (%)**	**No. (%)**
Overall study sample (*n* = 85)			
Systolic or diastolic	59 (69)	25 (29)	6 (7)
Systolic	46 (54)	17 (20)	5 (6)
Diastolic	26 (31)	10 (12)	1 (1)
Upper-arm devices (*n* = 79)			
Systolic or diastolic	54 (68)	21 (27)	5 (6)
Systolic	42 (53)	14 (18)	5 (6)
Diastolic	24 (30)	9 (11)	0 (0)
Wrist devices (*n* = 6)			
Systolic or diastolic	5 (83)	4 (67)	1 (17)
Systolic	4 (67)	3 (50)	0 (0)
Diastolic	2 (33)	1 (17)	1 (17)
Validated (*n* = 59)			
Systolic or diastolic	39 (66)	15 (25)	2 (3)
Systolic	28 (47)	8 (14)	2 (3)
Diastolic	20 (34)	7 (12)	0 (0)
Not Validated (*n* = 26)			
Systolic or diastolic	20 (76)	10 (38)	4 (15)
Systolic	18 (69)	9 (35)	3 (12)
Diastolic	6 (23)	3 (12)	1 (4)
Omron device (*n* = 46)			
Systolic or diastolic	33 (72)	15 (33)	2 (4)
Systolic	23 (50)	8 (17)	2 (4)
Diastolic	18 (39)	8 (17)	0 (0)
Miscellaneous device (*n* = 39)			
Systolic or diastolic	26 (67)	10 (25)	4 (10)
Systolic	23 (59)	9 (23)	3 (8)
Diastolic	8 (21)	2 (5)	1 (3)
Soft cuff (*n* = 48)			
Systolic or diastolic	31 (65)	12 (25)	5 (10)
Systolic	26 (54)	12 (25)	5 (10)
Diastolic	11 (23)	2 (4)	0 (0)
Hard cuff (*n* = 37)			
Systolic or diastolic	28 (76)	13 (35)	1 (3)
Systolic	20 (54)	5 (14)	0 (0)
Diastolic	15 (41)	8 (21)	1 (3)

Table 4. Linear regression analyses predicting BP differences between home BP device and auscultation

Variable	Parameter estimate	*P* value
Systolic BP overestimation		
Age (per year increase)	0.05	0.49
Sex (male vs. female)	3.22	0.04
Stroke	4.71	0.07
Device age (per year increase)	0.22	0.09
Arm circumference (per cm increase)	0.61	0.004
Hypertension	1.76	0.31
Systolic BP underestimation		
Coronary artery disease	−2.90	0.26
Diabetes	−2.26	0.24
Wrist device	−1.27	0.67
Diastolic BP overestimation		
Age (per year increase)	0.16	0.01
Sex (male vs. female)	0.28	0.82
Arm circumference (per cm increase)	0.38	0.03
Hypertension	0.42	0.77
Wrist device	1.69	0.50
Hard cuff design	3.81	0.002
Omron device	0.54	0.70
Diastolic BP underestimation		
Dyslipidemia	−2.06	0.12
Device age (per year increase)	−0.24	0.03

Abbreviation: BP, blood pressure.

>10 mm Hg.[21] Regarding device age, we speculate that this association may result from variations in device algorithms over time. Interestingly, our finding was not explained by deterioration of device accuracy over time because older devices appeared more accurate. After dichotomizing device age above and below the mean of 6.1 years, mean differences from auscultation were −1.1 ± 7.6/−0.01 ± 5.9 for older devices compared to −4.4 ± 7.0/1.4 ± 6.2 for newer ones.

In aggregate, the findings of the present study and past research indicate the importance of confirming that a given oscillometric device is accurate when used to measure BP in its owner. While abbreviated versions of BP validation standard protocols have been proposed as a compromisory and pragmatic solution to enable clinicians to more easily and rapidly assess device accuracy in the clinic, this proposal is unlikely to be implemented in a busy clinical setting.[18] A separate, stand-alone service to verify accuracy is a potential alternative solution, but feasibility and economic viability are unproven. An additional question raised by these findings is whether the acceptable margin of error of oscillometric devices is, in general, considered too lax and whether tightening this margin would lead to greater accuracy in individual patients. The proprietary nature of the algorithms used to determine BP from oscillometric measurements and the lack of open display of the oscillometric waveforms and waveform envelopes has hampered progress by academic institutions and in the public domain. Indeed, even fundamental discoveries, such as conclusively establishing

an oscillometric "marker" for systolic and diastolic BP have yet to take place. Given these challenges, further research into the oscillometric technique and the factors accounting for discrepancies against reference quality auscultation is required.[23] This would enable development of more accurate oscillometric devices.

In the present analysis, mean differences from the reference standard were slightly lower for unvalidated devices compared to validated ones; however, the variability around this difference was higher for unvalidated devices. Still, the overall results for unvalidated and validated devices were relatively similar, indicating that prior validation did not ensure more accurate results. This contrasts with the results of prior studies, which found that previously validated devices were more accurate than unvalidated ones.[16,20] However, in the largest of these 2 studies, the proportion of inaccurate validated devices was still relatively high at 32%.[16] It is possible, given these findings, that current validation standards are too lax in terms of their requirements for accuracy. Furthermore, performance of a validation study may not guarantee accuracy if the validation study is not conducted rigorously. Indeed, validation study procedures and data may not be made available for public review (there is no requirement in any current standard to even list the contact information of the principle investigator or test center that performed the validation study) and, to our knowledge, no certification of validation study test centers is required to ensure that studies are being performed properly. We suspect that there is little appreciation or awareness of these issues amongst consumers and clinicians. Indeed, even hypertension societies that "endorse" products based on the availability of validation data, as indicated by listing in an online registry for example, likely do not review the data directly and may not be aware of these potential limitations of some validation studies.

Strengths of this study include use of 2-observer auscultation with a mercury sphygmomanometer as the reference standard and assessment of device accuracy under "real world" conditions, whereby devices were tested on their owners. Limitations include the underpowered subgroup analyses, which were exploratory in nature, and the relative dearth of study subjects with advanced age, severe obesity, vascular disease, and other comorbidities (limiting generalizability). Regarding the latter, we expect that accuracy may be compromised to a greater extent in these patient populations because of arterial stiffness and/or widened pulse pressure. Further study to confirm or refute this hypothesis is clearly warranted. One final potential limitation is selection bias. Participants who volunteered for this study may have had suspicions regarding the inaccuracy of their home machines.

In conclusion, these findings demonstrate that home BP monitors are not acceptably accurate to within 5 mm Hg in nearly 70% of patients and that arm circumference is a consistent and important predictor of BP differences. These findings indicate the need to assess and optimize the device-subject pairing, but operationalizing this objective will be difficult. Further, improving the accuracy of these commonly used, guideline-endorsed devices should be urgently prioritized. A more individualized approach to the derivation of BP from the oscillometric data is needed.[23] The lack of accuracy is not widely appreciated or understood by the clinicians recommending or the patients using these devices. Greater collaboration between industry and academia would be an important first step towards optimizing oscillometric device accuracy in individual patients.

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