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A Comparison of Home Measurement and Ambulatory Monitoring of Blood Pressure in the Adjustment of Antihypertensive Treatment

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Background: The purpose of this study was to compare home and ambulatory blood pressure (BP) in the adjustment of antihypertensive treatment.

Methods: After a 4-week washout period, patients whose untreated daytime diastolic ambulatory BP averaged ≥85 mm Hg were randomized to be treated according to their ambulatory or home BP. Antihypertensive treatment was adjusted at 6-week intervals according to the mean daytime ambulatory diastolic BP or the mean home diastolic BP, depending on the patient's randomization group. If the diastolic BP stayed above 80 mm Hg, the physician blinded to randomization intensified hypertensive treatment.

Results: Ninety-eight patients completed the study. During the 24-week follow-up period both systolic and diastolic BP decreased significantly within both groups ($P < .001$). At the end of the study, the systolic/diastolic differences between ambulatory ($n = 46$) and home ($n = 52$) BP groups in home, daytime ambulatory, night-time ambulatory, and 24-h ambulatory BP changes averaged 2.6/2.6 mm Hg, 0.6/1.7 mm Hg, 1.0/1.4 mm Hg, and 0.6/1.5 mm Hg, respectively (P range .06 to .75) A nonsignificant trend to more intensive drug therapy in the ambulatory BP group and a nonsignificant trend to larger share of patients reaching (57.7% *v* 43.5%, $P = .16$) the target pressure in the home BP group was observed due to the 3.8 mm Hg difference in ambulatory and home diastolic BP at randomization.

Conclusions: The adjustment of antihypertensive treatment based on either ambulatory or home BP measurement led to good BP control. No significant between-group differences in BP changes were seen at the end of the study. Additional research is needed to provide more conclusive results. Am J Hypertens 2006;19:468–474

Key Words: Blood pressure, blood pressure determination, ambulatory blood pressure monitoring, home blood pressure monitoring.

Accurate blood pressure (BP) measurement is essential for the reliable assessment of hypertension and the need of antihypertensive treatment. Office BP is routinely used for that purpose. Yet, the optimal technique for measuring BP remains controversial. Home BP measurement and ambulatory BP monitoring are at present only complementary to conventional office measurement, although they accomplish several advantages over office BP measurement: better reproducibility,[1–4] better correlation to end-organ damage,[5–7] the absence of the white coat effect,[8,9] and, when automated devices are used, the lack of digit preference and observer bias.

Two studies by Staessen et al in 1997[10] and 2004[11] have reported that antihypertensive treatment based on 24-h ambulatory monitoring or home measurement instead of office measurement led to less intensive drug treatment and less BP control with fairly similar costs. No differences were seen in short-term end-organ damage. However, no studies have directly compared ambulatory BP monitoring and home BP measurement in the management of hypertensive patients. The purpose of this study was to compare home and ambulatory BP in the adjustment of antihypertensive treatment.

Methods

Patients

The study cohort consisted of previously treated or untreated patients from 40 to 80 years of age, with off-

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treatment daytime ambulatory diastolic BP between 86 and 110 mm Hg. Subjects were excluded if they had one or more of the following findings: secondary hypertension, childbearing potential, a stroke or myocardial infarction within 12 months before randomization, decompensated congestive heart failure, other serious concomitant diseases that may affect survival, other indication than hypertension for drugs used in the trial, hypersensitivity to drugs used in the trial, heart rate <50 beats/min, insulin-treated diabetes mellitus, serious hepatic or renal insufficiency, atrial fibrillation, or body mass index >35 kg/m^2.

Study Design

This study was a blinded, randomized, controlled clinical trial that took place between April 1999 and November 2003 in the outpatient clinic of Turku University Hospital. The protocol for this study was approved by the Ethics Committee of the University of Turku, Finland. The study was conducted according to the Declaration of Helsinki and written informed consent was obtained from all patients.

At an initial pre-entry screening, we obtained a medical history for all patients and performed a standard physical examination. Previous possible antihypertensive medication was discontinued and the patients underwent a 4-week placebo washout period. During the pre-entry period the patients measured their BP daily using a home monitor to obtain a baseline BP estimate. At the end of the 4-week wash-out period a 24-h ambulatory BP measurement was performed on all patients.

Patients who met the inclusion criteria and who had no identifiable cause for exclusion were included in the study and were randomly allocated by random number generator to be treated either according to their home or ambulatory BP.

After randomization, follow-up visits were scheduled at 6, 12, 18, and 24 weeks. All patients measured their home BP during the week preceding the follow-up visit. Ambulatory BP monitoring was also performed on all patients 1 day before the follow-up visit. The treating physician was blinded to randomization and received only the BP values for the method of measurement to which the patient was randomized, but was not told which method was used to obtain the BP values. All patients were treated by a single physician (IMK). The target pressure in the study for both the home- and ambulatory-based BP measurement groups was a diastolic BP ≤80 mm Hg. To achieve this goal, a standardized stepped-care antihypertensive drug regimen was implemented. After randomization, all patients began therapy with 8 mg/d candesartan (step 1). At later visits, if the mean diastolic pressure guiding treatment was above the target pressure (>80 mm Hg), the treatment was intensified stepwise to 16 mg/d candesartan (step 2), 16 mg/d candesartan + 12.5 mg/d hydroclorothiazide (step 3), and 16 mg/d candesartan + 12.5 mg/d hydroclorothiazide + 5 mg/d felodipine (step 4). Previous treatment was continued if BP was below target pressure, or was reduced if the patient had symptoms of hypotension.

BP Measurements

Before the pre-entry screening period, all patients received individual guidance on how to measure BP correctly. Home BP was measured using an automatic, oscillometric, validated[12] Omron M4, model HEM-722C (Omron Corp., Kyoto, Japan) home monitor. After 5 min of rest in the sitting position, patients performed two consecutive self-measurements of BP twice daily, in the morning between 6 and 10 AM at trough and in the evening between 6 and 10 PM. They wrote down the BP values and the time of day. The self-measured BP was the average of all 28 readings collected during 7 consecutive days (including a weekend) preceding each follow-up visit.

The 24-h ambulatory BP monitoring was performed at 0, 6, 12, 18, and 24 weeks on all patients using a validated[13] oscillometric SpaceLabs Medical 90207 (Spacelabs Inc., Redmond, WA) ambulatory BP monitor. Measurements were performed at 15-min intervals during the day (6 AM to 11 PM) and at 30-min intervals in night-time (11 PM to 6 AM). All patients received verbal and written instructions about its operation and care. All recipients completed a sleep and activity diary during the ambulatory BP monitoring and night times were defined as full hours of self-reported actual patient sleep times.

In addition, office BP measurement was performed at 0, 6, 12, 18, and 24 weeks on all patients. The values from these measurements were not used in guiding antihypertensive treatment and were not disclosed to the doctor. Systolic and diastolic office BP (Korotkoff sounds, phase V) was the mean of three consecutive BP measurements taken at 2-min intervals after the patients had been seated for 5 min using a calibrated conventional sphygmomanometer.

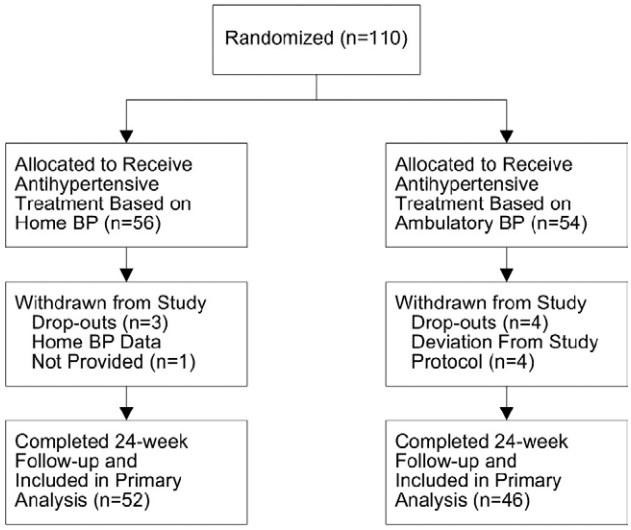

FIG. 1. Flow of study participants. BP = blood pressure.

Table 1. Baseline patient characteristics

Characteristics	Home BP group	Ambulatory BP group	*P*
Age, mean (SD), y	53.8 (10.0)	53.6 (7.0)	.91
BMI, mean (SD), kg/m^2	28.2 (4.0)	27.2 (3.7)	.21
Women (%)	63.5	50.0	.18
Previous antihypertensive treatment (%)	71.2	65.2	.53
Smokers (%)	5.8	8.7	.57
Serum creatinine, mean (SD), μmol/L	89.5 (11.6)	91.4 (14.5)	.47
Serum total cholesterol, mean (SD), mmol/L	5.3 (0.9)	5.6 (0.9)	.14
Plasma fasting glucose, mean (SD), mmol/L	5.6 (0.9)	5.6 (0.5)	.90

P values are for the differences between groups. BP = blood pressure; SD = standard deviation.

Statistical Analysis

With a type I error of 5% and a type II error of 20%, approximately 44 patients per treatment group were needed to detect differences of 3 mm Hg for systolic and diastolic BP, assuming a standard deviation of 5 mm Hg for both. The number of patients withdrawing from the study was estimated at 10%, and therefore approximately 50 patients were enrolled per treatment group.

Database analysis and management were performed with SAS statistical software, version 8.2 (SAS Institute Inc., Cary, NC). The between-group differences in continuous measurements were calculated by subtracting the mean changes from baseline in the home BP group from those of the ambulatory BP group. The variables were tested for normality. The between-group comparisons for baseline characteristics and BP changes were done with the two-sample Student *t* test or the Mann-Whitney U test for continuous variables, or χ^2 test in case of categorical variables. The within-group comparisons for BPs were done with the paired Student *t* test. A repeated-measures ANOVA was used to evaluate the between-group changes in BP during the study. P values $< .05$ were considered significant.

Results

Study Population

One hundred ten patients met the inclusion criteria and underwent randomization (Fig. 1), 56 in the home BP group and 54 in the ambulatory BP group. In the home BP

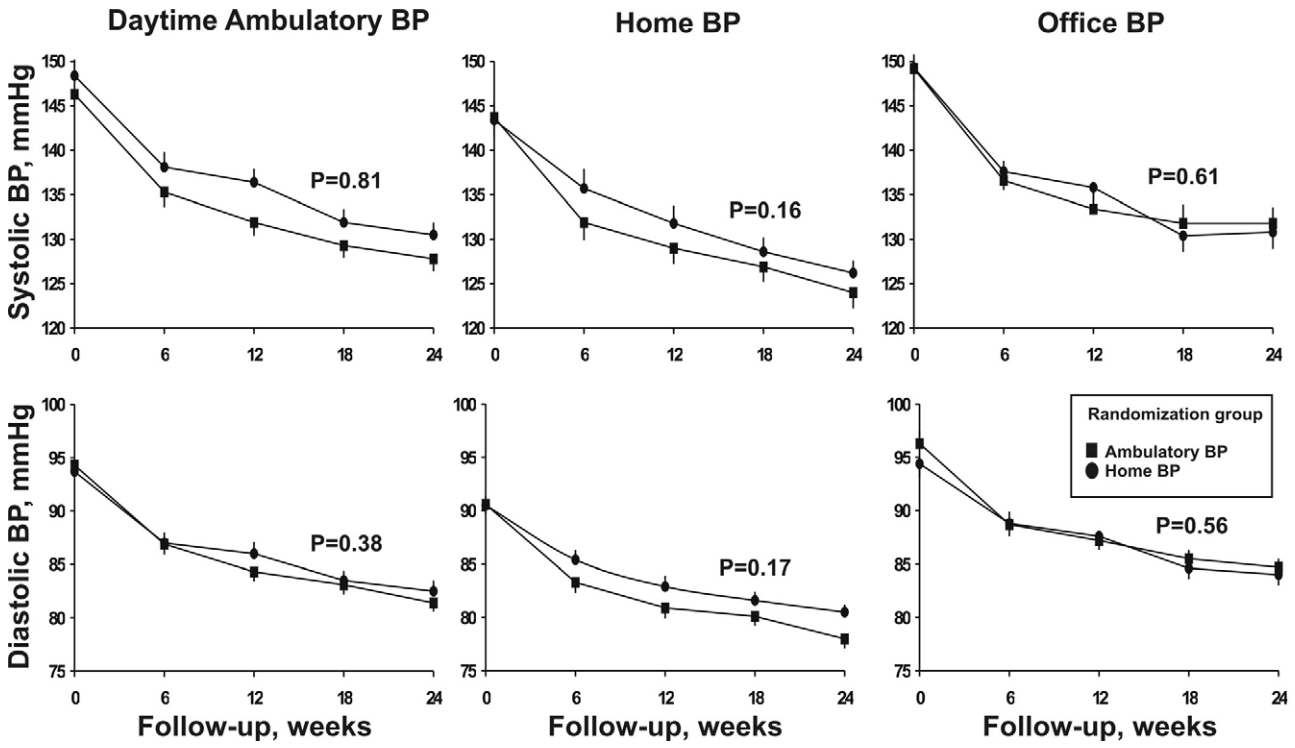

FIG. 2. Mean home, daytime ambulatory, and 24-h ambulatory blood pressures during the study. Error bars indicate SEs. *P* values refer to comparison of curves by ANOVA for repeated measures. BP = blood pressure.

Table 2. Blood pressures for the two treatment groups at randomization and after a 24-week follow-up

BP	Home BP group (n = 52)	Ambulatory BP group (n = 46)	Difference, mean (95% CI)	P
Home				
Systolic				
At randomization	143.4 (15.1)	143.7 (14.6)	−0.3 (−6.3 to 5.6)	.91
Change	−17.1 (1.7)	−19.7 (1.7)	2.6 (−2.3 to 7.4)	.29
Diastolic				
At randomization	90.5 (6.7)	90.6 (6.3)	−0.1 (−2.8 to 2.5)	.91
Change	−10.0 (0.8)	−12.6 (1.1)	2.6 (−0.1 to 5.2)	.06
Ambulatory: 24-h				
Systolic				
At randomization	144.9 (12.0)	143.2 (11.0)	1.7 (−2.9 to 6.4)	.46
Change	−17.3 (1.2)	−17.9 (1.3)	0.6 (−3.0 to 4.3)	.72
Diastolic				
At randomization	90.7 (7.1)	91.7 (5.9)	−1.0 (−3.6 to 1.7)	.46
Change	−10.8 (0.9)	−12.3 (0.8)	1.5 (−1.0 to 3.9)	.23
Ambulatory: daytime				
Systolic				
At randomization	148.4 (12.8)	146.3 (11.0)	2.1 (−2.7 to 6.9)	.39
Change	−17.9 (1.3)	−18.6 (1.4)	0.6 (−3.2 to 4.4)	.75
Diastolic				
At randomization	93.7 (7.6)	94.3 (6.0)	−0.7 (−3.4 to 2.1)	.63
Change	−11.2 (1.0)	−12.9 (0.8)	1.7 (−0.9 to 4.4	.20
Ambulatory: night-time				
Systolic				
At randomization	128.4 (13.1)	127.5 (12.0)	0.9 (−4.1 to 6.0	.72
Change	−14.8 (1.3)	−15.8 (1.5)	1.0 (−2.9 to 4.9)	.62
Diastolic				
At randomization	76.6 (7.9)	78.8 (7.5)	−2.2 (−5.3 to 0.9)	.16
Change	−9.8 (1.0)	−11.2 (1.0)	1.4 (−1.4 to 4.2)	.34
Office				
Systolic				
At randomization	149.3 (17.5)	149.2 (16.0)	0.1 (−6.6 to 6.9)	.97
Change	−18.5 (1.8)	−17.5 (1.6)	1.1 (−3.7 to 5.9)	.66
Diastolic				
At randomization	94.4 (9.6)	96.3 (8.1)	−2.0 (−5.6 to 1.6)	.28
Change	−10.3 (1.3)	−11.7 (1.2)	1.3 (−5.0 to 2.3)	.46

Values at randomization are expressed as mean (SD). Change refers to the mean changes (SE) from randomization to the end of the 24-week follow-up. All within-group differences were significant ($P < .001$). BP = blood pressure.

group, 52 patients (92.9%) completed the study, 3 patients withdrew their consent and 1 patient did not provide the home monitoring data. In the ambulatory BP group, 46 patients (85.2%) completed the study, 4 patients withdrew their consent and 4 patients had used antihypertensive medication during the washout period. The baseline characteristics of the patients in the ambulatory BP group and home BP group were similar (Table 1). Most patients had taken antihypertensive medication. No serious adverse events were reported during the study.

BP Control and Treatment Intensity

Home, ambulatory, and office BP decreased significantly ($P < .001$), both in the home and ambulatory BP groups during the 24-week follow-up. A nonsignificant trend in favor of the ambulatory BP group was seen in home and daytime ambulatory BP curves (Fig. 2). This trend was not found for office BP. There were no significant between-group differences in BP changes at the end of the study (Table 2).

Although BP decreased somewhat more in the ambulatory BP group, the prespecified BP guiding treatment (diastolic home or ambulatory daytime BP) was 0.9 mm Hg lower in the home BP group at the end of the study (Fig. 3). The achieved corresponding BP values were 80.5 ± 5.4 mm Hg in the home BP group and 81.4 ± 5.2 mm Hg in the ambulatory BP group.

By week 24, diastolic home BP was ≤80 mm Hg for 30 of 52 patients (57.7%) in the home BP group and for 28 of 46 patients (60.9%) in the ambulatory BP group. Diastolic daytime ambulatory BP was ≤80 mm Hg for 20 of 52 patients (38.5%) in the home BP group and for 20 of 46 patients (43.5%) in the ambulatory BP group. Thus, the prespecified target BP in the home BP group (diastolic home BP ≤80 mm Hg) was reached in 57.7% of the patients and in the ambulatory BP group (diastolic daytime ambulatory BP ≤80 mm

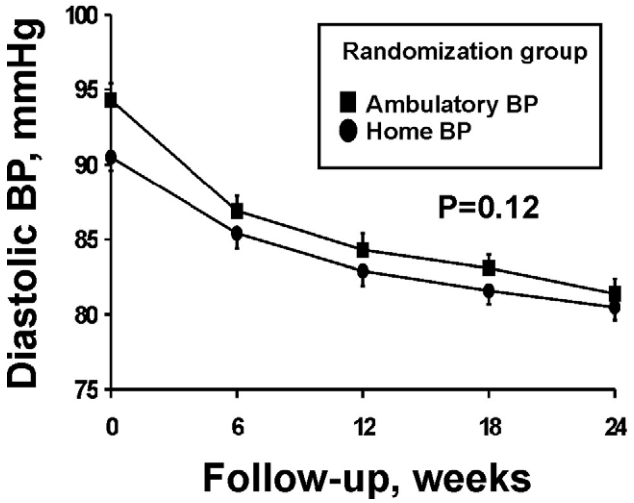

FIG. 3. Mean blood pressures guiding treatment during the study. Error bars indicate SEs. *P* value refers to comparison of curves by ANOVA for repeated measures. BP = blood pressure.

Hg) in 43.5% of the patients. This 14.2% difference between groups did not reach statistical significance (95% confidence interval [CI] −5.4% to 33.8%, $P = .16$).

Antihypertensive treatment based on ambulatory BP led to slightly more intensive drug treatment. A similar share of patients had progressed to combination drug therapy in both treatment groups by the end of the study (65.4% *v* 67.4%, $P = .83$). Nonsignificantly more patients were receiving drug therapy step 4 in the ambulatory BP group (19.2% *v* 32.6%, $P = .13$) (Table 3).

Discussion

In this randomized, blinded, parallel group trial of patients with mild-to-moderate hypertension, we found that antihypertensive treatment based on either home BP measurement or ambulatory BP monitoring while using the same target pressure led to good BP control. The BP decreased slightly more in the ambulatory BP group, but no statistically significant difference was observed in BP changes between the groups at the end of the study. A trend to more step 4 (candesartan + diuretic + felodipine) drug therapy was seen in the ambulatory BP group, although the difference was not statistically significant. More patients reached the target BP in the home BP group, but this difference did not reach statistical significance. These between-group differences might have become significant if a larger study sample had been used. As far as we know, no studies have been published comparing antihypertensive treatment based on home BP and ambulatory BP.

The small nonsignificant between-group difference in BP changes at the end of the follow-up is most likely explained by the difference in the prespecified BP guiding treatment at randomization. Diastolic ambulatory daytime BP was 3.8 mm Hg higher in the ambulatory BP group than the diastolic home BP in the home BP group at randomization. However, if the target BPs had been different in the two treatment groups, blinding of the treating physician would have been impossible. The difference in diastolic BP at randomization also probably resulted in a trend of more intensive treatment in the ambulatory group and in a trend of more patients reaching the target BP in the home BP group because the difference between target BP and prespecified BP guiding treatment was smaller at randomization in the home BP group.

The marked difference at baseline in BP values between different methods of BP measurement while using the same target pressure was also one of the main limitations in the studies by Staessen et al.[10,11] In the 2004 Treatment of Hypertension Based on Home or Office Blood Pressure (THOP) study[11] comparing antihypertensive treatment based on office or home monitoring, the diastolic BP guiding treatment was 9.5 mm Hg higher at randomization for the office BP group than for the ambulatory or home BP group while using the same target BP. This unsurprisingly led to more intensive drug therapy and greater BP decrease in the office BP group. A 5 mm Hg higher target pressure should be used for office BP,[14,15] which was not taken into account in the THOP study. In our study, comparing home and ambulatory BP, the problem of a difference in randomization BP values still exists, but to a much lesser extent. Furthermore, the current guidelines recommend the same thresholds for elevated home and daytime ambulatory BP.[14,15] Our study shows that there are discrepancies in daytime ambulatory and home BP and therefore both methods require their own diagnostic and treatment thresholds.

The recommended threshold for elevated home BP is

Table 3. Treatment status of the patients at the end of the study

Treatment step	Home BP group ($n = 52$)	Ambulatory BP group ($n = 46$)	Difference (95% CI)	*P*
Step 1 (CS 8 mg), %	17.3	15.2	2.1 (−12.5 to 16.7)	.78
Step 2 (CS 16 mg), %	17.3	17.4	−0.1 (−15.1 to 14.9)	.99
Step 3 (CS 16 mg + HCTZ 12.5 mg), %	46.2	34.8	11.4 (−7.9 to 30.7)	.25
Step 4 (CS 16 mg + HCTZ 12.5 mg + FD 5 mg), %	19.2	32.6	−13.4 (−30.7 to 3.9)	.13

Values expressed as percentage. CS = candesartan; HCTZ = hydrochlorothiazide; FD = felodipine.

derived from statistical considerations in large populations. However, thresholds should be related to cardiovascular outcomes of which there are only limited data currently available for home BP measurement. Several prospective studies[16,17] have documented that the average level of ambulatory BP predicts risk of morbid events better than office BP, but only two published studies have addressed the correlation between home-measured BP and cardiovascular outcome. The results from the Japanese Ohasama study[18] and the French Self Measurement of Blood Pressure at Home in the Elderly: Assessment and Follow-up (SHEAF) study[19] indicated that the predictive power of the home BP level for subsequent mortality was stronger than that of office BP measurement. The Ohasama study also proposed a level of 137/83 mm Hg as an acceptable upper limit for home readings on the grounds that cardiovascular risk increases above this level.[20]

Home monitoring has many of the benefits of ambulatory BP monitoring, and is even better on some areas. Low compliance to treatment is one of the most important causes for poor control of hypertension. Home measurement of BP allows the patient to be more actively involved in their treatment, thereby improving adherence to treatment.[21,22] Home measurement of BP is also relatively inexpensive and feasible when compared to ambulatory monitoring and can be easily performed in the basic healthcare system. A meta-analysis of 18 randomized controlled trials by Cappuccio et al[23] reported that using home BP measurement rather than office BP measurements in the healthcare system resulted in better BP control (2.2/1.9 mm Hg, when allowing for publication bias) and greater achievement of BP targets (10% greater proportion on target). Our recent study in Finnish primary care setting also confirmed these findings.[24] A study of 200 patients randomized to either usual care or home monitoring in a closed model health maintenance organization found that self-measurement of BP may be also cost effective. After a 1-year follow-up, the costs of care were 29% lower in the self-monitoring group, and BP was equally well controlled in both groups.[25] Ambulatory monitoring also causes discomfort and disturbance of sleep. A study by Little et al[26] showed that home measurement of BP was the most acceptable method for patients, when compared to ambulatory monitoring, measured by a doctor or a nurse, or self-measurement in a room provided by the hospital. Home BP should therefore be considered as a good option for measuring BP and even as a method of choice when treating a patient with white coat hypertension in the primary care setting, poor compliance to treatment, or not enough time for clinic BP measurements.

Home BP measurement also has its downsides: the accuracy of some home monitors is inadequate,[27] observer bias is possible if the patient reports the BP readings him/herself,[28] and the BP measurements are not always performed correctly. However, these shortcomings can often be avoided by following the current recommendations for home BP measurement.[14,15] The clinical use of home measurement should require the use of validated and calibrated home monitors, at least 3 days of observation, a printed or electronic report of the measurements, and good patient training.

Our study had some limitations. First, this study of 110 patients, of which 98 completed the study, spanned a follow-up period of 24 weeks. The nonsignificant between-group differences in BP changes and treatment intensity might have become significant if a larger study sample had been used. Therefore, our findings require further validation in larger, long-term prospective studies. The clinical significance of the differences in BP changes (ranging from 0.6 to 2.6 mm Hg) would nevertheless be relatively small because a 1 mm Hg lower systolic BP would involve, for example, approximately a 5.6% lower risk for stroke in younger adults, dropping to a 1.8% lower risk in adults aged 75 years and older.[29] Second, if the study had included an office measurement group, there would have been a possibility to compare all three methods of BP measurement in the management of hypertension, but blinding had been impossible due to a different target BP for office measurements. Third, a home monitor without a printer or memory was used, which allows for possible observer bias.

In conclusion, the present findings suggest that adjustment of antihypertensive treatment based on either home BP measurement or ambulatory BP monitoring while using the same target pressure led to good BP control. A nonsignificant trend to more intensive drug therapy in the ambulatory BP group and a nonsignificant trend to a larger share of patients reaching the prespecified target pressure in the home BP group was seen due to the 3.8 mm Hg difference in daytime ambulatory and home diastolic BP at randomization. The difference in actual achieved BP between the groups was small. There should have been a 4 mm Hg higher target pressure in the ambulatory BP measurement group to prevent the observed difference. According to our study, home BP measurement may be considered as a convenient, inexpensive, and widely available option for ambulatory BP monitoring in the management of some hypertensive patients, especially in the primary care. However, because of the relatively small number of patients in our study, larger long-term prospective studies are still needed to validate our results and to determine the prognostic, diagnostic, and treatment thresholds for home-measured BP.

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