

Agreement Between Community Pharmacy, Physician's Office, and Home Blood Pressure Measurement Methods: The Palmera Study

José Sendra-Lillo¹, Daniel Sabater-Hernández², Ángel Sendra-Ortolá¹ and Fernando Martínez-Martínez²

BACKGROUND

The usefulness of the community pharmacy blood pressure (BP) (CPBP) method in assessing the effectiveness of antihypertensive treatment has not been adequately studied. The aim of this study was to assess the agreement between community pharmacy, home, and physician office BP (POBP) measurement methods in treated hypertensive patients.

METHODS

BP was measured at the pharmacy (three visits), at home (4 days) and at the physician office (three visits). The Lin correlation-concordance coefficient (CCC) was used to evaluate the quantitative agreement. The qualitative agreement between methods to establish the patient's hypertensive state was evaluated using the κ -coefficient. Using home BP (HBP) monitoring as the reference method, the sensitivity, specificity, positive and negative likelihood ratios of the CPBP and POBP measurement methods were calculated.

RESULTS

The study included 70 patients. Agreements were acceptable-moderate between CPBP and HBP (CCC (systolic BP (SBP)/diastolic BP

(DBP)) = 0.79/0.66; κ = 0.56), moderate between CPBP and POBP (CCC = 0.57/0.61; κ = 0.35), and moderate-poor (CCC = 0.56/0.49; κ = 0.28) between POBP and HBP. The sensitivity, specificity, positive and negative likelihood ratio for the CPBP and the POBP measurement methods were: 60.7%, 92.9%, 8.5, 0.4 and 75.0%, 54.8%, 1.7, 0.5, respectively.

CONCLUSIONS

In this sample of treated hypertensive patients, the agreement between the community pharmacy and HBP measurement methods was acceptable-moderate and greater than other agreements. The CPBP measurement method was more reliable than the POBP measurement method for detecting the presence of both uncontrolled and controlled BP and could be a good alternative to HBP monitoring when the latter lacks suitability.

Keywords: agreement; blood pressure; blood pressure monitoring; community pharmacy blood pressure monitoring; home blood pressure monitoring; hypertension; physician office blood pressure

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The measurement of blood pressure (BP) is the cornerstone in the management of hypertension and clinical decision-making. BP measurement in the physician office (POBP) is the method traditionally used for patient evaluation and is widely used to make clinical decisions. However, this method has some limitations, which can sometimes lead to inadequate assessments and decisions. Among the main limitations of the method, the white-coat effect (WCE) is defined as an increase in the patient's BP when the measurement is performed in the presence of a health care professional or in an unfamiliar environment.^{1,2} Ambulatory BP monitoring and home BP (HBP) monitoring (HBPM) are methods that provide a greater number of BP readings in more realistic settings, without interference of the WCE, and correlate better with target organ damage and cardiovascular risk than

POBP.^{3,4} Therefore, these methods are considered relevant and are preferred in the management of hypertension and clinical decision-making.^{5,6}

In some patients, assessing the degree of BP control (controlled/uncontrolled) in the clinical setting may not coincide with assessments made outside this setting: (i) individuals with normal office BP (<140/90 mm Hg) may have elevated ambulatory or HBP values (called masked hypertension) or (ii) patients whose office BP are persistently elevated while daytime or 24-h BP or HBP, are within their normal range (called white coat hypertension).⁶ Broadly speaking, the problem associated with masked hypertension is that in the absence of ambulatory BP monitoring (or HBPM) data, antihypertensive treatment may not be used because the office BP is in the normal range.^{7,8} On the other hand, white coat hypertension could result in overtreatment for hypertensive patients.⁶ In short, in some cases, the POBP measurement method is insufficient in making a proper assessment of the patient's clinical condition, and therefore it is necessary to use alternative methods.

¹Community Pharmacist in Palmera, Valencia, Spain; ²Pharmaceutical Care Research Group, University of Granada, Granada, Spain. Correspondence: José Sendra-Lillo (jose_sendra_lillo@yahoo.es) or (jsendralillo@gmail.com)

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Apart from HBPM and ambulatory BP monitoring measurement methods, there are other methods for BP measurement outside the clinical setting, such as BP measurement in the community pharmacy (CPBP), which is not affected by WCE.^{9–11} The CPBP measurement method is readily available, widely demanded by patients,¹² and recommended by scientific associations concerned with hypertension.^{13,14} However, this method has not been well studied and therefore, its usefulness in clinical practice remains uncertain.¹⁵ In order to assess the usefulness of the CPBP measurement method, both systematic and random errors with respect to other BP measurements obtained by the reference methods in the management of hypertension (ambulatory BP monitoring or HBPM) should be analyzed through agreement studies.¹⁶

Thus, the aim of the PALMERA study was to assess the agreement between community pharmacy, home and physician's office BP measurement methods in treated hypertensive patients. Additionally, we measured the prevalence of community pharmacy-white coat hypertension and -masked hypertension.

METHODS

The PALMERA study was a cross-sectional study that attempted to cover the entire treated hypertensive population (over 18 years old) in a rural community pharmacy located in Palmera (Valencia, Spain). The study was initiated and promoted by the pharmacy in collaboration with the health centre and began and concluded in November 2009 and in September 2010, respectively. Patients with any of the following criteria were excluded: systolic BP (SBP) ≥ 200 mm Hg and/or diastolic BP (DBP) ≥ 110 mm Hg on the initial visit to the pharmacy, arm circumference > 42 cm, atrial fibrillation, physical or mental impairment, inability to perform HBPM, history of changes in the antihypertensive treatment schedule during in the previous 4 weeks, history of cardiovascular disease < 6 months, or pregnancy. Patients were identified and consecutively recruited in the community pharmacy during medication dispensation.

BP measurement methods. BP measurements were taken in three settings: at the community pharmacy, at the physician's office and at home. The same automatic OMRON M10-IT (Omron, Tokyo, Japan) device was used in the three different settings. This device is equivalent to the clinically validated OMRON M6 (see http://www.dableducational.org/sphygmomanometers/recommended_cat.html).¹⁷ All of the BP monitors were new and checked for accuracy at the beginning of the study.

The CPBP was always measured by the same pharmacist over five visits to the pharmacy. Three measurements per visit (2 or 3 min apart) on the control arm (the arm in which the CPBP was higher on the first visit) were taken. Visits to the pharmacy were scheduled for each patient, with at least two visits in the morning and two visits in the evening. The five visits took place over a 5-week time period.

The POBP was measured by the physician during the three study visits (all of which were scheduled in the morning). Three measurements were taken per visit (2 or 3 min apart) on

the control arm. The three physician's office visits took place over a 3-week period. Both the pharmacist and the physician were previously instructed on how to perform the BP measurements according to international published guidelines.¹⁸ Generally, BP measurements were taken after 5 min of rest, with the back supported, feet flat on the floor, and the proper-size cuff at heart level. The subject refrained from drinking coffee or tea, smoking or exercising for at least 30 min before the measurement. The mean CPBP and POBP were calculated using all the BP measurements collecting during the first three visits.¹⁹ The BP measurements taken during visits 4 and 5 to the community pharmacy were discarded to enable comparison to a similar number of BP measurements in the physician's office. For both methods, BP control was defined as SBP < 140 mm Hg and DBP < 90 mm Hg.

At home, patients monitored their BP over four consecutive working days, taking three measurements in the morning (each measurement taken 2 min apart, between 6.00 AM and 9.00 AM) and three measurements in the evening (between 6.00 PM and 9.00 PM) on the control arm. Thus, the minimum number of HBP measurements established by international guidelines was obtained.⁵ All of the HBP measurements (morning and evening) were recorded before the antihypertensive medication was administered. The patients were instructed on the HBP measurement technique during a 20-min training session provided by the pharmacist. At the end of the session, the HBP measurement technique was tested by three consecutive self-measurements that were performed in the presence of the pharmacist. The patients were also provided written guidelines to reinforce the training. The HBP readings were stored in the device's memory and were retrieved by the pharmacist for subsequent statistical analyses. The mean HBP was calculated discarding BP measurements taken on the first day.⁵ HBP control was defined as SBP < 135 mm Hg and DBP < 85 mm Hg.

To characterize the study sample, the following variables were collected by the pharmacist: age, gender, heart rate (community pharmacy, physician's office, home), smoking status, body mass index, the number of antihypertensive drugs, any history of previous cardiovascular diseases (cerebrovascular disease, myocardial infarction, angina and peripheral artery disease), the presence of diabetes or dyslipidemia (a documented diagnosis or a previously prescribed drug treatment). The PALMERA study was approved by the research ethics committee of the University of Granada, Granada, Spain. The patients' participation was voluntary and all of the patients provided their informed consent.

Statistical analysis. The SPSS statistical package for Windows (version 15.0; SPSS, Chicago, IL), R (version 2.10, the R Foundation for Statistical Computing) and Epidat (version 3.1; Dirección Xeral de Saúde Pública de la Consellería de Sanidade, Xunta de Galicia, Santiago de Compostela, Spain) were used to analyze the data. To summarize the quantitative variables, the mean and s.d. were used. For the qualitative variables, frequencies and percentages were used. Patients in the following situations were excluded from the analysis: (i) they did not have

CPBP or POBP measurements taken at least three visits, and (ii) they monitored HBP for <4 days or provided fewer than 12 valid HBP measurements in the last 3 days of HBPM.

The Lin correlation-concordance coefficient (CCC)^{20,21} was used to evaluate the quantitative agreement between the BP measurements determined by each method. Fleiss *et al.*²² proposed the following CCC limits that were used for agreement interpretation: very good (CCC >0.9), acceptable (0.71 ≤ CCC ≤ 0.9), moderate (0.51 ≤ CCC ≤ 0.7), poor (0.31 ≤ CCC ≤ 0.5) or no agreement (CCC <0.31). The qualitative agreement between the BP measurements methods that were used to establish the patient's hypertensive state (controlled or uncontrolled) was evaluated using the κ -coefficient.²³ As a function of the κ value, the agreement was determined as follows:²⁴ very good (0.8 ≤ κ ≤ 1), acceptable (0.61 ≤ κ ≤ 0.8), moderate (0.41 ≤ κ ≤ 0.6), weak (0.21 ≤ κ ≤ 0.4), poor (0 ≤ κ ≤ 0.2) or no agreement (κ < 0). CPBP control was defined as SBP <140 mm Hg and DBP <90 mm Hg.

Community pharmacy-masked hypertension was defined as a CPBP (SBP/DBP) <140/90 mm Hg in the presence of HBP ≥135 and/or 85 mm Hg; whereas community pharmacy-white coat hypertension was defined as CPBP ≥ 140 and/or 90 mm Hg in the presence of a normal HBP (<135/85 mm Hg). Physician's office-masked hypertension was defined as a POBP (SBP/DBP) <140/90 mm Hg in the presence of HBP ≥135 and/or 85 mm Hg; whereas physician's office-white coat hypertension was defined as POBP ≥ 140 and/or 90 mm Hg in the presence of a normal HBP (<135/85 mm Hg). Using HBPM as the reference method, the sensitivity, specificity, positive and negative predictive values and positive and negative likelihood ratios of the CPBP and POBP measurement methods were calculated. The test was considered to be positive when SBP, DBP or both were ≥140/90 mm Hg for CPBP or POBP and ≥135/85 mm Hg for HBP. The 95% confidence intervals (CIs) were obtained, and a value of $P < 0.05$ was considered to be statistically significant.

RESULTS

The PALMERA study was offered to 117 treated hypertensive patients. A total of 21 patients declined to participate, and 20 were excluded due to physical or mental impairment ($n = 11$), an inability to perform HBPM technique ($n = 9$). Additionally, three patients died, two abandoned the study, and one suffered a cardiovascular disease during the study (before completion). Consequently, the final study sample included 70 patients. The mean age of the participants was 61.8 (s.d.: 12.4) years, 44.3% of the patients were females, and 94.3% were using one or two antihypertensive drugs. The general characteristics of the subjects and the mean BP obtained by each method are shown in **Table 1**. Scatter plots of CPBP versus HBP and POBP are shown in **Figure 1**.

Quantitative agreement

The CCCs revealed an acceptable-moderate agreement between the CPBP and HBP measurement methods (0.79 (95% CI: 0.68–0.86) for SBP and 0.66 (95% CI: 0.51–0.77) for

Table 1 | General characteristics of the sample (n = 70).

Age, mean (s.d.)	61.8 (12.4)
Female, n (%)	31 (44.3)
Body mass index	
Normal weight, n (%)	8 (11.4)
Overweight, n (%)	35 (50.0)
Obese, n (%)	27 (38.6)
Smokers, n (%)	19 (27.1)
Dyslipidemia, n (%)	35 (50.0)
Diabetes, n (%)	15 (21.4)
History of CVD (>6 months), n (%)	17 (24.3)
Antihypertensive drugs	
One drug, n (%)	33 (47.1)
Two drugs, n (%)	33 (47.1)
Three drugs, n (%)	3 (2.7)
Four drugs, n (%)	1 (0.9)
Community pharmacy BP	
SBP, mean (s.d.)	128 (14.8)
DBP, mean (s.d.)	77 (8.8)
HR, mean (s.d.)	72 (10.3)
Home BP	
SBP, mean (s.d.)	127 (15.4)
DBP, mean (s.d.)	78 (9.2)
HR, mean (s.d.)	72 (9.8)
Physician office BP	
SBP, mean (s.d.)	139 (15.5)
DBP, mean (s.d.)	81 (8.4)
HR, mean (s.d.)	74 (9.6)

BP, blood pressure; CVD, cardiovascular disease; DBP, diastolic BP; HR, heart rate; SBP, systolic BP.

DBP), a moderate agreement between the CPBP and POBP measurement methods (0.57 (95% CI: 0.43–0.69) for SBP and 0.61 (95% CI: 0.45–0.73) for DBP) and a moderate-poor agreement between the HBP and POBP measurement methods (0.56 (95% CI: 0.42–0.68) for SBP and 0.49 (95% CI: 0.30–0.64) for DBP).

Qualitative agreement

The CPBP and HBP measurement methods classified 56 patients in the same manner (80.0%) (**Table 2**). The κ -coefficient revealed a moderate agreement: 0.56 (95% CI: 0.46–0.66; $P < 0.001$). The prevalence of masked hypertension and white coat hypertension in the community pharmacy were 15.7% (95% CI: 8.1–26.4) and 4.3% (95% CI: 0.8–12.0), respectively. Using HBP as the reference method, the sensitivity and specificity of the CPBP measurement method were 60.7% (95% CI: 40.9–80.6) and 92.9% (95% CI: 83.9–100.0), respectively (**Table 3**).

The agreement between the POBP and HBP measurement methods is shown in **Table 4**. Forty-four subjects were

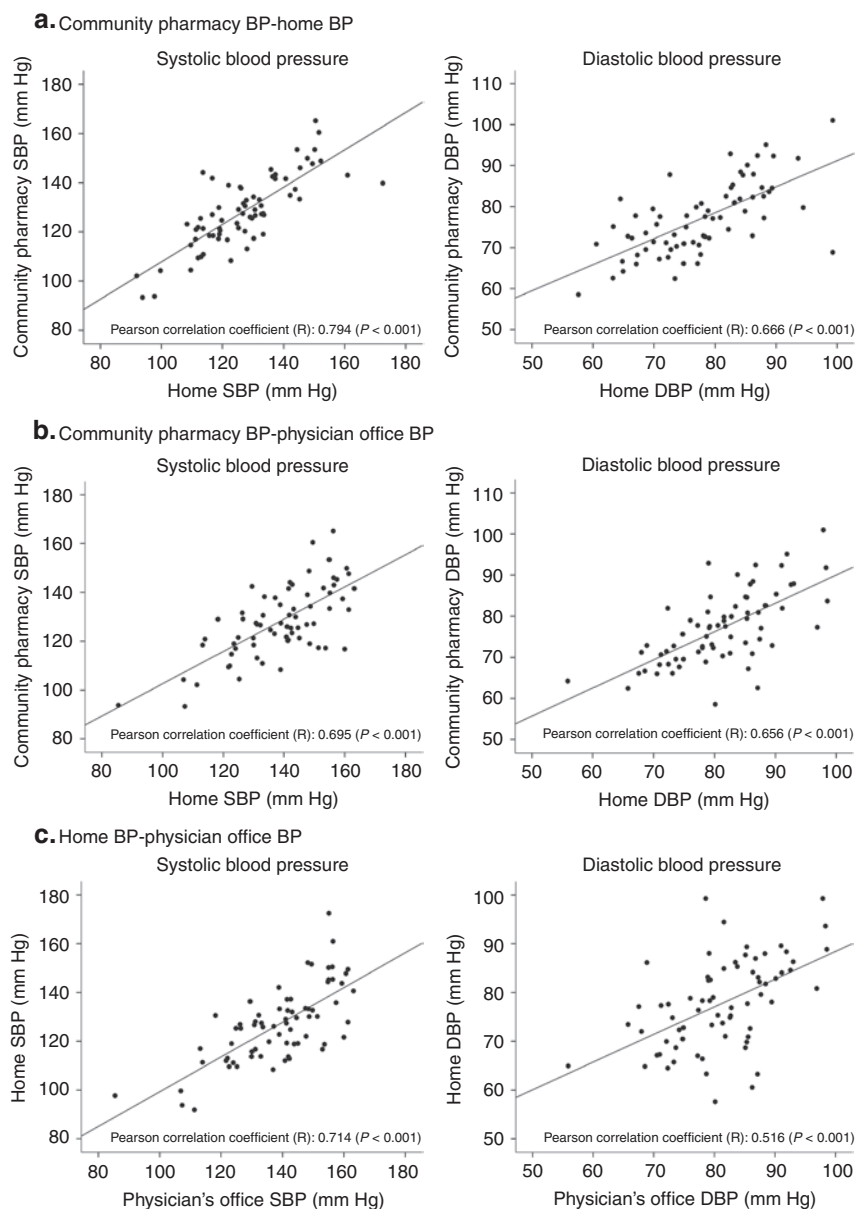


Figure 1 | Scatter plots of community pharmacy blood pressure versus home blood pressure and physician's office blood pressure with regression lines. BP, blood pressure; DBP, diastolic BP; SBP, systolic BP.

classified in the same manner (62.9%), and the κ -coefficient revealed a weak agreement between methods: 0.28 (95% CI: 0.17–0.38; $P = 0.014$). Using HBPM as the reference method, the prevalence of masked hypertension and white coat hypertension in the physician's office were 10.0% (95% CI: 4.1–19.5) and 27.1% (95% CI: 17.2–39.1), respectively. The sensitivity and specificity of the POBP measurement method were 75.0% (95% CI: 57.2–98.8) and 54.8% (95% CI: 38.5–71.0), respectively (Table 3).

The agreement between the CPBP and POBP measurement methods is shown in Table 5. Forty-six subjects were classified in the same manner (65.7%), and the κ -coefficient revealed a weak agreement between methods: 0.35 (95% CI: 0.26–0.45; $P < 0.001$).

The CPBP measurement method was more reliable than the POBP measurement method for detecting the presence of both uncontrolled (positive likelihood ratio of 8.5 and 1.7, respectively) and controlled BP (negative likelihood ratios of 0.4 and 0.5, respectively) (Table 3).

DISCUSSION

The PALMERA study presents original results, as it is the first study to assess the agreement between community pharmacy, home and physician's office BP measurement methods in treated hypertensive patients. In summary, the agreement between CPBP and HBP was acceptable-moderate and greater than the agreement between the HBPM and POBP measurement methods. Moreover, the CPBP measurement method

was very reliable to confirm the presence of uncontrolled HBP, but not to confirm the presence of controlled HBP.

In our opinion, the lack of the WCE in the community pharmacy^{9,10} could be the main factor explaining the acceptable-moderate agreement between the CPBP and HBP measurement methods. Although the results of this study cannot prove that the CPBP measurement method can replace HBPM in assessing the degree of BP control in patients with antihypertensive treatment (for which the agreement should be at least acceptable), we believe that future studies should further investigate in this direction. Future studies should overcome the weaknesses of this study by incorporating a larger sample size. In addition, CPBP measurements should be collected following a similar procedure to HBPM (i.e., from 8 to 10 visits, half in the morning and half in the evening). Thus, the agreement between methods in each period could be evaluated separately.

The PALMERA study results show that the CPBP measurement method was very reliable to confirm the presence of uncontrolled HBP (high specificity and positive predictive value with few false positives). Therefore, patients with uncontrolled CPBP should be referred to the physician because they may require adjustments in their antihypertensive therapy. However, the CPBP measurement method was unreliable for detecting the presence of controlled HBP (low sensitivity and negative predictive value, many false negatives). In this situation, it is recommended that all patients with controlled CPBP should carry out HBPM to avoid inappropriate treatments for

hypertension. Likelihood ratios (positive and negative) measured in the PALMERA study showed that CPBP measurement method was more reliable than the POBP measurement method to assess the degree of BP control in treated hypertensive patients (evaluation of treatment effectiveness). This situation may be due to the reduced WCE in the community pharmacy.^{9,10}

The prevalence of white coat hypertension in treated hypertensive patients in the community pharmacy was low (4.3%) and could be explained by the high specificity of the CPBP

Table 2 | Agreement between community pharmacy BP measurement method and home BP monitoring to classify patients according to their BP control

		HBPM		
		≥135 and/or ≥85 mm Hg (test +)	<135 and <85 mm Hg (test -)	Total
CPBP measurement method	≥140 and/or ≥90 mm Hg (test +)	17 (24.3%)	3 (4.3%)	20 (28.6%)
	<140 and <90 mm Hg (test -)	11 (15.7%)	39 (55.7%)	50 (61.4%)
Total		28 (40.0%)	42 (60.0%)	70 (100.0%)

Simple agreement: 80.0%; κ-coefficient: 0.56 (95% CI: 0.46–0.66; P < 0.001). BP, blood pressure; CI, confidence interval; CPBP, community pharmacy blood pressure; HBPM, home blood pressure monitoring.

Table 3 | Sensitivity, specificity, positive and negative predictive values of community pharmacy and physician office blood pressure measurements methods

	Sensitivity (%)	CI95%	Specificity (%)	CI95%	PPV	CI95%	NPV	CI95%	PLR	CI95%	NLR	CI95%
CPBP ^a	60.7	40.9–80.6	92.9	83.9–100.0	85.0	66.9–100.0	78.0	65.5–90.5	8.5	2.7–26.3	0.4	0.3–0.7
POBP ^a	75.0	57.2–98.8	54.8	38.5–71.0	52.5	35.8–69.2	76.7	59.9–93.5	1.7	1.1–2.5	0.5	0.2–0.9

^aHome blood pressure monitoring as reference method. CPBP, community pharmacy blood pressure; NLR, negative likelihood ratio; NPV, negative predictive value; PLR, positive likelihood ratio; POBP, physician's office blood pressure; PPV, positive predictive value.

Table 4 | Agreement between physician office BP measurement method and home BP monitoring to classify patients according to their BP control

		HBPM		
		≥135 and/or ≥85 mm Hg (test +)	<135 and <85 mm Hg (test -)	Total
POBP measurement method	≥140 and/or ≥90 mm Hg (test +)	21 (30.0%)	19 (27.1%)	40 (57.1%)
	<140 and <90 mm Hg (test -)	7 (10.0%)	23 (32.9%)	30 (42.9%)
Total		28 (40%)	42 (60%)	70 (100.0%)

Simple agreement: 62.9%; κ-coefficient: 0.28 (95% CI: 0.17–0.38; P = 0.014). BP, blood pressure; CI, confidence interval; HBPM, home BP monitoring; POBP, physician's office BP.

Table 5 | Agreement between community pharmacy BP and physician's office BP measurement methods to classify patients according to their BP control

		CPBP measurement method		
		≥140 and/or ≥90 mm Hg (test +)	<140 and <90 mm Hg (test -)	Total
POBP measurement method	≥140 and/or ≥90 mm Hg (test +)	18 (25.7%)	22 (31.4%)	40 (57.1%)
	<140 and <90 mm Hg (test -)	2 (2.9%)	28 (40.0%)	30 (42.9%)
Total		20 (28.6%)	50 (71.4%)	70 (100.0%)

Simple agreement: 65.7%; κ-coefficient: 0.35 (95% CI: 0.26–0.45; P < 0.001). BP, blood pressure; CI, confidence interval; CPBP, community pharmacy blood pressure; POBP, physician's office blood pressure.

measurement method. Meanwhile, the low sensitivity of the CPBP measurement method increased the prevalence of masked hypertension (15.7%). These results are consistent with the results shown in the study by Botomino *et al.*,²⁵ which is the only study that provides these data (using the ambulatory BP monitoring as a reference method) in the community pharmacy (the prevalence of white coat hypertension and masked hypertension were 4.5% and 22.7%, respectively). Another important finding of this study was that subjects with white coat or masked hypertension in the community pharmacy were not the same as in the physician's office (the agreement between methods was weak: κ -coefficient: 0.35). Therefore, it is possible that the relationship of the community pharmacy-white coat or -masked hypertension with target organ damage and/or cardiovascular risk could be different from the already established relationship for the white coat and masked hypertension in the clinical setting (generally, the risk shows the following trend: normotensive < white coat hypertension << masked hypertension = sustained hypertension).^{2,26} In our opinion, future studies should measure CPBP, ambulatory BP, HBP, and indicators of target organ damage or cardiovascular risk together.

In addition to the limitations mentioned above (small sample size and CPBP measurement schedule), it should be noted that the PALMERA study results are limited to a specific sample of treated hypertensive patients. Future studies should include patients who are not undergoing treatment or do not have hypertension as comparison groups. Caution should be exercised in interpreting these results more broadly as the CPBP measurements were measured by the same pharmacist. This is distinct to a patient measuring his/her BP in the community pharmacy without pharmacist supervision, which is, using self-attended BP monitors. Also different pharmacists or pharmacy technicians may impact on the results. Finally, although the terms "masked hypertension" and "white-coat hypertension" have been used in previous studies with treated hypertensive patients,²⁷⁻³⁴ we recognize that we have applied these definitions in a manner that is not entirely accepted, since it is not clear whether these terms should be used only for untreated patients. On the other hand, we have used the term WCE, which refers to the isolated increase in BP caused by the alerting reaction of a patient in the presence of a health care professional or in an unfamiliar environment. Thus, it is important to mention that white-coat hypertension and WCE are different entities, as the WCE is generally defined as the difference (expressed in mm Hg) between POBP (or CPBP) and HBP or daytime ambulatory BP.^{1,9,10}

In conclusion, in this sample of treated hypertensive patients, the agreement between the CPBP and HBP measurement methods was acceptable-moderate and was greater than other agreements between methods. The CPBP measurement method was very reliable to confirm the presence of uncontrolled HBP because of its high specificity and positive predictive value. Thus, the prevalence of white coat hypertension in the community pharmacy was low. However, due to its low sensitivity and negative predictive value, the

CPBP measurement method was not enough reliable to confirm the presence of controlled HBP, thus resulting in a high prevalence of masked hypertension. Finally, the CPBP measurement method was superior to the POBP measurement method for detecting the presence of both uncontrolled and controlled HBP.

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