Blood pressure differences between home monitoring and daytime ambulatory values and their reproducibility in treated hypertensive stroke and TIA patients

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Background Guidelines recommend ambulatory or home blood pressure monitoring to improve hypertension diagnosis and monitoring. Both these methods are ascribed the same threshold values, but whether they produce similar results has not been established in certain patient groups.

Methods Adults with mild/moderate stroke or transient ischemic attack (N = 80) completed 2 sets of ambulatory and home blood pressure monitoring. Systolic and diastolic blood pressure values from contemporaneous measurements were compared, and the limits of agreement were assessed. Exploratory analyses for predictive factors of any difference were conducted.

Results Daytime ambulatory blood pressure values were consistently lower than home values, the mean difference in systolic blood pressure for initial ambulatory versus first home monitoring was –6.6 ± 13.5 mm Hg ($P \leq .001$), and final ambulatory versus second home monitoring was –7.1 ± 11.0mm Hg ($P \leq .001$). Mean diastolic blood pressure differences were –2.1 ± 8.5mm Hg ($P = .03$) and –2.0 ± 7.2mm Hg ($P = .02$). Limits of agreement for systolic blood pressure were –33.0 to 19.9mm Hg and –28.7 to 14.5mm Hg for the 2 comparisons and for DBP were –18.8 to 14.5mm Hg and –16.1 to 12.2mm Hg, respectively. The individual mean change in systolic blood pressure difference was 11.0 ± 8.3mm Hg across the 2 comparisons. No predictive factors for these differences were identified.

Conclusions Daytime ambulatory systolic and diastolic blood pressure values were significantly lower than home monitored values at both time points. Differences between the 2 methods were not reproducible for individuals. Using the same threshold value for both out-of-office measurement methods may not be appropriate in patients with cerebrovascular disease. (Am Heart J 2019;207:58-65.)

Hypertension is a major modifiable risk factor for both primary and secondary stroke prevention.[1,2] Diagnosing hypertension and monitoring treatment response rely on being able to obtain an accurate and reproducible measurement of blood pressure (BP). Clinic BP measurement (CBPM) values taken manually by auscultation with a sphygmomanometer have been the traditional standardized method, yet they are limited by factors such as inadequate technique, observer bias, terminal digit preference, and blood pressure variability.[3,4] Although some of these limitations may be overcome by taking multiple clinic measurements over time, in patients with the white coat phenomenon or masked hypertension, an accurate BP is unlikely to be obtained using CBPM alone.[5] For these reasons and because they better predict cardiovascular risk,[6-8] current hypertension guidelines recommend the additional use of out-of-office measurements (either ambulatory BP monitoring [ABPM] or home BP monitoring [HBPM]) to support diagnosis and for monitoring BP control.[9-12] Some authorities recommend ABPM as the "gold standard,"[9,13] but HBPM has become more popular as evidence indicating that its use can improve BP control has emerged.[14] However, whether HBPM is effective in patients with cerebrovascular disease remains uncertain.[15]

Clinic BP values are frequently at variance with out-of-office values, and so using the same diagnostic and

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monitoring threshold value for all BP measurement methods is not necessarily appropriate. Comparisons of daytime ABPM and CBPM suggest that for a CBPM of 140/90 mm Hg, the equivalent readings from daytime ABPM are on average 4/3 mm Hg lower.[16] The threshold set by several guideline groups for the upper limit of "normal" for daytime ABPM values is <135/85 mm Hg.[9,11,12] The same threshold value has been ascribed to HBPM, although this has not been fully established,[13] with recent studies suggesting the threshold should be lower.[17,18] Furthermore, there are limited comparisons of ABPM with HBPM, despite ABPM being considered the reference standard. Reports of their equivalence are inconsistent, have not investigated the reproducibility of any variation between the 2 methods, and have not assessed their equivalence in high-risk patient groups.[19-25]

TEST-BP was a randomized controlled trial of HBPM with or without guided self-management of antihypertensive therapy in a population with cerebrovascular disease, with participants also undertaking daytime ABPM contemporaneously to HBPM. The aims of this study were to evaluate if there are differences between BP values measured using daytime ABPM and HBPM, assess their reproducibility, and explore factors that may relate to any differences.

Methods

The methodology used in TEST-BP has been previously reported.[26] Ethical approval was obtained from the NRES Committee East of England–Norfolk (ref. 11/EE/0147). The trial was registered with the ISRCTN trial database (ISRCTN 86192648), where the trial protocol is publicly available.

The methodology as relevant to this analysis is summarized here. Adults with a history of stroke (National Institute of Health Stroke Scale <15) or transient ischemic attack (TIA) between 72 hours and 12 weeks postevent and requiring treatment for *hypertension* (defined as being on antihypertensive medications prior to the recent cerebrovascular event or having postevent untreated BP ≥140/90 mm Hg from the mean of 3 clinic readings) were included. Patients in atrial fibrillation, with life expectancy less than 6 months, or with established cognitive impairment were excluded. Participants provided written informed consent before being randomized in a 1:1:1 ratio to treatment as usual, home monitoring only, or home monitoring with guided self-management of blood pressure. BP data from participants in both home monitoring groups have been used for this secondary analysis.

All participants underwent CBPM at screening; ABPM at baseline and 6 months; and HBPM at 6 weeks, 3 months, and 5 months. HBPM data from the recordings at 3 months were not used in this study. Clinic BP was measured by the trial nurse using a semiautomated oscillometric BP monitor and appropriately sized cuff (Omron 705IT; Omron Healthcare UK Ltd, Milton Keynes, UK), with the subject seated, after 5 minutes rest following British Hypertension Society (BHS) guidelines,[27] taking the mean of 3 measurements. ABPM was measured with a Spacelabs 90207 monitor (Spacelabs Healthcare Ltd [UK], Hertford, UK) set to measure BP every 20 minutes during the daytime and hourly overnight (22:00-07:00) following National Institute for Health and Care Excellence guidelines.[9] HBPM was performed following guideline recommendations with participants taking duplicate readings twice daily at home for 7 consecutive days.[9,11] Morning measurements were taken prior to antihypertensive medication, and all measurements were taken before meals. Readings from day 1 were discarded prior to analysis. The home monitoring–only group used a validated BHS-approved monitor with integrated memory and printer (Omron 705IT; Omron Healthcare UK Ltd, Milton Keynes, UK). The home monitoring and guided self-management group used a validated BHS-approved monitor (A&D UA-767PBT; A&D Instruments Ltd, Abingdon, UK) with a linked Bluetooth modem (iModem; Netmedical, Utrecht, Netherlands) that automatically transmitted readings to the trial team to allow for treatment decisions to be made in conjunction with the participant. Different monitors were used to incorporate telemonitoring of results into the intervention for the home monitoring with guided self-management group. Medication adherence was assessed using the Hill-Bone compliance questionnaire at baseline and 6 months. Participants were excluded from this analysis if any daytime ABPM recording had <14 readings or if any home monitoring period provided <21 readings. Medications were checked at each study visit, and those who had their antihypertensive medications altered between recordings for comparison or in the 2 weeks prior to any BP measurement were also excluded from this analysis.

Outcomes for this analysis were the comparison of mean systolic BP (SBP) and diastolic BP (DBP) from the baseline daytime ABPM readings with the first (6-week) HBPM readings, the follow-up ABPM readings with the last (5-month) HBPM readings, and the CBPM readings with both the baseline daytime ABPM and first HBPM readings.

Statistical analysis

Data were analyzed using SPSS version 23.0. A comparison of those included and excluded in the analysis was based on a 2-sample Student *t* test and a χ^2 test. Mean SBP and DBP for each measurement method were calculated with the SD. Paired Student *t* tests were used to compare the mean difference in SBP and DBP between the measurement methods stated above. BP differences were first analyzed for each intervention group separately, and then data from both groups were pooled when it was apparent that there were no significant differences between the separate analyses. Sensitivity and specificity of the diagnostic accuracy of HBPM were assessed against daytime ABPM (as the reference standard) using the kappa statistic with a diagnostic threshold for hypertension by both methods of ≥135/85mm Hg.[9,11,12] For the comparisons between

Table I. Baseline demographics of those included and excluded from analysis

	Included (n = 80)	Excluded (n = 19)
Age	74.1 (10.3)	75.4 (8.8)
Male	53 (66%)	12 (63%)
Diagnosis of TIA	53 (66%)	14 (74%)
Time from event to recruitment (wk)	8.9 (3.5)	9.1 (3.3)
Baseline mRS (stroke only)	1.0 (1.0)	1.0 (1.0)
BMI	28.6 (5.3)	26.8 (2.1)
Never smoked	36 (45%)	6 (32%)
Alcohol (U/wk)	9.4 (12.0)	7.1 (8.3)
On antihypertensive therapy	75 (94%)	17 (89%)
Antihypertensive monotherapy	35 (44%)	7 (37%)
Dual antihypertensive therapy	24 (30%)	8 (42%)
Triple antihypertensive therapy	14 (17%)	1 (5%)
ACEi/ARB	63 (79%)	14 (74%)
β-Blocker	15 (19%)	6 (32%)
Calcium channel blocker	33 (41%)	6 (32%)
Thiazide diuretic	14 (18%)	3 (16%)

Data presented are mean (SD) or frequency (%). Modified Rankin score is presented as median (interquartile range). No significant differences between groups. mRS, modified Rankin score; ACEi; angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker.

contemporaneous ABPM and HBPM readings, the limits of agreement for both SBP and DBP were assessed using the Bland and Altman method.[28] Exploratory univariate analyses were undertaken to investigate possible relationships between individual variance in SBP and DBP difference from ABPM and HBPM with potential predictor variables. Analyses were initially descriptive, using scatter plots for continuous variables and box and whisker plots for categorical variables, with formal testing using Pearson correlation for continuous variables and independent-samples *t* tests for categorical variables only where appropriate. The variables tested were age, sex, body mass index, baseline clinic BP, being on antihypertensive treatment, history of diabetes, diagnosis (TIA or stroke), baseline disability depicted by modified Rankin score, baseline cognition assessed using Montreal Cognitive Assessment score, and the number of measurements from daytime ABPM and HBPM.

Results

Ninety-nine subjects were randomized to 1 of the 2 intervention arms involving HBPM. Nineteen were excluded, 8 because of insufficient HBPM measurements from 1 or both of the recording periods and 11 because they had their antihypertensive medications changed between the ABPM and HBPM recording periods, leaving 80 participants for this analysis. Demographics of those included compared to those excluded showed no significant between-group differences (Table I). All participants were ambulant with a modified Rankin Score <2.

Mean SBP and DBP by CBPM were higher than both daytime ABPM and HBPM, with values from HBPM being higher than ABPM (Table II). The mean SBP and DBP from HBPM were higher than values from ABPM for both comparisons, and the difference was consistent over time (Figure 1). BP differences were similar for both intervention groups and independent of the home monitor that was used (Supplementary Table I, online supplement). Comparing the mean SBP and DBP from morning and evening HBPM recordings with daytime ABPM separately revealed greater differences with morning readings, but this did not significantly alter the findings (Supplementary Table II, online supplement). Self-reported medication adherence was excellent throughout the trial (median Hill-Bone score 9.0 [interquartile range 1.0] at both baseline and follow-up).

Table II. Mean group SBP and DBP from each measurement method

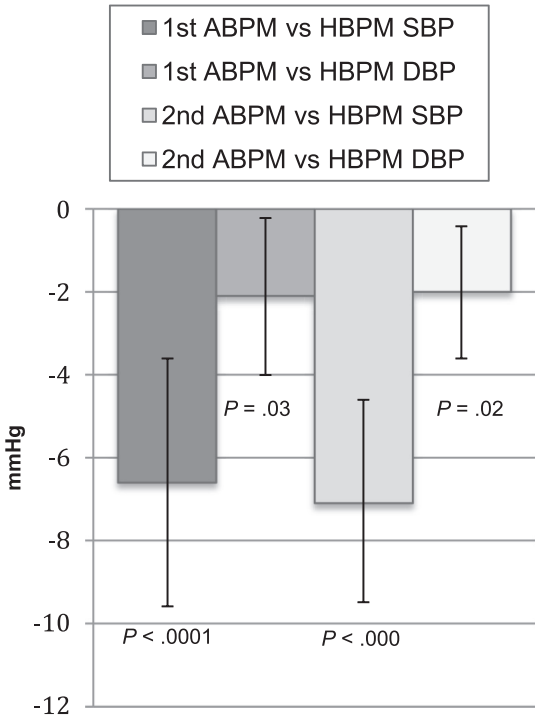
Measurement method	No. of measurements	Mean SBP (mm Hg)	Mean DBP (mm Hg)
Baseline CBPM	3 (0)	150.8 (20.2)	85.1 (11.8)
Baseline daytime ABPM	38.1 (9.1)	133.5 (13.7)	76.4 (8.5)
Home BP at 6 wk	27.3 (1.4)	140.1 (15.8)	78.5 (8.7)
Home BP at 5 m	26.8 (3.1)	134.7 (13.7)	76.2 (9.7)
Daytime ABPM at 6 m	37.2 (8.4)	127.6 (12.2)	74.2 (9.2)

Data presented are mean (SD).

The limits of agreement for SBP from ABPM versus HBPM were −33.0 to 19.9 mm Hg for the first comparison and −28.7 to 14.5 mm Hg for the second comparison (Figure 2). Limits of agreement for DBP were −18.8 to 14.5 mm Hg and −16.1 to 12.2 mm Hg, respectively. Although the difference in mean SBP and DBP from ABPM and HBPM for the whole cohort was consistent over time, the difference in BP recorded by each method was not consistent for individuals. The mean change in the difference between daytime ABPM SBP and HBPM SBP was 11.0 ± 8.3 mm Hg (range 0.65-43.3 mm Hg). For DBP, the mean change was 6.5 ± 5.1 mm Hg (range 0.21-19.8 mm Hg) (Figure 3).

Using daytime ABPM as the reference standard and a diagnostic threshold value for hypertension of ≥135/85 mm Hg for both methods, HBPM had a diagnostic sensitivity of 76.1% and specificity of 55.9% ($\kappa = 0.36$, $P = .004$) when comparing the baseline and first readings. At follow-up, HBPM had a diagnostic sensitivity of 70.8% and specificity of 55.4% ($\kappa = 0.22$, $P = .03$). From the baseline daytime ABPM recordings, 46 of 80 (57.5%, 95% CI 46.3%-67.9%) participants were classified as having uncontrolled hypertension, and from the follow-up daytime ABPM, the rate was 24 of 80 (30.0%, 95% CI 20.0%-40.3%). For HBPM, 50 of 80 (62.5%, 95% CI 52.5%-72.7%) were classified as uncontrolled hypertension on the first recording and 42 of 80 (52.5%, 95% CI 41.7%-63.6%) on the second recording. For the first comparison, 54 of 80 (67.5%, 95% CI 57.8%-77.8%) participants were classified the same according to both daytime ABPM and HBPM (35 uncontrolled

Figure 1



Mean differences in blood pressure for head-to-head comparisons of out-of-office measurement methods. Error bars are 95% CIs. *P* values represent paired Student *t* tests comparing the difference between measurement methods.

hypertension and 19 controlled hypertension). For the second comparison, this proportion was 48 of 80 (60.0%, 95% CI 49.4%-71.6% [17 uncontrolled hypertension and 31 controlled hypertension]).

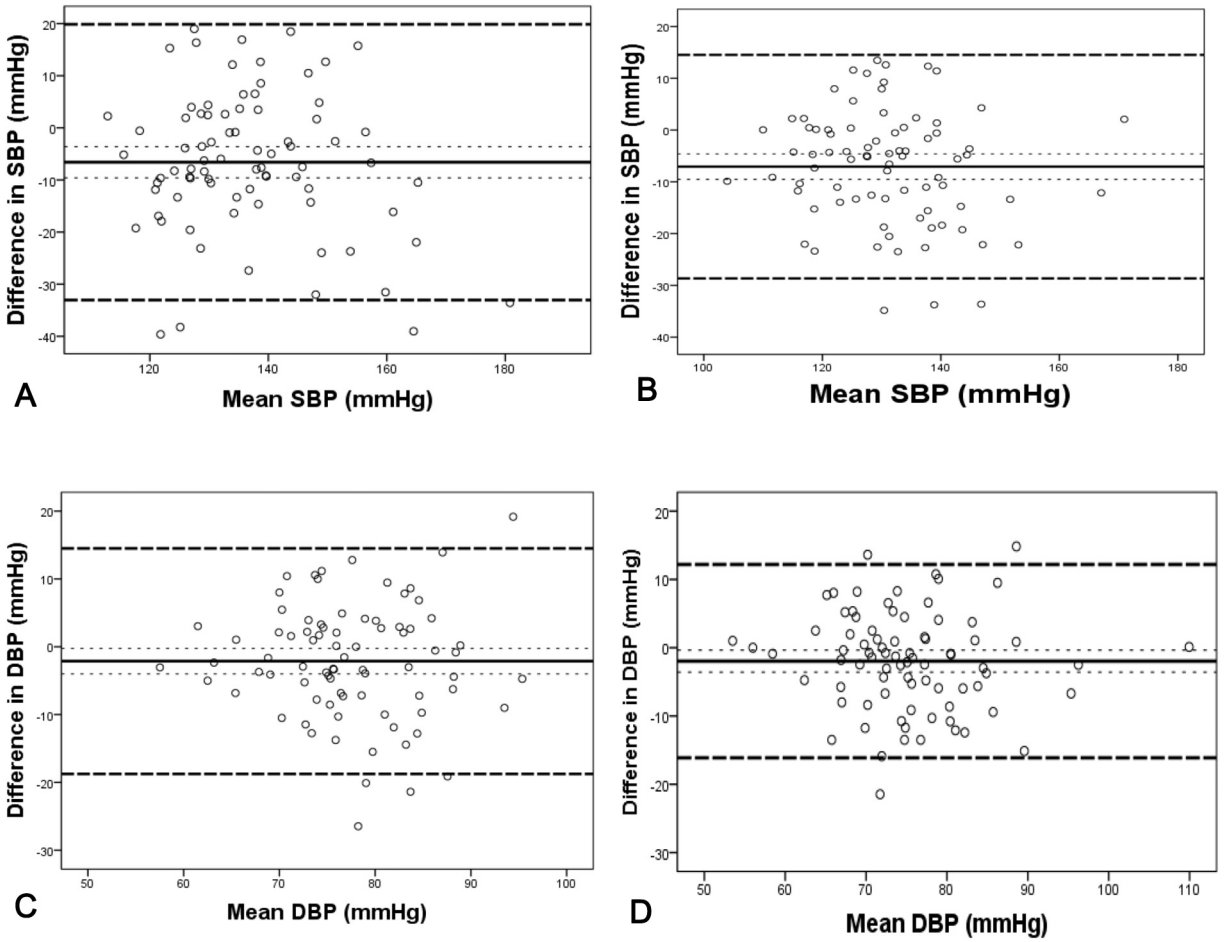
In the exploratory analyses for independent predictor variables for the differences between daytime ABPM and HBPM values, the descriptive testing only suggested possible relationships with baseline clinic SBP and being on antihypertensive treatment, with all other variables unrelated (Supplementary Figures 1 and 2, online supplement). However, further testing for the relationship with baseline clinic SBP revealed no significant correlation with the first comparison and only a weak correlation ($r = -0.25$, $P = .02$) with the second comparison. Further testing of the relationship with being on antihypertensive treatment was not possible because of the small number of untreated participants (n = 5).

Discussion

This work aimed to assess if important differences exist, which may affect clinical management of BP levels in stroke or TIA patients, between the commonest methods of assessing out-of-office BP levels. We found that significant and prominent differences exist in BP values obtained from daytime ABPM compared to HBPM in this patient group. The mean differences in BP values were consistent between the 2 groups (who used different home monitors) and over the 2 measurement phases of the 6-month trial; however, the limits of agreement were wide-ranging, and BP differences between the 2 measurement methods were not reproducible for individuals across the 2 measurement periods. This suggests that daytime ABPM and HBPM may not be interchangeable methods, as BP values obtained using one method cannot be used to infer values from the other. Furthermore, the difference between the methods was large enough to potentially affect patient management, with a mismatch in hypertension control at a threshold value of ≥135/85 mm Hg in 26 of 80 (32.5%) of participants at baseline and 32 of 80 (40.0%) at outcome. This indicates that there is the potential for discordant treatment decisions depending on which method is used to gauge treatment response. We were unable to demonstrate any predictive factors for the observed differences in BP between the 2 methodologies, with the significant correlation between baseline clinic SBP and SBP difference from the second comparison probably being a chance finding.

ABPM and HBPM have both been assessed against CBPM[16,29]; however, fewer studies have directly compared the 2 out-of-office methods using an HBPM protocol consistent with current guidelines. One randomized controlled trial of the therapeutic effect of HBPM in a primary care cohort of treated hypertensive adults reported a difference between daytime ABPM and HBPM of −3.1/+0.7 mm Hg at the end of the trial, although this difference was not assessed further.[30] Three cross-sectional studies in a mixture of treated and untreated hypertensive adults have shown differences ranging from −5 to −7 mm Hg for SBP and −1 to −4 mm Hg for DBP, with mean ABPM values lower than HBPM in each study, similar to our results.[19-21] The limits of agreement we found are also comparable to those reported elsewhere.[31] In contrast, 1 cohort study in untreated hypertensive adults reported no difference between BP values from HBPM and daytime ABPM.[23] This inconsistency may relate to the age of included participants, as other studies have demonstrated that differences in BP values from out-of-office methods are not consistent across age groups, with daytime ABPM values being higher than HBPM values in children but lower or similar in adults older than 60 years.[24,25] The age of our cohort may therefore partly explain our findings, and the narrow age range of participants may explain why age was not a predictive factor for the differences we found. Nevertheless, the findings potentially remain of relevance to managing stroke secondary prevention, as many stroke patients experience their first cerebrovascular event at older ages. Importantly, none of these studies have performed repeated BP measures to investigate the reproducibility of any differences. Both ABPM and

Figure 2

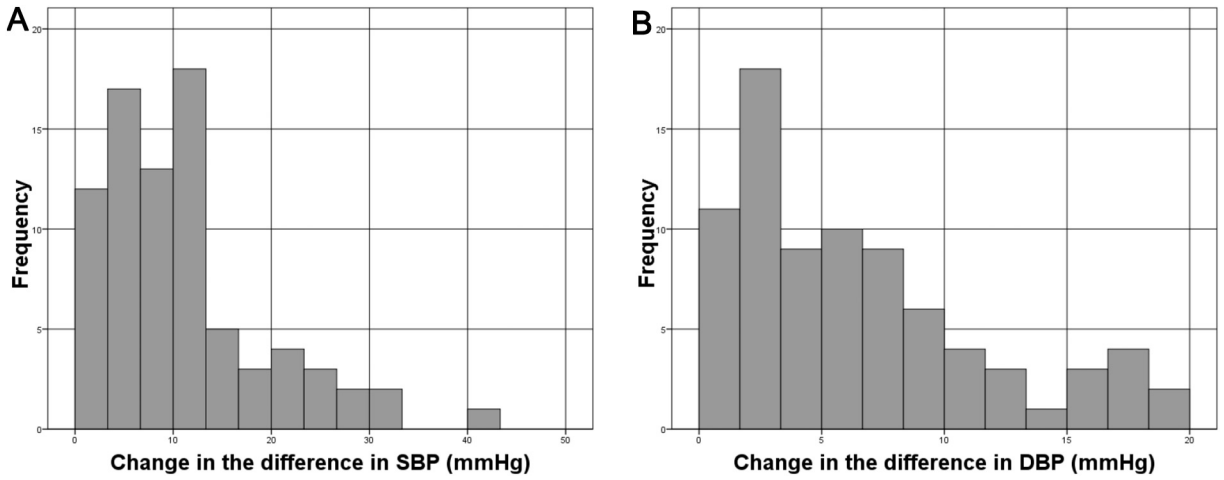


Bland-Altman plots to show the limits of agreement for within-individual blood pressure recorded by ABPM and HBPM. Thick lines show the mean difference, dotted lines the 95% CI for the mean difference, and dashed lines the limits of agreement (±2 SDs). **A**, SBP comparing baseline ABPM and the first HBPM. **B**, SBP comparing follow-up ABPM and the last HBPM. **C**, DBP comparing baseline ABPM and the first HBPM. **D**, DBP comparing follow-up ABPM and the last HBPM.

HBPM have been individually shown to be reproducible.[32] However, they do not seem to provide the same BP information for individuals, with one study showing that, despite both methods diagnosing the same proportion of a cohort with masked hypertension, almost half of those diagnosed as masked hypertensive on daytime ABPM were not according to HBPM.[33]

Using ABPM as the reference standard and with a diagnostic threshold value of ≥135/85 mm Hg, HBPM has been reported to have a diagnostic sensitivity of 86% and specificity of 62%, which are similar to our findings.[22] Despite this, daytime ABPM and HBPM have been ascribed the same threshold values for hypertension diagnosis.[9,11,12] Furthermore, they are deemed equivalent for categorizing patients by stage of hypertension.[12] This may not be the case, as other studies have suggested that the difference between them may depend upon BP level.[34,35] This may relate to increased blood pressure variability, which has been shown to increase with BP level,[36] and could have a greater influence on mean BP from HBPM compared to ABPM due to the different number of measurements. Other factors which may be relevant include age, gender, and being on antihypertensive treatment.[19,35] Our data also suggested that the latter may be a relevant factor, but we were unable to formally test this because of our small sample size. A possible explanation for the relevance of antihypertensive treatment status is that morning HBPM measurements are routinely taken before antihypertensive medications, therefore capturing BP at the trough of antihypertensive activity. Because of the larger number of measurements obtained with ABPM throughout the day, the influence of these "trough values" will be diluted, resulting in a lower daytime mean BP than that obtained with HBPM. However,

Figure 3



Histograms to show the change in the BP difference recorded by ABPM and HBPM from the first to the second comparison for individuals. **A**, The change in SBP. **B**, The change in DBP.

although our data did show that morning HBPM mean BP was higher than in the evening, the difference was not large enough to support this explanation.

This study is, to the best of our knowledge, the first to compare different out-of-office BP measurement methods and assess their limits of agreement in a population with cerebrovascular disease. Given the prevalence of stroke and the importance of BP management in secondary stroke prevention, we believe that the study is of importance.[1,2,37] Its main strength is that we were able to compare ABPM and HBPM measurements at 2 different time points in the same population of patients who were treated but had not altered therapy between measurement timings, thereby investigating the consistency of any discrepancy and its reproducibility in individuals.

Limitations that should be considered include that this was a post hoc analysis of data from a randomized controlled trial. The population recruited all had cerebrovascular disease, and the majority were elderly and on treatment for hypertension. Consequently, our findings may not be generalizable to a broader population. Secondly, because of the relatively small sample size, our findings should be interpreted with caution. Thirdly, because of the design of the trial, the 2 intervention groups used different home monitors, and this could account for some of the difference with daytime ABPM values that was found. However, both types of monitor have been validated. Furthermore, we have shown that any differences with daytime ABPM values were not significantly different between the 2 groups and therefore are not likely to have been significantly influenced by the equipment. Fourthly, most our participants were on antihypertensive treatment throughout the trial, which may have influenced BP readings. However, other studies discussed have also included participants on treatment, and we have shown that poor adherence is unlikely to have been a confounding factor in our cohort.[16,19,20,30] Fifthly, the ABPM and HBPM measurements that we have compared were not precisely contemporaneous, which may have introduced some natural variation. However, we excluded patients whose antihypertensive medications were changed in between measurements for comparison to try to ensure stability. Also, we have shown that the group variation between methods was consistent over time. Some other studies discussed have also compared measurements up to 4 weeks apart. Finally, there was a larger-than-expected difference between the BP values from clinic measurement and out-of-office measurement in our group, suggesting a marked white coat effect in some individuals. Home BP values, but not ABPM values, could also have been influenced by any anxiety around BP measurement, thereby influencing our findings. However, the difference between clinic versus ABPM and clinic versus HBPM was consistent with the difference between ABPM versus HBPM, suggesting that any differences were not attributable to measurement differences from just 1 method. Furthermore, although we did not assess it in our cohort, there is evidence to show that patients with cerebrovascular disease do not experience additional anxiety due to HBPM and they can reliably measure their own BP at home.[38,39]

In this patient group with incident cerebrovascular events, we found significant differences between BP values obtained from ABPM and HBPM leading to inconsistency in hypertension control status if the current guideline threshold of $\geq$135/85 mm Hg is applied to both methods. This is clinically important because it creates the potential to overtreat individuals if relying on HBPM to assess treatment response or, conversely, undertreat if

relying on ABPM. The variation between methods is not consistent between individuals, suggesting that ABPM and HBPM should not be considered interchangeable methods of BP evaluation. Considering this, the threshold value for monitoring BP treatment with HBPM may not be the same as that for initial diagnosis and at present may need to be individualized. Further work in larger cohorts of both treated and untreated hypertensive individuals to establish values for HBPM with ABPM as the reference standard would be valuable.

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Author contributions

The authors are solely responsible for the design and conduct of this study, all study analyses, the drafting and editing of the paper, and its final contents.

Appendix. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ahj.2018.09.005.

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