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Level of blood pressure control in a hypertensive population when measurements are performed outside the clinical setting

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Abstract

Background: *To determine whether the number of optimally controlled hypertensive patients is higher using self-measurement of blood pressure at home and ambulatory monitoring, compared to using conventional blood pressure measurements at the doctor's office.*

Method: *An observational, cross-sectional, multicentre, descriptive study of a random sample of 237 primary health care patients, known to be hypertensive, from Badajoz (Spain). Blood pressure was measured at the doctor's office and by self-measurement at home. Those patients showing good control by self-measurement were subjected to 24-hour ambulatory monitoring. Optimal control was understood as blood pressure < 140/90 mm Hg when measured at the doctor's office, and < 135/85 mm Hg when self-measured at home and by daytime ambulatory monitoring.*

Results: *Mean systolic/diastolic measurements at the doctor's office and by self-measurement were 145.6/83.9 and 134.0/78.7 mm Hg, respectively ($p<0.000$). In the population optimally controlled by self-measurement and who subsequently received ambulatory monitoring, the mean blood pressure was 121.8/73.4 and 125.6/76.2 mm Hg, respectively ($p = 0.002$; $p < 0.000$). When measured at the doctor's office blood pressure was controlled in about 29.5% (95% CI 23.7–35.3%) of patients, in 38% when self-measured (95% CI 31.4–44.2%; $p < 0.000$), and in 24.5% when it was confirmed through ambulatory monitoring (95% CI 15.4–33.6%). Sensitivity and positive predictive values of the office measurements for the detection of patients who were well-controlled by self-measurement were 50% and 64.3%, respectively, and 53.4% and 73.8% as regards ambulatory monitoring.*

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Conclusions: *A higher level of control is achieved with self-measurement at home not confirmed by ambulatory monitoring. Therefore, the white coat effect does not seem to influence the percentage of well-controlled patients detected at the doctor's office. Office blood pressure does not appear to be useful in distinguishing which individual patients are optimally controlled.*
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Key words: hypertension, ambulatory blood pressure, home blood pressure, blood pressure control, primary care

Introduction

Hypertension is the main risk factor for cardiovascular disease [1, 2], which is the primary cause of death worldwide [3]. Blood pressure (BP) measurement is a crucial aspect when it comes to making clinical decisions, and precise and accurate readings are needed. Even though all the epidemiological and intervention studies are performed using conventional blood pressure measurements (CBPM) at the doctor's office, this procedure is fraught with many errors and biases affecting its reproducibility and validity.

These CBPM limitations can be overcome by using other techniques such as ambulatory blood pressure monitoring (ABPM) and self blood pressure measurement (SBPM) at home [4]. These techniques use electronic devices, take more measurements, and are performed outside the clinical setting. The superiority of both techniques when compared to CBPM has been demonstrated through their better correlation with organ damage and their greater predictive capacity regarding the onset of diseases and cardiovascular mortality [5–8].

In population studies on the level of control there was a high degree of patient unawareness of hypertensive status, and poor level of control [9–12]. These results are slightly lower in Spain than in neighbouring countries [13, 14]. Most primary health care (PHC) studies are not very representative of the hypertensive population (consecutive patients recruited at a doctor's office), and different methods are used to measure variables (measurement techniques and values, timetables, instruments, etc.). This makes them more difficult to compare, but in Spain a significant trend towards better control levels has been observed in recent years [15, 16]. However, some authors believe that findings from such studies could be affected by the biases mentioned above as regards techniques, the white coat effect (WCE), or morning BP increase. These authors also consider that the percentage of optimally controlled patients could be higher [17–19]. We do not know if there are any studies showing the control degree of BP in a representative sample of a hypertensive population using SBPM or ABPM to control these biases.

Many hypertensive patients have white coat hypertension or WCE [20–23], and this could be the main cause for the lack of accuracy of CBPM, as well as the insufficient numbers of measurements. It has been suggested that SBPM avoids the WCE, but it does not have the necessary sensitivity and positive predictive value (PPV) to be used alone. Therefore, a confirmation of the effect, by means of ABPM, is highly recommended [4, 20, 23–26].

Our aim is to determine if the bias control of studies regarding control levels of BP, using measurements outside the clinical setting, could provide better and more reliable control levels among the hypertensive population. The protocol used for measurements outside the clinic was proposed for hypertension diagnosis and to start drug treatment in patients with high BP in consecutive visits [4, 24]. We have used it to have a specific diagnosis of good control outside the clinic, taking into account its high specificity and good negative predictive value in WCE detection [23, 25–39].

Methods

Design

Multicentre, observational, cross-sectional, descriptive study with a random sample of a hypertensive population.

Target population

Population known to be hypertensive, aged over 18 years, and treated at PHC clinics, from three basic health zones in Badajoz, Spain. The PHC service in this region covers a total of 87,953 inhabitants, including rural and urban populations.

Sample

The sample size necessary to estimate a difference of 36.5% versus 20% of controlled subjects was calculated. The statistical power was 80%, and the significance level was 95%. The resulting sample size was 232 subjects. This amount was increased to 300 to cover any possible dropouts. The total sample was divided into three sub-samples of 100 subjects for each of the three basic health zones. The cluster sampling technique was used and was proportional to the number of hypertensive patients registered at each health care unit from every health centre or local health facility. The individual patients were selected by systematic random sampling. The selected patients were phoned by their respective doctors and asked to go to the PHC clinic.

Inclusion criteria:

— patients over 18 years old treated at the participant PHC clinics;
— patients diagnosed with hypertesnion (JNC VII criteria) [31], such diagnosis and/or the administration of hypotensives being recorded in their medical record;
— stable treatment for hypertension (pharmacological or non-pharmacological) administered for at least 4 weeks before the start of study;
— having given informed consent to participate in the study.

Exclusion criteria:

— patients unable or unwilling to give their consent;
— heart rate alterations (atrial fibrillation) preventing BP from being measured by oscillometric methods;
— cognitive impairment or physical disabilities which, according to the family doctor and/or the investigators, prevented the patient from learning and/or carrying out the SBPM and ABPM techniques.

Study protocol

Data on family history of cardiovascular diseases or hypertension, personal history of cardiovascular disease (ischemic heart disease, cerebrovascular disease, peripheral vascular disease, and heart failure), smoking, diabetes (recorded in the medical record, or treatment with anti-diabetic oral drugs or insulin), alterations of glucose metabolism (diagnosis of glucose intolerance or altered basal glycemia recorded in medical record), hypercholesterolemia (recorded in the medical record or being pharmacologically treated with antihyperlipidemic drugs), and hypertension evolution time, in years, were recorded. Weight, height, abdominal perimeter, and office BP were measured using standard guidelines [4] (3 consecutive BP measurements were taken by the habitual doctor of every patient using a mercury sphygmomanometer, with a 2-min interval between them, recording the median value of the 2nd and 3rd measurements). The results of the recent biochemical analysis (last 3 months) after a 12-hour fasting period were noted. Such analysis included glycemia, ions, total cholesterol, HDL, LDL, and triglycerides. The presence of metabolic syndrome was defined according to the criteria from ATP III [27]; obesity by body mass index (BMI) ≥ 30; the white coat effect (WCE) as a poor control by CBPM and a good control by SBPM or ABPM, and a masked poor control with a good control by CBPM and poor control by SBPM or ABPM. Collection of all sample variables took place from September 2004 to November 2005.

The study was approved by the local bioethical committee and all patients gave their informed consent.

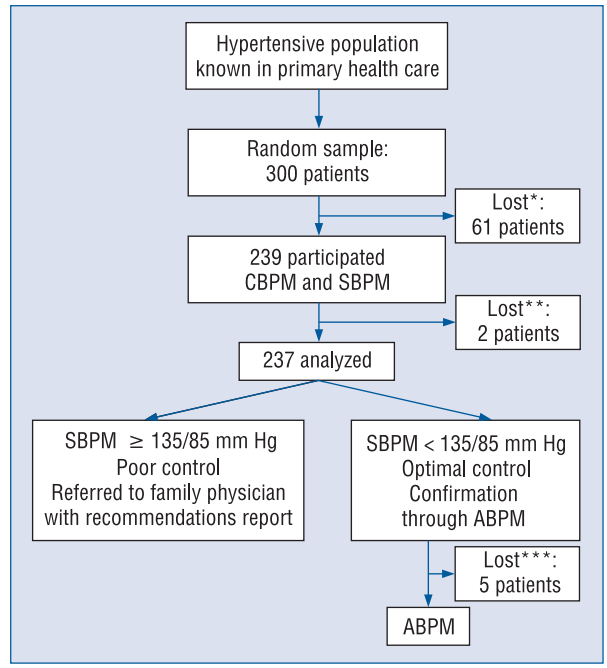

Figure 1. General scheme of the study; *no patients were recruited over the duration of the study; **violation of study protocol; ***refused, could not be found, or did not meet ambulatory blood pressure measurement (ABPM) quality criteria; CBPM — conventional blood pressure measurement; SBPM — self blood pressure measurement.

General study scheme (Fig. 1)

The participating patients were classified as poorly controlled if they had a BP equal or superior

to 140/90 mm Hg, and optimally controlled when their BP was lower, measured by CBPM. Subsequently, patients were asked to perform home self-measurements using an OMRON 705 CP monitor [28] by their regular doctors: two measurements in the morning and two at night, for three consecutive working days. Prior to this they received oral and written information on the ideal conditions for taking this type of measurement [4], and use of the monitor was demonstrated at the doctor's office. They were provided with a 12 cm × 26 cm cuff if they had an arm circumference of less than 33 cm and a 12 cm × 40 cm cuff, if their arm circumference was larger. Measurements were printed out by the monitoring device.

The self-measurements taken on the first day were ignored because of the alarm reaction to using the device [29], and the arithmetic mean of the other 8 measurements — corresponding to the 2nd and the 3rd day — were quantified. Patients whose mean BP was higher than or equal to 135/85 mm Hg were classified as poorly controlled and were withdrawn from the study. These patients were referred to their doctor for appropriate hypertension management.

Patients with a mean BP less than 135/85 mm Hg were classified as optimally controlled and were invited to continue in the study using 24-hour ABPM. This was performed using SpaceLabs 90207 monitors [30]. Good control was confirmed if they had a mean daytime BP of lower than 135/85 mm Hg. This criterion was established in order to avoid the high variability of night measurements and the different activity-resting periods among the participants [4, 24].

Statistical analysis

The results of the survey, complementary tests, and measurements were entered on an Access database and the SPSS 13.0 statistics program was applied. Quantitative variables were defined via the means and standard deviation. Qualitative variables were defined using percentages. BP means were compared using the Wilcoxon test (when the CBPM was included due to a non-normal distribution) and using the *t*-test with the other paired data. When dichotomous variables were compared to non-normal quantitative variables (number of antihypertensive drugs), the Mann-Whitney U test was used, and when such variables were normal, Student's *t*-test was used. Qualitative variables were assessed by means of χ^2. A crosstable was built in order to study the sensitivity, specificity, predictive values, and the odds ratio in the determination of the control level by means of CBPM and SBPM and between CBPM and ABPM. The level of concordance between the different methods was studied using the Kappa index.

Results

The study population characteristics are given in Table 1. The high mean age, the large proportion of women, and the high prevalence of obese patients and metabolic syndrome in women are noteworthy. Male patients received the highest mean number of drugs, and women the highest proportion of non-pharmacological measures, as single a treatment, with statistically significant differences.

The mean systolic and diastolic BP obtained using CBPM was 145.6 ± 15.9/83.9 ± 9.8 mm Hg (Fig. 2). Using this technique, 29.5% of the patients were controlled (95% confidence interval [CI]): 23.7–35.3%, with the level of control of the diastolic component being higher than the systolic (Fig. 3). There were no significant differences in the level of control as regards gender, age, BMI, metabolic syndrome, or number of drugs the patients were receiving (Table 2, 3).

Using SBPM, the systolic and diastolic BP were 140.0 ± 19.1/78.7 ± 9.9 mm Hg, which are significantly lower than those obtained using CBPM (Fig. 2). The means of the values obtained in the different days are given in Figure 4. The measurements obtained during the first day were not taken into account for the calculations of systolic and diastolic BP means, according to the general study scheme. The mean systolic BP decreased each day, and statistically significant differences among the means of the three days were found. The mean diastolic BP also decreased, and statistically significant differences were found between the first day and days 2 and 3. No differences were found between the last two days. Mean systolic BP from 2° and 3° day by the morning was 142.0 mm Hg (20.6; 139.4––144.7) and systolic BP in the evening was 137.9 (19.4; 135.4–140.4; p = 0.000). Diastolic BP by the morning was 79.9 mm Hg (10.4; 78.5–81.2) and in the evening 77.6 mm Hg (10.4; 76.2–78.9; p = 0.000). Control degree with SBPM obtained by the morning was 34.2% and in the evening 43.9% (p = 0.000) with a Kappa index of 0.587 (SE 0.005; p = 0.000).

About 38% of hypertensive patients were well-controlled using SBPM (95% CI 31.8–44.2%), 28.6% more than with CBPM (p < 0.000), with the level of control of the diastolic component being greater than that of the systolic component (Fig. 3).

Table 1. Study population characteristics.

	Total (n = 237)	Male (n = 92; 38.8%)	Female (n = 145; 61.2%)	Sig. level (p)
Mean age (years) 95% confidence interval	65.2 ± 10.5 63.9–66.6	63.7 ± 11.4 61.2–66.1	66.4 ± 9.8 64.8–68.0	0.020
Hypertension mean time (years) 95% confidence interval	9.1 ± 6.8 8.2–10.0	7.5 ± 5.2 6.4–8.6	10.2 ± 7.5 9.0–11.5	0.001
Active smoking (%)	13.9	20.9	9.7	0.016
Diabetes (%)	19.4	18.5	20	0.773
Other hydrocarbon alterations (IFG, IGT) (%)	14.3	12	15.9	0.403
Mean body mass index (BMI) 95% confidence interval	30.6 ± 4.6 30.01–31.19	30.0 ± 3,4 29.3–30.7	30.9 ± 5.1 30.1–31.8	0.112
Obesity (%) (BMI ≥ 30)	48.7	47.3	49.7	0.721
Mean cholesterol [mg/dL] 95% confidence interval	207.1 ± 34 202.8–211.5	202.6 ± 35.5 195.1–210.1	209.6 ± 31.9 204.3–215.0	0.053
Metabolic syndrome (%)	43.2	29.7	51.7	0.001
Associated cardiovascular disease (%)	17.3	20.7	15.2	0.277
Number of antihypertensive drugs (%)				
0 only LSM	19	12	23.4	0.028
1	51.9	51.1	52.4	
2	23.2	27.2	20.7	0.032
3 or more	5.9	9.8	3.5	

IFG — impaired fasting glycemia: basal glycemia in venous blood ranging from 110 to 125 mg/dL, both included; IGT — impaired glucose tolerance: oral glucose test tolerance after 2 h between 140 and 199 mg/dL, both included; LSM — life style modifications; p — sig. level t test or χ^2

The population who were poorly controlled using this method had a higher mean age and received, on average, a greater number of antihypertensive drugs (Table 3).

When SBPM was used, the prevalence of the white coat effect was 19%, and that of masked poor control was 10.5% (Table 4).

The optimally controlled BP using SBPM was confirmed by ABPM in 68.2% of the patients, with control of the diastolic component being better (as in the previous cases; Fig. 3), i.e. 24.5% (95% CI 15.4–33.6%) of the hypertensive patients from the initial sample. Systolic and diastolic BP means obtained were higher than the means obtained using SBPM (Table 5). No significant differences were observed between the two samples regarding gender, age, BMI, presence of metabolic syndrome, or mean quantity of drugs (Table 2, 3).

Pharmacological treatment with antihypertensive drugs showed its influence only in the control degree detected by SBPM, good control in 51.1% of patients with no pharmacological drugs and 34.9% of good control in drugs treated patients (p = 0.044). There were no differences with CBPM 28.9% *vs.* 29.7% (p = 0.916) and by ABPM 65% *vs.* 69.2% (p = 0.722), respectively.

CBPM sensitivity for the detection of well-controlled patients was about 50%, compared to SBPM, and had a PPV of 64.3%. Both the negative predictive value (NPV) and the specificity were higher (Table 4). These parameters are presented in Table 6, which compares the CBPM results with ABPM results. Figure 5 shows the proportion of every patient in each situation when using different techniques.

Discussion

It is essential to have valid, periodical estimates on the level of control of risk factors for the primary cause of death in order to assess the intermediate results of work being performed in the field of PHC cardiovascular prevention. In the case of hypertension, it is becoming increasingly evident that BP measurement methods carried out outside the clinical setting, despite being considered complementary to the measurements taken there [4, 31], are superior in stratifying risk [32–34], and recommendations for their use are becoming more widespread [35]. Studies to determine the level of control of the population treated at PHC clinics using these techniques [19] are scarce, and they have

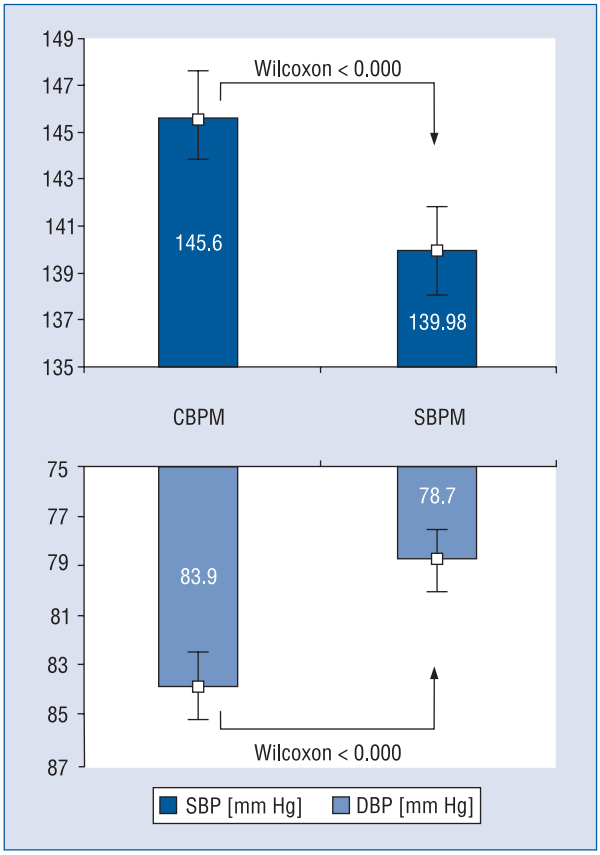

Figure 2. Blood pressure components (mean, SD, CI) by conventional blood pressure measurement (CBPM) and self blood pressure measurement (SBPM); SBP — systolic blood pressure; DBP — diastolic blood pressure; SBP and DBP by CBPM presented a non-normal distribution.

several biases, including selection biases (such as using consecutive patients) or information biases (use of SBPM for only one day or failure to take into account the sensitivity, specificity, and predictive value limitations of these techniques).

With CBPM, we obtained a lower level of BP control than that published in Spain by other authors [15, 16]. This finding could be due to the random selection of the sample, including patients who would not usually visit the doctor (probably with a lower level of control) and who are, therefore, less likely to be recruited for studies in consecutive patients. Using SBPM, the level of control increases to almost 40%, an increase of 28.6% over the well-controlled population by means of CBPM. This good control with SBPM is confirmed by ABPM in only a little over two thirds of patients, which means that the real level of control could decrease to 24.5%, even less than that obtained by CBPM, thus questioning the validity of SBPM.

Although in most studies the correlation between SBPM and ABPM is good, some differences are bound to exist due to the characteristics of each technique [37]: patients at rest in ideal conditions with SBPM versus patients performing everyday activities with no posture restrictions or mental or physical exercise restrictions, with ABPM. This explains the differences we found between the two methods as regards the mean values for systolic and diastolic BP (higher values were obtained with ABPM) and agrees with other studies, both population-

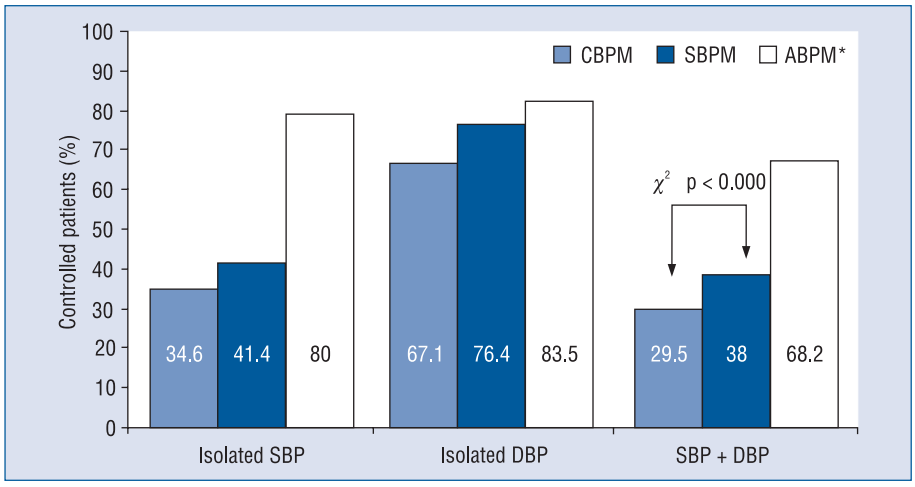

Figure 3. Control level of blood pressure according to systolic and diastolic components, and both, with all the different measurements techniques; *only those patients presenting a good control by means of self blood pressure measurement (SBPM) received ambulatory blood pressure measurement (ABPM); SBP — systolic blood pressure; DBP — diastolic blood pressure; CBPM — conventional blood pressure measurement.

Table 2. Characteristics of the population regarding the level of control (qualitative variables) (χ^2 test).

	Sex			Diabetes			Metabolic syndrome		
	M	F	p	Yes	No	p	Yes	No	p
CBPM % control*	33.7	26.9	0.267	32.6	28.8	0.611	28.4	30.6	0.718
SBPM % control**	35.9	39.3	0.595	32.6	39.3	0.404	35.3	40.3	0.433
ABPMd % control**	73.6	59.4	0.173	73.3	67.1	0.640	75.0	64.2	0.298

M — male; F — female; *blood pressure control if < 140/90 mm Hg; **blood pressure control if < 135/85 mm Hg; CBPM — conventional blood pressure measurement; SBPM — self blood pressure measurement; ABPMd — ambulatory blood pressure monitoring daytime

Table 3. Characteristics of the population regarding the level of control (quantitative variables).

	Average age (years)			Mean BMI			Average no. drugs		
	OC	PC	p†	OC	PC	p†	OC	PC	p#
CBPM*	64.47	65.57	0.468	30.34	30.71	0.568	1.14	1.17	0.812
SBPM**	62.23	67.09	0.001	30.37	30.74	0.540	1.02	1.25	0.032
ABPMd**	62.88	59.67	0.173	30.65	29.25	0.224	1.03	1.11	0.625

*blood pressure control if < 140/90 mm Hg; **blood pressure control if < 135/85 mm Hg; †Student's t-test; #Mann-Whitney U test; OC — optimally controlled; PC — poorly controlled; BMI — body mass index; CBPM — conventional blood pressure measurement; SBPM — self blood pressure measurement; ABPMd — ambulatory blood pressure monitoring daytime

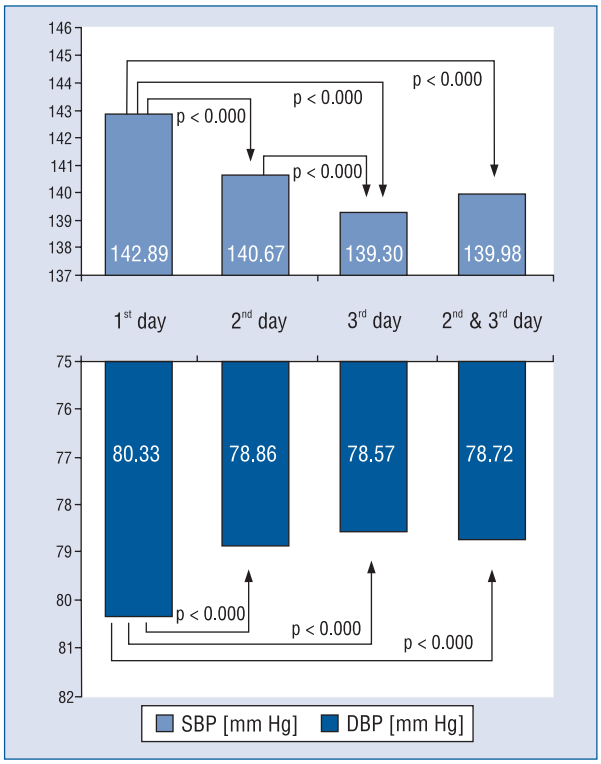

Figure 4. Analysis of the measurements obtained by means of self blood pressure measurement (SBPM) regarding different days (T-test for paired samples); SBP — mean systolic blood pressure of the 4 measurements taken per day; DBP — mean diastolic blood pressure of the 4 measurements taken per day.

-based [38] and those in untreated hypertensive patients [39].

The low rate of confirmation of the optimal control patients by ABPM corresponds with the previously demonstrated deficient PPV of the SBPM for the detection of the WCE and which the protocol relies on. Several studies find similar isolated clinical hypertension prevalence with both methods, but the mismatch among the identified individuals reaches 20–25% [37].

One of our most noteworthy findings was the low sensitivity in the detection of optimal control among the hypertensive patients by means of CBPM compared to SBPM. PPV is also low, though to a lesser extent. Doctors should think twice before giving an optimal control diagnosis, and the results should be confirmed using another technique, in spite of this parameter being dependent on the prevalence of the studied problem.

On the other hand, we obtained acceptable specificity and NPV. Therefore, doctors may give a confident no-control diagnosis, which is contrary to the reasoning commonly used in clinical practice. Furthermore, the CBPM method offers likelihood ratios — both positive and negative — that are insufficient for use as a diagnostic method in determining which patients are well controlled in comparison to SBPM, which is confirmed by the low Kappa index between them. This interpretation of

Table 4. Crosstabs level control through conventional blood pressure measurement (CBPM) and self blood pressure measurement (SMBP).

	OC SBPM	PC SBPM	Total	
OC CBPM	45 (19%)	25 (10.5%)	70 (29.5%)	PPV: 64.3%
PC CBPM	45 (19%)	122 (51.5%)	167 (70.5%)	NPV: 73.1%
Total	90 (38%)	147 (62%)	237 (100%)	
	Sensitivity: 50%	Specificity: 83%		

OC CBPM — optimal control (< 140/90 mm Hg); PC CBPM — poor control (≥ 140/90 mm Hg); OC SBPM — optimal control (< 135/85 mm Hg); PC SBPM — poor control (≥ 135/85 mm Hg; PPV — positive predictive value, VPN — negative predictive value; likelihood ratio (positive) — S/1-E: 2.94; likelihood ratio (negative) — 1-S/E: 0.60; Kappa index of agreement — value 0.345 ($p < 0.000$)

Table 5. Systolic and diastolic means of optimally controlled population through self blood pressure measurement (SBPM) compared to ambulatory blood pressure monitoring in the daytime (ABPMd).

	SBPM* (n = 90)	ABPMd (n = 85)	p (t-test paired samples)
Systolic mean [mm Hg]	121.8 ± 8.7	125.6 ± 11.8	< 0.002
95% confidence interval	120.0–123.7	123.0–128.2	
Diastolic mean [mm Hg]	73.4 ± 7.1	76.2 ± 8.8	< 0.000
95% confidence interval	71.9–75.0	74.3–78.1	

*Well-controlled population by means of SBPM < 135/85 mm Hg

Table 6. Crosstabs level control through conventional blood pressure measurement (CBPM) and ambulatory blood pressure monitoring in the daytime (ABPMd).

	OC ABPMd	PC ABPMd	Total	
OC CBPM	31 (36.5%)	11 (13%)	42 (49.4%)	PPV: 73.8%
PC CBPM	27 (31.8%)	16 (18.9%)	43 (50.6%)	NPV: 37.2%
Total	58 (68.2%)	27 (31.8%)	85 (100%)	
	Sensitivity: 53.4%	Specificity: 59.3%		

OC CBPM — optimal control (< 140/90 mm Hg); PC CBPM — optimal control (≥ 140/90 mm Hg); OC SBPM — optimal control (< 135/85 mm Hg); BC ABPMd — poor control (≥ 135/85 mm Hg); PPV — positive predictive value; NPV — negative predictive value; likelihood ratio (positive) — 1.31; likelihood ratio (negative) — 0.79; Kappa index — 0.11 ($p = 0.275$)

the findings agrees with the ABPM results, where the proportion of well-controlled patients by this method and those who were controlled or not by means of the CBPM (36.5%/31.8%) is similar (Table 6).

In view of our results, we can also question the use of SBPM for the diagnosis and control of hypertensive patients. There are new investigations that question this point too [40, 41]. Until further studies are performed that demonstrate which techniques are more effective in reducing the risk of treatment decisions, this question will remain unsolved. However, the prognostic results obtained in the PAMELA study [42] give added value to the information obtained with SBPM for improving the predictive value for cardiovascular events and death from all causes. This fact, together with the greater accessibility, suggests that its use may be recommended as long as its limitations are taken into account. We must also emphasize the improved prognostic value of measurements obtained by CBPM when compared to other techniques. Therefore, for the time being, the most reasonable way forward would be to integrate all the information using protocols that, like those we used, try to improve the decision making process in clinical practice.

Limitations of the study

There may have been a selection bias because we excluded patients who were immobilized or who had cognitive or physical deficiencies and therefore could not perform the self-measurement and ambulatory techniques. Such a bias might have decreased the proportion of patients suffering advanced hypertensive disease. In spite of this there were some patients (17.3%) with established cardiovascular

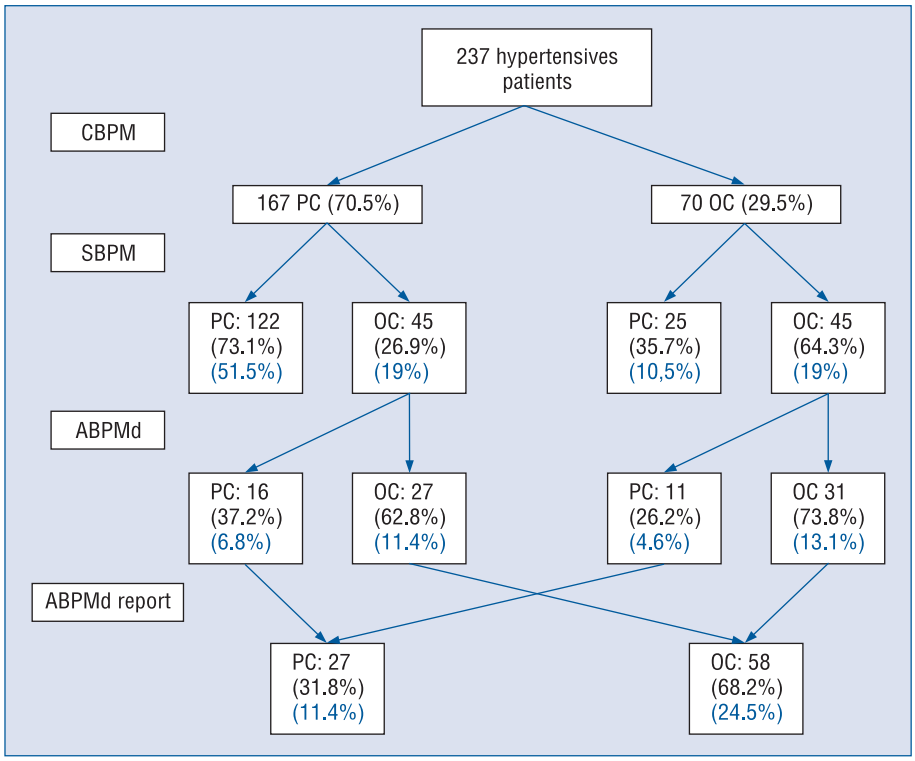

Figure 5. Control level when using different techniques; PC — poor control; OC — optimal control; (%) up — percentage from portion; (%) down — percentage from total; conventional blood pressure measurement (CBPM): OC: PA < 140/90 mm Hg; self blood pressure measurement (SBPM): OC: PA < 135/85 mm Hg; ambulatory blood pressure monitoring daytime (ABPMd): OC: PA < 135/85 mm Hg.

disease. Likewise, we must take into account the 21% of patients who were lost after the initial sample calculations. The lack of response, however, was mainly due to not having the collaboration of some family physicians.

With regard to SBPM, it may have been necessary to include another measurement day, or increase the number of measurements per day, because the systolic arterial pressure means were not stable between the second and the third day. Nevertheless, the trend was to keep decreasing, and the result of the bias would probably have been to obtain a smaller total mean regarding all the days. One factor that was also taken into account was the fact that the patients could change the results obtained by SBPM and provide the doctor with their preferred results [43]. Even though we used monitors with memory storage and printers, this eventuality was not studied.

Finally, some of our results could have been different if we had performed ABPM on all the patients. There are patients that may have bad control by SBPM and good control by ambulatory blood pressure. This matter was not investigated in our study because of its design based on the high specificity and negative predictive value of SBPM compared with ABPM in WCE detection [23, 39], and of course the lower disposal of this technique in Primary Healthcare Centres. In others words, SBPM has a high sensitivity and positive predictive value to detect bad control patients, but lower to detect those who are well controlled. If we extrapolate the results of other investigators regarding patients that have bad control by self-monitoring and optimal by ABPM [23, 39], with regard to our study, the control degree out of the office could be improved by between 2.4% and 11%.

Restrictive criteria of optimal control outside the clinic (SBPM and ABPM) could influence the results in this setting.

Conclusions

In summary, we may conclude that the level of control in the hypertensive population does not improve using measurement techniques outside the clinical setting. Office blood pressure measurements do not seem to be useful in distinguishing which

individual patients are poorly- or well-controlled, and are more valid when they show no control.

The use of measurement with ambulatory devices may always be advisable, but especially when the results show good control in the office.

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References

1. Stamler J, Stamler R, Neaton JD. Blood pressure, systolic and diastolic, and cardiovascular risk: US population data. Multiple Risk Factor Intervention Trial (MRFIT study). Arch Intern Med, 1993; 153: 598–615.
2. Banegas JR, Rodríguez-Artalejo F, de la Cruz JJ, de Andrés B, del Rey J. Mortalidad relacionada con la hipertensión y la presión arterial en Espańa. Med Clín (Barc), 1999; 112: 489–494.
3. The Atlas of Heart Disease and Stroke. WHO http://www.who.int/cardiovascular_diseases/resources/atlas/en
4. O'Brien E, Asmar R, Beilin L et al. European Society of Hypertension Recommendations for conventional, ambulatory and home blood pressure measurement. European Society of Hypertension Working Group on Blood Pressure Monitoring. J Hypertens, 2003; 21: 621–848.
5. Okhubo T, Imai Y, Tsuji I et al. Home blood pressure measurement has a stronger predictive power for mortality than does screening blood pressure measurement: A population based observation in Ohasama. J Hypertens, 1998; 16: 971–975.
6. Ohkubo T, Imai Y, Tsuji I et al. Reference values for 24-hour ambulatory blood pressure monitoring based on a prognostic criterion. The Ohasama Study. Hypertension, 1998; 32: 255–259.
7. Verdecchia P, Reboldi G, Porcellati C et al. Risk of cardiovascular disease in relation to achieved office and ambulatory blood pressure control in treated hypertensive subjects. J Am Coll Cardiol, 2002; 39: 878–885.
8. Staessen JA, Thijs L, Fagard R et al; for the systolic hypertension in Europe (Syst-Eur) trial investigators. Predicting cardiovascular risk using conventional vs. ambulatory blood pressure in older patients with isolated systolic hypertension. JAMA, 1999; 282: 539–546.
9. Banegas JR, Rodríguez-Artalejo F, de la Cruz JJ et al. Blood pressure in Spain: Distribution, awareness, control and benefits of a reduction in average pressure. Hypertension, 1998; 32: 998–1002.
10. Puras A, Sanchis C, Artigao LM et al. Prevalence, awareness, treatment and control of hypertension in a Spanish population. Eur J Epid, 1998; 14: 31–36.
11. Masia R, Pena A, Marrugat J et al. High prevalence of cardiovascular risk factor in Gerona, Spain, a province with low myocardial infarction incidence. REGICOR Investigators. J Epidemol Community Health, 1998; 52: 707–715.
12. Pineda M, Custardoy J, Ortin JM, Cano JG, Andreu MT, Grau C. Grado de conocimiento, tratamiento y control de la hipertensión arterial, hipercolesterolemia y diabetes mellitus en la población general adulta. Aten Primaria, 2004; 33: 254–260.
13. Primatesta P, Brooks M, Poulter NR. Improved hypertension management and control: results from the Health Survey for England 1998. Hypertension, 2001; 38: 827–832.
14. Henauw S, Bacquer D, Fonteyne W et al. Trends in the prevalence, detection, treatment and control of arterial hypertension in the Belgian adult population. J Hypertens, 1998; 16: 277–284.
15. Coca A. Evolución del control de la hipertensión arterial en atención primaria en Españа. Resultados del estudio Controlares 2003. Hipertension, 2005; 22: 5–14.
16. Llisterri Jl, Rodríguez GC, Alonso FJ et al. Control de la presión arterial en la población hipertensa española atendida en atención primaria. Estudio PRESCAP 2002. Med Clin (Barc), 2004; 122: 165–171.
17. Weber MA. Whole-day blood pressure. Hypertesion, 1988; 11: 288–298.
18. de la Figuera M, Vinholes E. Los hipertensos con mal control en la consulta. Estudio mediante monitorización ambulatoria de la presión arterial. Aten Primaria, 1996; 18: 351–356.
19. Redon J; Estudio APACHE. Control of arterial hypertension base don self-measurement of blood pressure: APACHE study. Med Clin (Barc), 2003; 120: 728–733.
20. Stergiou GS, Skeva II, Baibas NM, Kalkana CB, Roussias LG, Mountolakakis TD. Diagnosis of hypertension using home or ambulatory blood pressure monitoring: comparison with the conventional strategy based on repeated clinic blood pressure measurements. J Hypertens, 2000; 18: 1745–1751.
21. Pickering TG, James JD, Boddie C, Harshfield GA, Blank S, Laragh JH. How common is coat hypertension? JAMA, 1988; 259: 225–232.
22. Martínez MA, García-Puig J, Martin JC et al. Frequency and determinants of white coat hypertension in mild to moderate hypertension a primary care based study. MAPA-Area 5 Working Group. Am J Hypertens, 1999; 12: 251–259.
23. Stergiou GS, Zourbaki AS, Skeva II, Mountokalakis TD. White coat effect using self-monitoring of blood pressure at home: Comparison with ambulatory blood pressure. Am J Hypertens, 1998; 11: 820–827.
24. Pickering TG; for an American Society of Hypertension ad hoc panel. Recommendations for the use of home (self) and ambulatory blood pressure monitoring. Am J Hypertens, 1995; 9: 1–11.
25. Brueren MM, Shouten HJ, de Leeuw PW, van Montfrans GA, van Ree JW. A series of self measurements by the patients is a reliable alternative to ambulatory blood pressure measurement. Br J Gen Pract, 1998; 48: 1585–1589.
26. Nesbitt SD, Amerena SV, Grant E et al. Home blood pressure as a predictor of future blood pressure stability in borderline hy-

pertension. The Tecumseh Study. Am J Hypertens, 1997; 10: 1270–1280.
27. Executive summary of the third report of the national cholesterol education program (NCEP) expert panel on detection, evaluation and treatment of high blood cholesterol in adults (Adult Treatment Panel III). JAMA, 2001; 285: 2486–2497.
28. O'Brien E, Mee F, Atkins N, Thomas M. Evaluation of three devices for self-measurement of blood pressure according to the revised British Hypertension Society Protocol: the Omron HEM-705 CP, Philips HP5332 and Nissei DS-175. Blood Press Monit, 1996; 1: 55–62.
29. Stergiou GS, Skeva II, Zourbaki AS, Mountokalakis TD. Self--monitoring of blood pressure at home: how many measurements are needed? J Hypertens, 1998; 16: 725–731.
30. Gropelli A, Omboni S, Parati G, Mancia G. Evaluation of noninvasive blood pressure monitoring devices Spacelabs 90202 and 90207 versus resting and ambulatory 24-hour intra-arterial blood pressure. Hypertension, 1992; 20: 227–232.
31. Chobanian AV, Bakris GL, Black HR et al. and the National High Blood Pressure Education Program Coordinating Committee. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure. The JNC 7 Report. JAMA, 2003; 289: 2560–2572.
32. Hansen TW, Jeppesen J, Rasmussen S, Ibsen H, Torp-Pedersen C. Ambulatory blood pressure and mortality. A population-based study. Hypertension, 2005; 45: 499–504.
33. Ohkubo T, Asayama K, Kikuya M et al. How many times should blood pressure be measured at home for better prediction of stroke risk? Ten year follow-up results from the Ohasama study. J Hypertens, 2004; 22: 1099–1104.
34. Kikuya M, Ohkubo T, Asayama K, Metoki H, Obara T, Saito S. Ambulatory blood pressure and 10-year risk of cardiovascular and noncardiovascular mortality. The Ohasama Study. Hypertension, 2005; 45: 240–245.
35. Pickering TG, Hall JE, Appel LJ et al. Recommendations for blood pressure measurement in humans and experimental animals. Part 1: Blood pressure measurement in humans. A statement for professionals from the Subcommittee of Professional and Public Education of the American Heart Association Council on High Blood Pressure Research. Hypertension, 2005; 45: 142–163.
36. Boix R, Cañellas J, Cerrato E, Mesegur CM, Medrano MJ. Mortalidad cardiovascular en Espańa. Año 2000. BES, 2003; 11: 241–252.
37. Parati G, Stergiou GS. Self measured and ambulatory blood pressure in assessing the white coat phenomenon. J Hypertens, 2003; 21: 677–682.
38. Mancia G, Sega R, Bravi C et al. Ambulatory blood pressure normality: Results from the PAMELA study. J Hypertens, 1995; 13: 1377–1390.
39. Den Hond E, Celis H, Fagard R et al. Self-measured versus ambulatory blood pressure in the diagnosis of hypertension. J Hypertens, 2003; 21: 717–722.
40. Stergiou GS, Alamara CV, Skeva II, Mountokalakis TD. Diagnostic value of strategy for the detection of white coat hypertension based on ambulatory and home blood pressure monitoring. J Human Hypertens, 2004; 18: 85–89.
41. Bayó J, Cos FJ, Roca C, Dalfó A, Martin-Baranera MM, Botey A. Home blood pressure self-monitoring: diagnostic performance in white coat hypertension. Blood Press Monit, 2006; 11: 47–52.
42. Sega R, Fanchetti R, Bombelli M et al. Prognostic value of ambulatory and home blood pressures compared with office blood pressure in the general population. Follow-up results from the PAMELA Study. Circulation, 2005; 111: 1777–1783.
43. Mengden T, Hernandez R, Beltran B, Alvarez E, Kraft K, Vetter H. Reliability of reporting self-measured blood pressure values by hypertensive patients. Am J Hypertens, 1998; 11: 1413––1417.