Does Self-measurement of Blood Pressure (SMBP) Contribute to Improve the Degree of Hypertension Control?

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Abstract

Background and objectives: Self-measurement of blood pressure can be associated with a better control of blood pressure. The objectives of this study were to determine the degree of control with two measuring methods (clinical blood pressure measure and self-measurement of blood pressure) and determine the factors associated with poor control.

Methods: Multicenter randomized cross-sectional Study in Hypertensive patients diagnosed and treated at Primary Care. Recollected data included: socio-demographic profiles, personal history, standard blood tests and arterial pressure measure by self-measurement of blood pressure and clinical blood pressure measure. Control objectives included for self-measurement of blood pressure (<135/85 mmHg) and for clinical blood pressure measure (<140/90 mmHg). Data are expressed in percentages and averages with a CI of 95%.

Results: 514 patients where included (59.3% female) with a mean age of 70.84 (80.01-61.67) years old and 10.37 (14.87-5.62) years of hypertensive disease evolution. The degree of control was 84.67% (83.58-85.76) with self-measurement of blood pressure and 68.54% (67.31-69.77); p < 0.0001. Patients controlled by self-measurement of blood pressure took 2.58 (1.65-3.51) versus 2.97 (2.11-3.83) with clinical blood pressure measure; p < 0.001. Being more frequent the use of fixed combinations. Obesity, diabetes, hyperlipidemia, cardiovascular disease, severity of hypertension, measurement method, number of drugs and age were associated with poorer control of the blood pressure; p < 0.001.

Conclusions: The degree of control with self-measurement of blood pressure is very high, compared with ambulatory monitoring, with important clinical significance. Although the characteristics of this study can not infer causality, this finding reinforces the recommendations of the Clinical Practice Guidelines for the regularly use of the self-measurement of blood pressure in our daily practice.

Keywords: Hypertension; Ambulatory blood pressure measurement; Control; Treatment

Introduction

Cardiovascular disease (CVD) is the leading cause of death worldwide and also in the whole of Spain [1]. Hypertension is one of the major cardiovascular risk factors contributing to this mortality: 33% of the Spanish population is hypertensive, reaching 68% at the age of 60. Out of these, nearly two thirds know that they have the disease. Among these, 79% are treated with antihypertensive drugs. Finally, among those treated, 46% have blood pressure controlled. Therefore, just over 20% of hypertensive Spanish people are adequately controlled [2].

The degree of control of hypertensive patients seen in primary care is insufficient; although it has been observed a progressive increase in the different studies CONTROLPRES from 1995 to 2003, increasing from 13% to 38.8% [3]. More recently in the PRESCAP study, the degree of BP control was 36.1% in 2002 [4] and 41.4% in 2006 [5]. Although there have been important advances in the understanding, treatment and control of hypertension in recent years in Spain [2,6] the reality is that the level of control and treatment remain improvable.

The method traditionally used for the diagnosis and management of hypertension has been the measurement of BP in Primary Care with mercury or aneroid sphygmomanometers. At the population level this method has proven BP relationship to cardiovascular morbidity and mortality.

Moreover, it is known that with the clinical measures to outpatients the alert reaction of the consult is not avoided, the BP variability is not reported and mistakes in the measurement process are frequent. Leading to committing errors in the process of diagnosis and monitoring of hypertension. It is estimated that 20-30% of the decisions made based only on clinical measures will be wrong [7].

The domiciliary measures (SMBP) have shown a good correlation with ambulatory motorization of blood pressure (AMBPM), high
degree of agreement to diagnose white-coat hypertension, masked hypertension and a similar prognostic value to that of the AMBP, with lower cost and with greater accessibility. Furthermore with domiciliary measures it has been observed that clinical inertia is diminished and therapeutic fulfillment improved. An estimated 80-90% of the doubts in the process of diagnosis and monitoring can be solved with SMBP and these are extremely useful for monitoring the HTA [7-9].

As for the evaluation of hypertensive patients under treatment, domiciliary measures give more complete information than clinical blood pressures (CBP) as they report the degree of control at home and allow a better characterization of the response to treatment at different times of day. They help us identify pseudorefractory patients avoiding unnecessary overtreatment, and give us information about the residual effect of the drug, allowing to assess the true degree of control, detecting patients not controlled in the early hours of the morning.

This study bases its justification on scientific evidence indicating that the SMBP based on self-management of the hypertension by the patient gets better results in the degree of control of blood pressure than CBP outpatient measurement [8].

The main objective of this study was to determine the number of hypertensive patients who have their BP controlled, the degree of control achieved in patients using SMBP as a protocolized manner and to assess whether there are significant differences in the degree of control with the use of both methods of measurement, determine the number of drugs used to control the PA and determine the factors associated with poor control.

Materials and Methods

Study design

We designed a descriptive, cross-sectional, multicenter and not controlled study where outpatients with an age over 18 years old from the health region of Bierzo (León, Spain) defined by the presence of essential hypertension diagnosed and treated at clinical practice of Primary Care were included.

The study was conducted during 2014 by basic healthcare units (General practitioner and nurse per share) randomly selected by sample units of 10 health areas of Primary Care Health District of Bierzo. A total of 55 participating healthcare units participated, each of them selected by consecutive sampling 10 patients. Finally 514 patients who met the inclusion criteria and signed informed consent were included.

Inclusion criteria in the study were: hypertensive patients of both sexes, patients older than 18 years old diagnosed and treated for hypertension (at least 6 months of treatment!), hypertensive patients with control and monitoring of the BP by SMBP and hypertensive patients with control and tracking by CBP willing to participate in the study. Patients were included after being fully informed of the objectives of the study and living their consent. Exclusion criteria involved: individuals who had received a diagnosis of hypertension recently (less than 6 months) and those who received antihypertensive treatment for no longer than 6 months.

The Ethics Committee of the University Hospital of León approved the study protocol. The data collection period lasted from April 1st to November 30th of 2014. Two visits were made: a initial visit for the inclusion in the study and a second visit to collect SMBP protocol developed for half of the sample to compare it with outpatient measurements taken and collected on this visit to the other half of the sample.

In a case report data completed by the physician, based on the existing data in the medical record, the following variables were recorded:

**Patient data**

Age (years), sex, weight (kg), height (cm), body mass index (BMI) (kg/m²), waist circumference (WC) (cm), years of evolution of the hypertension, family history of premature cardiovascular disease (before the age of 55 in men and before 65 in women) and associated cardiovascular risk factors (hypercholesterolemia, hypertriglyceridemia, smoking, obesity, diabetes, alcoholism, sedentary lifestyle, history and presence of cardiovascular disease (ischemic heart disease, acute coronary syndrome, cerebrovascular disease, peripheral artery disease and nephropathy).

It was considered that a patient was obese when their BMI was generally equal to or greater than 30 kg/m², had abdominal obesity when waist circumference was greater than 102 cm in men and 88 cm in women and hypercholesterolemia, diabetes, alcoholism, smoking if there were recorded in their medical record any of these conditions.

The following analytical data were collected: Blood glucose, creatinine, urea, albumin/creatinine ratio, ions: Na⁺ and K⁺, total cholesterol, triglycerides, HDL and LDL cholesterol.

**Blood pressure data**

For half of the sample we collected ambulatory BP computerized data records in a standardized manner of the previous month. If the BP measures were old two separate takes separated by two minutes in a sitting position were made, and the arithmetic average of the two of them was obtained following the recommendations of the Guide of the Spanish Society of Hypertension / League for the Fight Against Hypertension (SEH-LELHA in Spanish). We used a mercury sphygmomanometer or a recently calibrated aneroid or an automatic electronic device homologated for measuring the PA. It was considered that the patient had a good control of his hypertension (optimal control) when the SBP and DBP (arithmetic mean of the 2 measurements in the visit) were less than 140 mmHg and 90 mmHg, respectively.

For the other half of the sample we recorded the SMBP data available in their medical records for the previous month as well as domestic BP measuring at with an homologated electronic equipment for evaluation and follow-up treatment in long term hypertensive patients. Before each nursing/physician consult: SMBP during 7 consecutive days with at least 2 takes in the morning and 2 afternoon. The first day’s takes were discarded as recommended by the SEH-LELHA. It was considered that the patient had a good control of his hypertension (optimal control) when the SBP and DBP were less than 135 mmHg and 85 mmHg, respectively [8,10].

**Antihypertensive treatment data**

Kind and number of antihypertensive therapeutic subgroups used in the treatment of hypertension and the antiquity of therapy (months or years).

**Statistics**

We defined variables and data was entered into a database of SPSS 15.0. Only patients who had available a minimum of 75% of the variables correctly fulfilled were included. Likewise manual and computer reviews of the clinical data were performed to determine the consistency and quality of the data recorded according to the study protocol.
After purging the database from possible errors, we conducted a descriptive study of the variables included in the study. Results were expressed as frequencies and percentages for qualitative variables and as mean, standard deviation (SD), median and extremes for quantitative variables. We calculated the Confidence interval (CI) of 95% for the variables of interest, assuming normality and using the exact method for small proportions. We used the t-Student test for independent data to compare the means. For comparison of quantitative data not normally distributed nonparametric Mann-Whitney test was used, and for the possible association between qualitative variables we employed Chi-square test or Fisher’s exact test. Statistical significance was established at p<0.05. Finally, We used the logistic regression analysis to determine which variables were associated with poor control of hypertension with ambulatory measures (SBP equal to or greater than 140 mmHg and / or DDB equal to or greater than 90mmHg in the general population, or equal to or greater than 135 and / or 85 mmHg in patients with SMBP) [11].

Results
Sample description

The 55 participating physicians provided a valid sample of 514 patients out of the 550 patients originally studied, 59.3% were women, with an average age of 70.84 (80.01-61.67) years old and 16.37 (21.89-10.85) years of hypertensive evolution. Average SBP from SMBP was 127.92 (135.74-118.26) mmHg. The average ambulatory SBP was 145.07 (133.3-156.84) mmHg. Average DBP from SMBP was 74.18 (65.08-82.92) mmHg, p<0.0001. The statistically significant differences between the two methods of measurement: 145.07 (133.3-156.84) mmHg Vs. 127.92 (126.9-129.9) mmHg, p<0.0001. The degree of global control of the BP is much better when SMBP is used (BP<135/85 mmHg) than when the CBP is performed (BP<140/90 mmHg) reaching in this study up a global control degree of 84.65% vs. 68.54%, respectively, p<0.0001 (Table 3) and being better in women aged between 55 to 74 years old and in rural and semi-urban media (Figure 1).

As every patient was a treated hypertensive, the mean number of antihypertensive drugs prescribed was significantly higher in patients with CBP control than in patients controlled by SMBP: 2.97 (2.11-3.83) versus 2.58 (1.65-3.51), p<0.001. Very few patients received monotherapy (8%) compared to a 92% of patients in combined therapy

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Table 1: General characteristics of the sample.

<table>
<thead>
<tr>
<th>N = 514 Hypertensive Patients</th>
<th>%</th>
<th>95% CI</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Socio-demographic characteristics:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>40.7</td>
<td>40.01-41.14</td>
<td>0.01</td>
</tr>
<tr>
<td>Female</td>
<td>59.3</td>
<td>58.70-59.90</td>
<td>0.01</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 54 y.o.</td>
<td>18.5</td>
<td>18.20-18.80</td>
<td>0.01</td>
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<td>55-64 y.o.</td>
<td>34.2</td>
<td>33.40-34.20</td>
<td>0.01</td>
</tr>
<tr>
<td>65-74 y.o.</td>
<td>30.1</td>
<td>29.7-30.50</td>
<td>0.01</td>
</tr>
<tr>
<td>≥ 75 y.o.</td>
<td>17.2</td>
<td>16.27-18.13</td>
<td>0.01</td>
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<td>Habitat</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rural</td>
<td>22.7</td>
<td>22.05-23.35</td>
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</tr>
<tr>
<td>Semiurban</td>
<td>35.2</td>
<td>34.58-35.82</td>
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<tr>
<td>Urban</td>
<td>42.1</td>
<td>41.61-42.59</td>
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<td>Personal history:</td>
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<td></td>
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<tr>
<td>Family history of premature CVD</td>
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<td>12.88-15.52</td>
<td>0.001</td>
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<td>Hypercholesterolemia</td>
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<td>54.34-56.40</td>
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<td>Smoking</td>
<td>15.7</td>
<td>15.04-16.36</td>
<td>0.001</td>
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<tr>
<td>Obesity</td>
<td>47.7</td>
<td>46.80-48.50</td>
<td>0.001</td>
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<tr>
<td>Diabetes Type 2</td>
<td>28.6</td>
<td>27.57-29.61</td>
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<td>Alcoholism</td>
<td>11.7</td>
<td>11.02-12.37</td>
<td>0.001</td>
</tr>
<tr>
<td>Sedentarism</td>
<td>36.6</td>
<td>35.87-37.33</td>
<td>0.001</td>
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<td>34.5</td>
<td>33.91-35.09</td>
<td>0.001</td>
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<tr>
<td>Microalbuminuria</td>
<td>5.3</td>
<td>4.7-5.9</td>
<td>0.05</td>
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<tr>
<td>Left ventricular hypertrophy</td>
<td>12.3</td>
<td>11.52-13.08</td>
<td>0.05</td>
</tr>
<tr>
<td>Ischemic Heart Disease</td>
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<td>10.25-11.14</td>
<td>0.01</td>
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<td>Acute myocardial infarction</td>
<td>6.1</td>
<td>5.6-6.6</td>
<td>0.01</td>
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<tr>
<td>Cerebrovascular disease</td>
<td>5.18</td>
<td>4.61-5.75</td>
<td>0.01</td>
</tr>
<tr>
<td>Renal disease</td>
<td>1.72</td>
<td>1.56-1.88</td>
<td>0.05</td>
</tr>
<tr>
<td>Peripheral arterial disease</td>
<td>4.8</td>
<td>4.12-5.48</td>
<td>0.01</td>
</tr>
</tbody>
</table>

Table 2: Socio-demographic characteristics and personal history.
Discussion

The results of this study show that the degree of overall control of the BP is much better when the SMBP is used than when the ambulatory BP control is performed. In this study optimal control was achieved in 84, 63% of the patients using SMBP versus 68.54% when ambulatory BP control is used. A meta-analysis of 18 randomized trials demonstrated a greater reduction in BP in patients who performed domiciliary BP measurements than those controlled by ambulatory BP measurements. However, in the metacentric study THOP (Treatment of Hypertension Based on Home or Office Blood Pressure) [12], whose drug treatment group was based on the values of home BP of...
an entire year showed higher BP values of 24 hours of duration than did the conventional monitoring group (clinical BP). The first group had a lower consumption of antihypertensive drugs and somewhat lower overall cost of treatment. Similar results were obtained in the study HOMERUS (Home Versus Office Measurement, Reduction of Unnecessary Treatment Study) [13]. In this study the degree of control was greater when the severity of hypertension was lower, with lower consumption of drugs, in line with the aforementioned studies.

Published data and data from this study suggest that, much cheaper and affordable than ambulatory monitoring of blood pressure, Domiciliary BP measure is a potentially useful procedure in monitoring patients with antihypertensive treatment. However, we do not have sufficient evidence suggesting that antihypertensive treatment based on the values obtained through these techniques achieves better 24 hours control of BP nor reduce cardiovascular risk than those based on CBP values. Thus, domiciliary BP values should be considered as supplementary information to the ambulatory BP measures.

Although auscultation remains the gold standard for measuring blood pressure, being the one used to control it on an outpatient basis, studies have shown that the portion of patients with adequate control of BP is superior when instead of making the assessment of blood pressure in consultation; this is done in the patient’s home by SMBP. Different studies have shown a better correlation of the SMBP than ambulatory pressure measured in consultation with a higher target organ and predictive value for risk of cardiovascular disease (CV), these being similarly correlated to those obtained with Ambulatory monitoring of BP [14] (AMBp).

The Ohasama study [15], revealed a significant association of systolic BP (SBP) self-measuremed with cardiovascular morbidity and mortality (CV), which did not happen with the diastolic BP (DBP) and this association was not observed with clinical BP measurements. For every increase of 10 mmHg of clinical SBP an 8% risk of cardiovascular disease was observed and for the same increase in domiciliary SBP risk increase was 19%.

The SHEAF study observed that with SMBP for every 10 mmHg of increase in SBP: CV disease risk increased a 17.2% and for every 5 mmHg increase in self-measured DBP risk increased by 11.7%. In the same study, with the same increase in clinical BP no significant increase in CV risk was observed. The authors of both studies refer to the greater predictive value of SMBP regarding the CBP and suggest that SMBP should be recommended routinely for monitoring hypertensive patients.

As for the evaluation of hypertensive patients under treatment, domiciliary measures give more complete information than clinical pressures, report the degree of control at home and at different times allowing better characterization of the response to treatment at different times of the day. It allows to identify pseudorefractory patients, avoiding unnecessary overtreatment, and gives us information of the residual effect of the drug allowing us to assess the true degree of control, detecting patients not controlled in the early hours of the morning.

In the present study, when analyzed and compared separately the degree of control and the adequacy of treatment with the different measurement methods, the degree of control and adaptation to treatment was better when SMBP was used for any degree of hypertension, p<0.001. Patients with grade 1 hypertension was better controlled and used fewer antihypertensive drugs when the control and monitoring was performed with SMBP than when it was done with ambulatory BP measurement, 1.4 (1.12 to 1.52) vs. 1.8 (1.39 to 2.27), p<0.001.

Although there are few the studies that evaluate the degree of control with SMBP. In a study of 660 patients they found a prevalence of clinical isolated hypertension of 27% and out of 258 poorly controlled hypertensive patients 17% had normal domiciliary pressures and to 24% of them treatment was reduced or withdrawn [16]. PAMELA data [17,18] indicate poorer control with clinical measures of BP (29.9% for SBP and 41.5% for DBP) than with SMBP (38.3% and 54.6%) or with ambulatory monitoring of BP (50.8% and 64.9%). Lou Arnal et al. [19] describe that despite apparent poor control in the consultation when evaluated for a hole year with SMBP, antihypertensive treatment was unchanged in 57.7% of patients and decreased in 33.3% of them.

Mean BP obtained by SMBP was less than clinical BP and taken closer to the average diurnal BP obtained by AMBP [20]. Compared with CBP, the SMBP has greater reproducibility [21] due to the realization of a large number of readings, it is devoid of the white coat effect [22], has a higher correlation with target organ damage [23, 24], and has shown a higher predictive value of cardiovascular morbidity-mortality [25,26].

The BP measurement in the clinic is the standard criterion for determining the degree of control of hypertension. It is important to establish whether these measures are very different from those taken by patients at home. In this study, the mean difference in SBP and DBP taken in the clinic was 7.9/8.01 higher than the domiciliary BP, data consistent with those of other studies. The review by Yarows et al. [27] shows the differences observed in several studies [16,28], between clinical BP and domiciliary BP with SMBP.

The mean of the different measures of SBP and DBP taken at the clinic was 8.1/5.6 mmHg higher than the domiciliary BP. More recently in the PAMELA [15] study conducted in general population, the difference between SBP and DBP taken at the clinic and at home was 8.0/7.4 mmHg.

In our environment it has also been observed that the mean values of clinical pressures were significantly higher than those of home self-measured pressures and the AMBP [29,30]. The correlation found between BP obtained with different protocols of domiciliary SMBP and diurnal average of 24h AMBP was good; and increases with increasing days of self-measurement in both: untreated hypertensive population and hypertensives treated with antihypertensive drugs [7,8].

The realization of home SMBP achieves a superior sensitivity to those obtained with the specific measurement in the consultation. Validity indicators of domiciliary SMBP, its clinical utility and consistency, its correlation with the diurnal period of 24 h AMBP and its accuracy or reproducibility improves with the number of days of self-measurement and the amount of self-measures thereby decreasing the percentage of false positives. The observed data are consistent with those of the aforementioned studies, although it is necessary to have studies designed specifically to study that with more patients and a longer period of follow-up.

In opposition to previous recommendations, the 2013 ESC guidelines emphasized “out of office” blood pressure (BP) monitoring in form of home blood pressure monitoring (HBPM) and ambulatory blood pressure monitoring (ABPM), by favoring the former rather than the latter, in agreement with recent evidences showing that blood pressure values detected with these two methods predict organ damage and risk of cardiovascular outcomes better than BP assessed in the office (office pressure measurement). Although office pressure measurement,
i.e. the blood pressure evaluation in the medical environment, represents the gold standard for the diagnosis of arterial hypertension, the guidelines underline the complementary role of HBPM and ABPM in the general assessment of BP. Practically, a tight collaboration among researchers and medical doctors is the basis for the reduction of the great number of limitations of the current perspective on hypertension, in order to obtain a full control of this cardiovascular risk factor [31].

Conclusions

So we can conclude that the degree of control of patients with SMBP is high (84.67%), with important clinical significance. The degree of control of patients with CBP (68.54%) is similar to that found in other recent studies. Although the design of this study cannot infer causality, this finding reinforces the recommendations of the Clinical Practice Guidelines for the routinely use of SMBP in our consultations.

The poor control of CBP pressures that we obtain in our patients and the repeatedly demonstrated quality of the values obtained with the SMBP technique has led to almost all national and international scientific organizations that deal with the management of hypertension and cardiovascular risk to advocate the widespread use of this technique, especially in the field of primary care.

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