Magnitude of the White-Coat Effect in the Community Pharmacy Setting: The MEPAFAR Study

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BACKGROUND
There is little information regarding the community pharmacy blood pressure (CPBP) measurement method and their differences with home (HBP) or ambulatory BP (ABP). The aim of this study was to measure such differences and their variation over successive visits.

METHOD
Cross-sectional study carried out in eight pharmacies in Gran Canaria (Spain). The study included 169 treated hypertensive patients. BP was measured at the pharmacy (four visits), at HBP (4 days) and 24-h ABP monitoring. We defined pharmacy white-coat effect (PWCE) as differences between CPBP and HBP (home PWCE) or daytime ABP (ambulatory PWCE).

RESULTS
The overall (pooled values for all visits) ambulatory PWCE was not significantly different from zero for systolic BP (SBP) (−0.4 mm Hg (95% confidence interval (CI): −1.8 to 1.1)), but greater than zero for diastolic BP (DBP) (3.4 mm Hg (95% CI: 2.3 to 4.6)). The overall home PWCE was not significantly different from zero, both for SBP (1.2 mm Hg (95% CI: −0.1 to 2.6)) and DBP (0.1 mm Hg (95% CI: −0.7 to 1.0)). The ambulatory and home PWCE on the first visit were greater than zero ($P < 0.001$) (SBP/DBP): 3.5/4.8 and 1.9/1.5 mm Hg, respectively; but showed important reductions at the second visit and became not significantly different from zero, except the ambulatory PWCE in DBP, which persisted until the last visit.

CONCLUSION
The trend in the PWCE decreased over the successive visits to the pharmacy. Only the ambulatory PWCE in DBP proved to be statistically greater than zero after the second visit. Repeated CPBP measurements could be a useful alternative to assess the response to antihypertensive treatment.

Keywords: *blood pressure; blood pressure determination; blood pressure monitoring; community pharmacy services; hypertension; pharmacy; white-coat effect*

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The white-coat effect (WCE) is the alerting reaction experienced by patients when the blood pressure (BP) is measured by a health professional and/or in a nonfamiliar environment. Thus, the WCE is manifested by an isolated increase in BP which can lead to inappropriate clinical evaluations and decision-making (e.g., overdiagnosis, underestimate of effectiveness, use of unnecessary medication, etc.).[1,2] Moreover, this situation can result in an increase in the risk of undesired effects of the medication and/or an increase in the health-care expense.[1] Consequently, it is important to acknowledge the WCE and assess/measure its impact on clinical evaluations.

To avoid the possible consequences of the WCE, the best solution is to use BP measurement methods that are applied outside a clinical setting, such as home (HBP) or ambulatory BP (ABP) monitoring (ABPM).[1,3] When these methods are unavailable or cannot be used, multiple BP measurements obtained by other health-care professionals different from the physician (e.g., nursing staff) or by the patient him/herself are suggested in order to reduce the WCE and its associated complications.[4,5] Nonetheless, applying these solutions do not eliminate the WCE altogether and the problems mentioned above may persist.[5]

An alternative solution to address this issue could be the measurement of BP in the community pharmacy setting. The community pharmacy setting provides an environment which is more familiar for the patient and a possibility for interaction with a health-care professional who is considered more approachable.[6] However, the information on the BP measurement method in the community pharmacy is sparse[7] and only one study has reported analyzing the WCE in the community pharmacy environment.[8] In order to generate further knowledge in this area and other aspects related to the community pharmacy BP (CPBP) measurement method, the study on the clinical usefulness of the CPBP measurement (MEPAFAR study) has been carried out. Specifically, the aim of this work

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was to measure the overall community pharmacy WCE (PWCE) (differences with respect to HBP or ABP) in treated hypertensive patients. Moreover, we described the evolution (variation) of the PWCE during multiple visits at the community pharmacy.

METHODS

The MEPAFAR study was a cross-sectional study including eight community pharmacies from Gran Canaria (Spain) and conducted between June 2008 and June 2009. The study included treated hypertensive patients older than 18. Those 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 home BP measurement (HBPM), changes in the antihypertensive treatment schedule during the previous 4 weeks, history of cardiovascular disease in the previous <6 months, or pregnancy.

Sample size and patient recruitment. The sample size was calculated using Epidat version 3.1. and was based on the differences between community pharmacy SBP and daytime ambulatory SBP (comparisons for paired samples) reported in a previous study carried out in the community pharmacy setting.[8] Specifically, the data to calculate the sample size were: s.d. of community pharmacy SBP (19.0), s.d. of daytime ambulatory SBP (10.0), mean difference between SBP measurements (4.6), confidence level (95%), and power (80%). Thus, the estimated sample size was 171 patients. in addition, we added 20% to compensate possible incomplete data sets from patients who could withdraw or fail to complete the study (final sample size: 205 patients; 26 patients per community pharmacy). In each community pharmacy, patients were identified and consecutively recruited during the medication dispensing process.

BP measurement methods. The CPBP was measured by the same pharmacist at each pharmacy. A clinically validated OMRON M10-IT (Omron, Tokyo, Japan) automatic electronic device was used,[9–11] with a cuff adaptable to large (32–42 cm), medium (23–31 cm) and small (17–22 cm) arm perimeters. The CPBP was obtained on four different visits to the pharmacy (**Figure 1**) and at each visit triplicate measurements were taken (2 or 3 min apart) on the control arm (arm on which the CPBP was higher on the first visit). Visits 2–4 of each patient were scheduled at the same time as their first visit (± 1 h). All the pharmacists were previously instructed on how to perform BP measurements properly according to international published guidelines.[12] Generally, CPBP measurements were taken after 5 min of sitting/rest and the patient had assured the pharmacist that they had not consumed coffee or tea, smoked or exercised in the 30 min prior to the measurement. The mean CPBP at each visit was calculated using the last two measurements; the mean CPBP for all the visits was calculated using the mean BP values from the four visits. CPBP control was defined as SBP <140 and DBP <90 mm Hg.

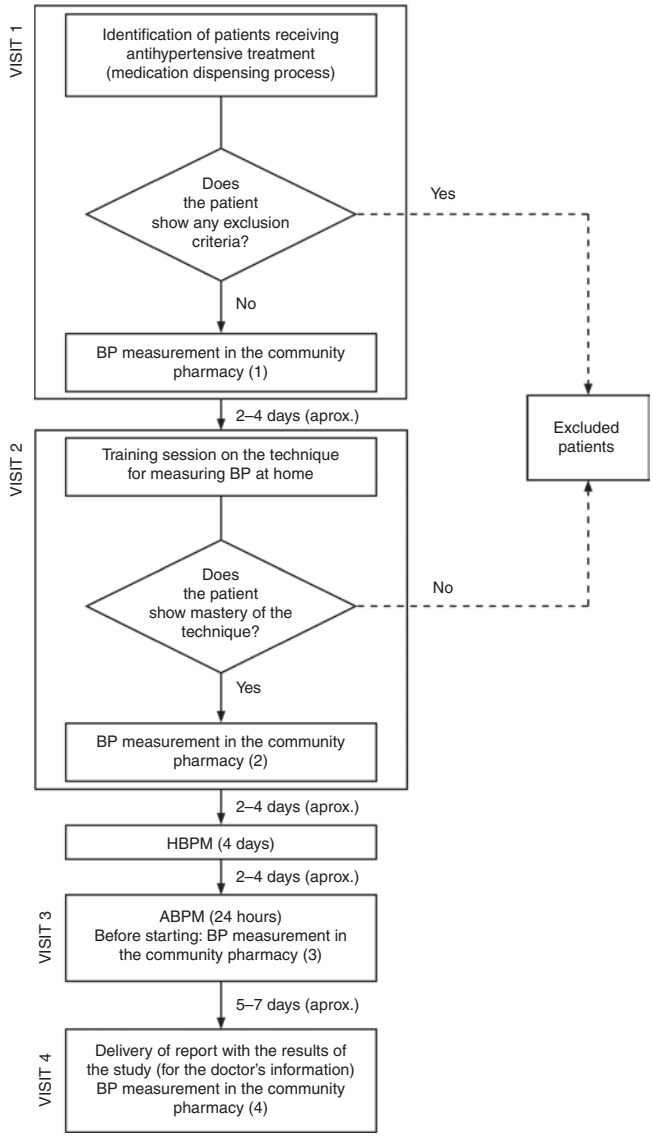

Figure 1 | General procedure of the study. ABPM, ambulatory blood pressure monitoring; BP, blood pressure; HBPM, home blood pressure measurement.

At home, the same device as at the pharmacy was used. All the patients were instructed on the HBPM technique[13,14] at a 20-min training session by their pharmacist. At the end of the session, the HBPM technique was tested by three consecutive self-measurements made in the presence of the pharmacist. Patients were also provided written guidelines to reinforce the training provided. Patients monitored their HBPM over a 4 day period, taking three measurements in the morning (each measurement 2 min apart, between 6:00 AM and 9:00 AM) and three in the evening (between 6:00 PM and 9:00 PM). The HBP readings were stored in the device's memory. The mean HBP was calculated discarding values obtained on the first day and the first measurement obtained each morning and each evening.

The ABPM was always performed on a working day (24 h), using the nondominant arm. The clinically validated Spacelabs Medical 90207-5Q monitor (Spacelabs, Redmond, WA) was used.[15] The recorders were programmed to measure BP at

20 min intervals between 7:00 AM and 10:00 PM, and at 30 min intervals between 10:00 PM and 7:00 AM. Patients were instructed to follow their usual daily activities (avoiding vigorous exercise) but to remain still with the forearm extended during each reading. Furthermore, they were asked to keep a record specifying the time when they went to bed and woke up. Patients used their prescribed antihypertensive medications during ABPM. A large cuff was used if the arm perimeter was between 32 and 42 cm, or a medium cuff if it was between 23 and 31 cm. The average BP of the daytime period was used, which was calculated according to the record kept by each patient.

The community PWCE was defined in two ways: differences between the CPBP and daytime ABP (ambulatory PWCE)[16] and differences between the CPBP and the HBP (home PWCE);[17] a positive PWCE value represents a higher CPBP compared to daytime ABP or HBP. The magnitude of the ambulatory and home PWCE were calculated for each visit to the pharmacy and for all of them as a whole (overall ambulatory or home PWCE). Additionally, to characterize the study population, the following variables were collected by the pharmacists: age, gender, heart rate (community pharmacy, daytime, home), smoking status, body mass index, number of antihypertensive drugs, history of previous cardiovascular disease (cerebrovascular disease, myocardial infarction, angina, and peripheral artery disease), presence of diabetes or dyslipidemia (documented diagnosis or previously prescribed drug treatment).

The MEPAFAR study was approved by the Research Ethics Committee at the University of Granada (Spain). The patients' participation was voluntary and informed consent was obtained from all participants. To process and manage the patient information, the online resources of the Spanish Society of Hypertension ABPM registry (CARDIORISC-MAPAPRES project) were used.[18] The general procedure of the study is reflected in **Figure 1**.

Statistical analysis. The SPSS statistical package for Windows version 15.0 (SPSS, Chicago, IL) was used to store and analyze the data. To summarize the quantitative variables the mean and s.d. were used, and for qualitative variables, frequencies and percentages were used. Patients in the following situations were excluded from the analysis: (i) they did not have all the CPBP measurements (four visits), (ii) the ABPM lasted <24 h or provided <75% of the scheduled readings during that period, (iii) they monitored HBP for <4 days or provided <12 valid HBP in the last 3 days of the HBPM. The differences between CPBP and HBP or ABP were assessed by paired *t*-tests: student *t* test for paired samples and repeated measures of ANOVA, applying the Bonferroni correction. To compare the magnitude of the PWCE between different strata of the sample (patients with controlled/uncontrolled CPBP) the student *t* test for independent samples was used. The 95% CIs were obtained and a value of $P < 0.05$ was considered statistically significant.

RESULTS

The MEPAFAR study was offered to 213 individuals. A total of 22 patients were excluded due to the following reasons: atrial fibrillation (five patients), changes in the antihypertensive treatment in the previous 4 weeks (one patient), SBP >200 mm Hg at the initial visit to the pharmacy (one patient), arm circumference >42 cm (one patient), unable to perform HBPM technique (14 patients). Additionally, eight patients left the study before completion, and the data for other 14 patients were eliminated because of lacking the aforementioned quality criteria. The final study sample was made up of 169 patients (59.8% women), with an average age of 56.4 (s.d.: 10.6) years. The general characteristics of the subjects are shown in **Table 1**. The average time taken by each patient to obtain the four CPBP measurements was 21.1 (s.d.: 7.7) days (90 percentile: 32 days). **Table 2** shows mean values of BP obtained at different settings during this study.

Magnitude of the overall ambulatory and home PWCE

The overall (pooled values for all visits) ambulatory PWCE in SBP was not significantly different from zero: −0.4 (s.d.: 9.8) mm Hg (95% condfidence interval (CI): −1.8 to 1.1).

Table 1 | General characteristics of the sample (*n* = 169)

General characteristics	
Age, mean (s.d.)	56.4 (10.6)
Female, *n* (%)	101 (59.8)
Body mass index, n (%)	
Normal weight	14 (8.3)
Overweight	70 (41.4)
Obese	85 (50.3)
Smokers, *n* (%)	25 (14.8)
Dyslipidemia, *n* (%)	68 (40.2)
Diabetes, *n* (%)	33 (19.5)
History of CVD, *n* (%)	7 (4.1)
Antihypertensive drugs, n (%)	
One drug	78 (46.2)
Two drugs	56 (33.1)
Three drugs	25 (14.8)
Four drugs	10 (5.9)

CVD, cardiovascular disease.

Table 2 | Systolic blood pressure, diastolic blood pressure (mm Hg), and heart rate (beats/min) mean values in the community pharmacy, at home and by ABPM (24 h, daytime and nighttime)

	SBP, mean (s.d.)	DBP, mean (s.d.)	HR, mean (s.d.)
Community pharmacy	128.3 (14.7)	81.4 (9.5)	71.8 (11.5)
HBPM	127.1 (14.9)	81.3 (9.3)	70.4 (11.0)
Daytime ABPM	128.7 (13.0)	78.0 (10.1)	75.7 (11.8)
24 h ABPM	124.9 (12.6)	74.7 (9.5)	72.7 (11.1)
Nighttime ABPM	114.1 (13.8)	65.8 (9.6)	64.7 (10.9)

ABPM, ambulatory blood pressure monitoring; DBP, diastolic blood pressure; HBPM, home blood pressure measurement; HR, heart rate; SBP, systolic blood pressure.

Table 3 | Ambulatory and home pharmacy white-coat effect in patients with controlled and uncontrolled blood pressure at the pharmacy

	PWCE in SBP; mean (s.d.) (95% CI)			PWCE in DBP; mean (s.d.) (95% CI)		
	Ambulatory	Home	*P* value[a]	Ambulatory	Home	*P* value[a]
Uncontrolled CPBP (*n* = 49)	5.0 (10.4) (2.0 to 8.0)	3.7 (11.3) (0.4 to 6.9)	*P* = 0.441	6.3 (8.4) (3.9 to 8.7)	2.3 (6.9) (0.3 to 4.3)	*P* < 0.01
Controlled CPBP (*n* = 120)	−2.6 (8.7) (−4.1 to −1.0)	0.2 (7.8) (−1.1 to 1.6)	*P* < 0.01	2.8 (6.7) (1.0 to 3.5)	−0.7 (5.1) (−1.7 to 0.1)	*P* < 0.001
P value[b]	*P* < 0.001	*P* = 0.054		*P* < 0.01	*P* < 0.01	

CI, confidence interval; CPBP, community pharmacy blood pressure; DBP, diastolic blood pressure; PWCE, community pharmacy white-coat effect; SBP, systolic blood pressure.
[a]For the differences between ambulatory and home PWCE (*t* test for paired samples). [b]For the differences between the PWCE in patients with controlled and uncontrolled CPBP (*t* test for independent samples).

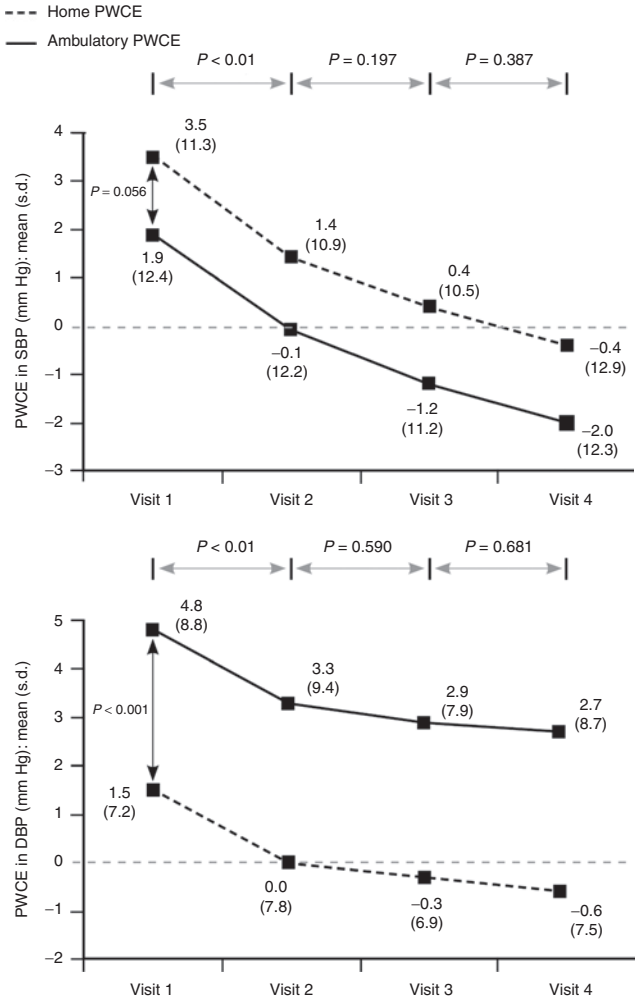

Figure 2 | Evolution of the community pharmacy white-coat effect during successive visits to the pharmacy. DBP, diastolic blood pressure; PWCE, community pharmacy white-coat effect; SBP, systolic blood pressure.

On the other hand, the ambulatory PWCE in DBP was statistically greater than zero: 3.4 (s.d.: 7.5) mm Hg (95% CI: 2.3–4.6). The home PWCE was also not significantly different from zero, both for SBP: 1.2 (s.d.: 9.0) mm Hg (95% CI: −0.1 to 2.6); and for DBP: 0.1 (s.d.: 5.8) mm Hg (95% CI: −0.7 to 1.0).

When the sample was stratified depending on CPBP control (values <140/90 mm Hg), it was observed that patients above those figures presented a statistically significant higher PWCE than patients with controlled CPBP (except the home PWCE in SBP) (Table 3). In patients with uncontrolled CPBP, both the ambulatory and the home PWCE were always positive and greater than zero, both in SBP and in DBP. On the other hand, in patients with controlled CPBP, the home PWCE (SBP and DBP) was not significantly different from zero, while the ambulatory PWCE in SBP was significant negative; only the ambulatory PWCE in DBP showed to be statistically greater than zero.

Evolution of the PWCE during the 4 pharmacy visits

Both the ambulatory PWCE and the home PWCE showed a decreasing trend during successive visits to the community pharmacy. Between the first and the fourth visit, the PWCE shown a reduction of 3.9 (s.d.: 11.9) mm Hg in SBP ($P < 0.001$) and 2.1 (s.d.: 7.2) mm Hg in DBP ($P < 0.001$). On the first visit, both the ambulatory and the home PWCE (SBP/DBP) were statistically greater than zero ($P < 0.001$): 3.5 (s.d.: 11.3)/4.8 (s.d.: 8.8) mm Hg and 1.9 (s.d.: 12.4)/1.5 (s.d.: 7.2) mm Hg, respectively (Figure 2). Between the first and second visit, the PWCE showed a statistically significant reduction of −2.0 (s.d.: 10.1) mm Hg (95% CI: 0.5–3.6) in SBP and −1.6 (s.d.: 6.9) mm Hg (95% CI: 0.5–2.6) in DBP. It is important to note that the ambulatory PWCE in SBP and the home PWCE in both SBP and DBP became significantly different from zero the second visit: the 95% CI obtained for the differences between CPBP and daytime ABP or HBP included the value zero. Only the ambulatory PWCE in DBP proved to be positive and statistically greater than zero during all visits.

DISCUSSION

The MEPAFAR study provides original information of a BP measurement method (community pharmacy) that is poorly studied,[7] but is commonly requested by patients[19] and firmly recommended by hypertension professional associations.[13,20] Therefore, it is important to generate evidence to clarify the clinical value of the CPBP measurement method. Specifically, this paper shows the overall magnitude of the PWCE in treated hypertensive patients and the decrease of this effect during successive visits to the community pharmacy. In brief, it was observed that the overall PWCE was not significantly different from zero and that the PWCE disappeared after the second visit to the pharmacy (except the ambulatory PWCE in DBP).

Regarding the magnitude of the PWCE in treated hypertensive patients, only one study was found in a previous review of the literature.[7] Botomino *et al.*[8] measured the magnitude of the PWCE in a group of 22 patients in one visit. The ambulatory PWCE was 12.8/6.8 mm Hg and the home PWCE was 11.5/8.4 mm Hg. In our sample, we have found these figures considerably lower, even considering only those obtained at the first visit. Differences can probably be explained on the basis of certain characteristics of the Botomino study: small sample size, observer's bias and digit preference (CPBP measurements were taken manually), use of the first CPBP measurement obtained at the visit (usually found to be higher) to calculate the mean CPBP (consequently, the PWCE could be overestimated). According to international recommendations,[21–23] to improve the evaluation of the patient's hypertensive status made by a BP measurement method, we discarded the first CPBP measurement taken at each pharmacy visit. Therefore, due to the reasons provided, in our opinion, the PWCE measured in the MEPAFAR study may be a better approach to the PWCE in treated hypertensive patients.

Magnitude of the PWCE in patients with controlled/uncontrolled CPBP

As previously observed in physician's offices,[24] patients with uncontrolled CPBP had a positive and higher PWCE than patients with controlled CPBP (**Table 3**). The main problem associated with this situation is that the positive PWCE in the first group of subjects may lead to unnecessary adjustments to treatment, particularly when their daytime ABP is normal and their cardiovascular risk is low or moderate.[25] For example, Ogebegbe *et al.*[26] observed a systolic WCE of 15.4 mm Hg in patients with uncontrolled clinic BP and controlled ABP (isolated clinic hypertension). It is possible that in many of these cases, changes in treatment might not bring any benefit, and could represent a risk for the patient.

Evolution of the PWCE during the four pharmacy visits

The PWCE clearly decreased over multiple visits to the community pharmacy.[27] In fact, PWCE became not significantly different from zero after the first visit to the pharmacy; only a small ambulatory PWCE in DBP persisted (**Figure 2**). In our opinion this is an essential and favorable finding to continue exploring whether the CPBP measurement method could be a good alternative to assess the response to therapy of or to make clinical decisions in treated hypertensive patients, especially when ABPM or HBPM are not available or cannot be used. Although further studies are required to increase the knowledge regarding the optimal number of visits and measurements, data from the present study suggest taking repeated measurements in at least three visits to the pharmacy (according to international guidelines)[25,28] and discard the data of the first visit.

It should be noted that the results from MEPAFAR study are limited to a specific sample of treated hypertensive patients. Other limitations include the lack of additional BP measurements taken by another health-care professional (physician or nurse). It is possible that the community pharmacy constitutes a more "familiar" or "approachable" setting for the patient,[6] where the patient alert reaction could be less than in the clinical environment. However, further research is needed to prove this hypothesis. In order to show an indication of the presumed lower PWCE, a number of studies have been found that measured the WCE in the clinical setting in treated hypertensive patients.[4,29–31] In brief, it is remarkable that in the clinical setting the disappearance of the WCE did not occur and thus the clinic BP measurement was always affected by an "unavoidable" WCE.[5,29,31]

An additional consideration is that of the PWCE's magnitude which may be affected by the provision of pharmaceutical care, the community pharmacy's business models, or other pharmacy characteristics.[32] However, these characteristics not only may differ between community pharmacies of different countries (e.g., in United States or the United Kingdom, community pharmacies are considered more commercial than in Spain) but also between pharmacies in the same country. Also, caution should also be exercised in interpreting the study results as the same pharmacist took the CPBP measurement in each. Different pharmacists or pharmacy technicians taking CPBP measurements in the same pharmacy may impact results.

It is necessary to point out that the definitions of the WCE used in this study are frequently used in research. However, they have been discussed. This is because the difference between the CPBP and the ABPM or HBPM can be affected by different factors other than the patient's alerting reaction in the pharmacy.[33,34] Some authors have proposed to measure the "real WCE" using methods that can record the beat-to-beat BP before, during, and after a physician visit.[35,36] However, this also presents its limitations, as the BP before the physician visit may be high (as a result of the clinical environment) and therefore the WCE may be underestimated.[5] For these reasons the differences between the CPBP (or clinic BP) and the ABPM or HBPM are accepted and frequently used to evaluate the severity, frequency, clinical relevance, or other matters related to the WCE.

In conclusion, the PWCE in this sample of treated hypertensive patients appeared only at the first visit to the pharmacy, and became not significantly different from zero in repeated visits. In fact, pooling the data from four consecutive visits to the community pharmacy, only ambulatory PWCE for DBP remained statistically greater than zero. These results suggest that repeated measurements of BP at the community pharmacy could be a suitable alternative to assess therapy response or to guide clinical decision making for treated hypertensive patients.

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