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ORIGINAL ARTICLE

Assessment of self-monitoring of blood pressure in the diagnosis of isolated clinic hypertension

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Abstract

Background. There are no studies assessing cardiovascular morbidity/mortality in patients with isolated clinical hypertension (ICH) with self-blood pressure monitoring (SBPM). *Objectives.* To determine the value of SBPM in the diagnosis of ICH. *Methods.* Cohort study. New hypertensive and normotensive patients 15–75 years, without cardiovascular events history. *Variables.* Oriented anamnesis hypertension; blood pressure measurements (BP): clinical BP, SBPM and ambulatory BP monitoring (ABPM); evaluation of target organ damage (TOD); electrocardiogram; retinography and microalbuminuria (MA). *Results.* One hundred and thirty-five patients, 95 hypertensive (62.1% males; mean age 59.08 ± 16.8 years), 40 normotensive (37.5% males; mean age 56.32 ± 10.22 years). BP measurements (mmHg) in normotensives vs hypertensives: clinical BP, 125.36/76.74 vs 149.81/87.86 mmHg ($p < 0.0001$) and SBPM, 114.90/69.96 vs 142.06/86.31 ($p < 0.0001$). Twenty-four-hour ABPM: 135.41/81.74. Prevalence of TOD in hypertensive: 23.10% left ventricular hypertrophy (LVH), 8.42% haemorrhage or exudates, 3.15% MA; 30.53% of hypertensives had ICH. The BP measurements in ICH vs sustained hypertension (SH): clinic BP, 149.88/86.34 vs 152.51/89.55 ($p > 0.10$); SBPM: 147.895/88.95 vs 128.17/79 ($p < 0.0001$) and ABPM, 141.72/88.22 vs 131.66/80 ($p = 0.053$ for systolic). TOD in SH vs ICH: LVH, 24.6% vs 19.2% ($p = 0.814$); exudates or haemorrhages, 7.7% vs 9.8% ($p = 0.580$). The risk of an occurrence of any TOD in ICH patients is lower for 125/80 (OR=2.5). *Conclusions.* VAMPAHICA will provide information about value of SBPM in the diagnosis of ICH. Advanced retinopathy is relative frequent in ICH patients. If TOD is accepted as a surrogate endpoint, the diagnostic values of ICH will be probably decreased.

Key Words: *Ambulatory blood pressure monitoring, isolated clinical hypertension, self-blood pressure monitoring, target organ damage*

Introduction

Most of the studies showing a reduction in both morbidity and mortality as a consequence of the treatment of hypertension (HT) are based on blood pressure (BP) obtained during consultations (clinic BP) (1,2). This monitoring, however, presents some problems (3): (i) the "white coat" effect and isolated clinical hypertension (ICH), affecting from 7.1% to 53% of the patients (4,5); (ii) variability of BP (± 15 mmHg in the diastolic BP of one patient in a 1-month period) (6); (iii) the reduced number of readings; and (iv) the existence of biases as reported in the literature (7,8). These limitations could lead to misclassifications of hypertensive patients and, consequently, to over-diagnoses and over-treatment.

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In order to reduce these problems, self-blood pressure monitoring (SBPM) and ambulatory blood pressure monitoring (ABPM) are recommended. It is found that these two procedures have a higher predictive power of target organ damage (TOD) and of cardiovascular morbidity/mortality (9–13).

Although international guidelines recommend SBPM as a means to obviate the "white coat" effect and to diagnose ICH (1,2,14,15), other studies have found that, although a good screening technique to detect ICH, SBPM is not sufficient, unless the patient is diagnosed as hypertensive. In particular, when the patient has ICH, it is necessary to confirm it with an additional APBM (16–20). Some studies show that ICH diagnosed by ABPM is a more benign condition than defined sustained hypertension (SH), in the sense that the former patients have a lower morbidity/mortality (21,22). Currently there are no studies showing this result for the SBPM. The SHEAF study (23) found that SBPM has a higher predictive value than clinical BP and that SBPM is a good procedure to rule out the "white coat" effect for treated hypertensive patients, but the study did not consider the validity of an ICH diagnosis. In this sense, it would be necessary to carry out a study to assess the cardiovascular morbidity/mortality for patients diagnosed as ICH by means of SBPM.

Objectives

The main objective of VAMPAHICA was to determine the value of SBPM in the diagnosis of ICH. The specific objectives of VAMPAHICA were: (i) to analyse the predictive value of SBPM to diagnose ICH, by means of surrogate endpoints of TOD in relation with clinical BP and ABPM; (ii) to analyse the predictive value of SBPM to diagnose ICH, by assessing cardiovascular morbidity/mortality in relation with clinic BP and ABPM; and (iii) to determine the normality threshold for SBPM.

The results of the first 135 patients included in the study are presented in this paper.

Population under study

The VAMPAHICA study has been previously described (24). In summary, it is a multicentre study involving 140 researchers from 14 primary healthcare areas of the Girona Health Region (Catalonia, Spain). The population under study includes all the patients attended in the surgeries of health professionals participating in the study. Three cohorts are being followed in a 4-year period (2004–2007): (i) patients with confirmed and sustained HT in 2004–2006; (ii) patients with ICH according to SBPM in the same period; and (iii) normotensive patients with no inverted "white coat" effect, also known as masked HT, during the same period.

Design of the study

VAMPAHICA is a prospective cohort study. Patients included in it fulfil the following criteria: (i) between 15 and 75 years old; (ii) clinical HT, defined as the average of two BP readings, with a 2-min lag, carried out in 3 different days, with results higher than or equal to 140 mmHg (systolic) and 90 mmHg (diastolic); (iii) recently diagnosed hypertensive patients with no antihypertensive treatment; and (iv) those with a correct record for both SBPM and ABPM. Normotensive patients were selected using systematic sampling, choosing the first normotensive patient that goes to the surgery after including a hypertensive patient.

The exclusion criteria were the following: explicit impossibility, according to the health professional, of carrying out SBPM; diabetes mellitus; secondary HT; previous cardiovascular disease; end-stage renal disease; advanced liver disease; alcoholism; severe psychiatric disorder; severe endocrine disease; severe haematological disease; other limitations that, according the health professional, impede SBPM. Diabetic patients were excluded to avoid confusing TOD as a consequence of diabetes and of HT.

BP determination and HT control

Determination of BP. The diagnosis of HT was based on the measurements made by nurses in the infirmary. In particular, two measurements, with a 5-min seated rest, were taken on 3 different days. An additional measurement was made when, on one particular day, the difference between the readings was higher than 5 mmHg. The BP was the average of all three (in some cases four) measurements. All measurements were made with Omron 705 CP and Omron 705 IT monitors in the standard conditions recommended by international organizations, using an armband around the perimeter of each patient's arm. Monitors used in the study were calibrated annually by the technical service.

SBPM procedure. This procedure was applied to all patients included in the study. Each participant was trained by an expert nurse in all the steps to follow to obtain a correct reading and was given some written instructions. The correct procedure was confirmed twice in the presence of the nurse. Measurements were taken with an armband around the perimeter of

the arm of each patient. Two readings were taken in the morning, just before breakfast, and two readings in the evening, just before dinner, during three workdays, with a 2-min lag and a 5-min resting period. The patient, besides recording his/her BP on a sheet prepared specifically for this purpose, printed the readings directly from the monitor. The readings for the first day are omitted to compute the average.

ABPM procedure. This procedure was applied to all patients included in the study. Each participant was trained by an expert nurse about all the steps to follow in order to obtain a correct reading. Measurements were taken with an armband around the arm of each patient. Readings were taken every 20 min during the day (08.00–23.00 h) and every 30 min at night (23.00–08.00 h). All measurements were taken with Spacelab 90217 monitors, calibrated annually.

HT control. All patients with clinic BP≥140/90 mmHg were considered hypertensive, independently of SBPM and ABPM results. Clinical decisions were made and treatment was carried out according to the protocols of the Girona Health Region. Information from SBPM/ABPM was used only according to most of the protocols: resistant HT; suspicion of a "white coat" effect; HT without TOD, and assessment of the response to treatment.

Data collection, variables and follow-up

Data collection. Data were recorded in a logbook specifically designed for the study and containing clinical variables, additional explorations and medical analyses. All data were included in an electronic database.

Initial study and follow-up. Initially, and then every year, all hypertensive patients of the study had an anamnesis, a physical examination, a medical analysis, an electrocardiogram (ECG) of 12 standard derivations and a fundus eye (FE) image with a retinography done with a retinograph equipped with a non-mydriatic digital camera with colour images (CANON CR6-45NM, Camera EOS D30). An expert physician, without knowing any patient data, assesses the images. Initially microalbuminuria (MA) was measured with first-morning urine. In case of a positive result, the presence of leucocytes, haematites or nitrites was ruled out using a reactive strip. Once the cause of the anomaly in the strip, if any, was analysed and treated, MA was measured again after 15 days. If it was positive, the albumin/creatinine index was computed using first-morning urine, based on the standards of the European Society of Hypertension (14). At least two out of three positive measures were needed to make the diagnosis. Ischaemic damage, arrhythmia and left-ventricle hypertrophy (LVH) were assessed with ECG.

Normotensive patients initially had an anamnesis, a physical examination and an SBPM (to rule out masked HT) and, with a yearly periodicity, an anamnesis and a clinical BP measurement. During the follow-up, if a patient's clinical BP is high, that patient is excluded from the study, being considered normotensive until just before this finding and the subsequent exclusion.

Variables. The main variable in the VAMPAHICA study is cardiovascular disease, including (24): ischaemic heart disease, stroke, heart failure, vascular disease, retinal impairment or advanced retinopathy (AR; cottonwood spot, hard exudates, haemorrhage), renal impairment, sudden death and other cardiovascular diseases such as an aortic aneurysm and hypertensive brain disease. A patient was classified as a smoker if he/she had smoked daily in the previous 6 months. Enough physical exercise was defined as 150 METs (metabolic equivalents) weekly. Healthy physical exercise was defined as higher than 1050 METs a week (150 METs a day). Weekly alcohol consumption higher than 14 standard drink unit (SDUs) (female) or 21 SDUs (male) was considered high-risk consumption.

TOD included: serum creatinine higher than 1.2 and 1.3 mg/dl in women and men, respectively; LVH using Cornell's electrocardiographic criteria modified by Dalfó et al. (25) or Sokolow–Lyon's criteria; MA using the standards of the European Society of Hypertension (14); renal function change with a glomerular filtration rate (GFR) lower than 60 ml/min according to the formulae of Cockroft & Gault (26) and Levey et al. (27); and vascular damage in the retina or mild retinopathy (MR; arteriovenous ratio alteration or focal spasm). In this study the variables included are: gender, age, body mass index (BMI), smoking status, alcohol status, physical exercise, systolic and diastolic BP, systolic and diastolic SBPM, heart rate by SBPM, systolic and diastolic 24-h ABPM, LVH, MA, GFR according to formulae of Cockroft–Gault and Levey et al., EF with MR, EF with AR, and EF any damage.

Statistical analysis

An exhaustive, descriptive statistical analysis was carried out for the entire cohort, for the normotensive

and hypertensive sub-cohorts, and also for the following categorization of the hypertensive sub-cohort: (i) SH and ICH hypertensive; and (ii) different cut-off points for ICH (135/85, 130/85, 130/80 and 125/80).

Mean difference and/or proportions between all these sub-cohorts for the variables of interest was tested using a Student's *t*-test (testing the equality of variances by means of Levene's test) and by a proportions test, respectively.

For the SH (SBPM) patients, the risk of TOD was estimated, by restricted maximum likelihood, using a logistic regression (dependent variable, occurrence or not of any TOD), controlling for gender, age, BMI, smoking status, alcoholism and physical activity. In all models, over-dispersion and heteroscedasticity were controlled for by properly weighting the estimates.

Results

The first 135 patients (95 hypertensive, 40 normotensive) included in the study were analysed. Among them, 37.5% of the normotensive and 62.1% of the hypertensive patients were male ($p=0.009$). Normotensive were older than hypertensive, 59.08 ± 16.8 years old (standard deviation) vs 56.32 ± 10.22, respectively ($p=0.015$). The clinical BP was 125.36 ± 12.75 mmHg (systolic) and 76.74 ± 7.56 mmHg (diastolic) for the normotensive vs 149.81 ± 17.48 mmHg (systolic) and 87.86 ± 11.08 mmHg (diastolic) for the hypertensive ($p<0.0001$). The SBPM figures were 114.90 ± 19.63 mmHg (systolic) and 69.96 ± 11.65 mmHg (diastolic) for the normotensive vs 142.06 ± 14.23 mmHg (systolic) and 86.31 ± 9.94 mmHg (diastolic) for the hypertensive ($p<0.0001$). The ABPM BP figures for the hypertensive were 139.40 ± 8.05 mmHg (systolic) and 86.32 ± 8.18 mmHg (diastolic); and 24-h ABPM was 135.41 ± 7.05 mmHg (systolic) and 81.74 ± 7.79 mmHg (diastolic); 23.10% of the hypertensive had LVH according the defined criteria; 42.26% had some damage in the eye fundus; 36.84% had alterations in the arteriovenous ratio or arterial spasms; and 8.42% had haemorrhage or exudates. The renal function, expressed as GFR, did not present statistically significant differences between normotensive and hypertensive; 3.15% of hypertensive had above normal MA figures (Table I).

In Table II, results corresponding to ICH and SH are shown. Of all hypertensive patients, 29 had ICH (30.53%). There were no statistically significant

Table I. Description of the patients included in the study, normotensive and hypertensive.

	Normotensive	Hypertensive	*p*-value
n (%)	40 (29.6)	95 (70.4)	
Men, *n* (%)	15 (37.5)	59 (62.1)	**0.009**
Age, years (TD[a])	49.08 (16.18)	56.32 (10.22)	**0.015**
BMI[b] (TD)	27.102 (4.987)	28.716 (4.104)	0.086
Tobacco, *n* (%)	5 (12.5)	17 (17.89)	0.438
Alcohol, *n* (%)		24 (25.26)	
Physical activity, *n* (%)		22 (23.16)	
Clinical BP S,[c] mmHg (TD)	125.614 (12.757)	149.810 (17.480)	**<0.001**
Clinical BP D,[c] mmHg (TD)	76.741 (7.566)	87.861 (11.084)	**<0.001**
SBPM S, mmHg (TD)	114.908 (19.637)	142.064 (14.230)	**<0.001**
SBPM D, mmHg (TD)	69.964 (11.657)	86.318 (9.943)	**<0.001**
SBPM Crc[d] (TD)	67.736 (14.360)	71.482 (9.640)	0.089
ABPM day S, mmHg (TD)		139.407 (8.053)	
ABPM day D, mmHg (TD)		86.324 (8.179)	
ABPM 24-h S, mmHg (TD)		135.415 (7.050)	
ABPM 24-h D, mmHg (TD)		81.745 (7.789)	
LVH, *n* (%)		22 (23.16)	
MA, mg/g (TD)		5.014 (9.217)	
Non-normal[e] MA, *n* (%)		3 (4.76)	
GF[f] Cockroft–Gault, ml/min		108.744	
GF Levey, ml/min		100.018	
EF[g] MR[h], *n* (%)		35 (36.84)	
EF AR[i], *n* (%)		8 (8.42)	
EF some damage, *n* (%)		43 (45.26)	

In bold type, statistically significant to 95%. [a]TD, typical deviation; [b]BMI, body mass index; [c]S, systolic, D, Diastolic; [d]Cr, cardiac rate; [e]normal values, <22 mg/g in men and <31 mg/g in women; [f]GF, glomerular filtration; [g]EF, eye fundus; [h] MR, mild retinopathy; [i]AR, advanced retinopathy.

Table II. Hypertensive patients included in the study; patients with isolated clinical hypertension and sustained hypertension (cut-off point 135/85 mmHg).

	Sustained hypertension	Isolated clinical hypertension	*p*-value
n (%)	61 (64.21)	29 (30.53)	
Men, *n* (%)	36 (59.0)	19 (65.5)	0.554
Age, years (TD[a])	57.448 (9.863)	55.708 (9.738)	0.468
BMI[b] (TD)	28.860 (3.827)	28.836 (4.522)	0.979
Tobacco, *n* (%)	8 (13.1)	6 (20.7)	0.354
Alcohol, *n* (%)	18 (29.5)	5 (19.2)	0.320
Physical activity, *n* (%)	13 (21.3)	7 (26.9)	0.569
Clinical BP S,[c] mmHg (TD)	152.517 (13.220)	149.885 (7.206)	0.320
Clinical BP D,[c] mmHg (TD)	89.556 (9.393)	86.345 (8.018)	0.117
SBPM S, mmHg (TD)	147.898 (12.553)	128.177 (15.450)	**<0.001**
SBPM D, mmHg (TD)	88.959 (9.955)	79.776 (10.455)	**<0.001**
SBPM Cr[d] (TD)	72.112 (9.583)	69.598 (12.042)	0.053
ABPM day S, mmHg (TD)	141.729 (5.537)	131.667 (11.590)	0.132
ABPM day D, mmHg (TD)	88.221 (6.657)	80.000 (11.136)	0.759
LVH, *n* (%)	15 (24.6)	5 (19.2)	0.814
MA, mg/g (TD)	4.49	5.56	0.852
Non-normal[e] MA, *n* (%)	2 (4.4)	1 (5.6)	0.646
GF[f] Cockroft–Gault, ml/min	110.844	100.910	0.560
GF Levey, ml/min	105.006	86.729	0.560
EF[g] MR[h], *n* (%)	24 (39.34)	10 (38.46)	0.448
EF AR [i], *n* (%)	6 (9.8)	2 (7.7)	0.560
EF some damage, *n* (%)	30 (49.18)	12 (46.15)	0.291

In bold type, statistically significant to 95%. [a]TD, typical deviation; [b]BMI, body mass index; [c]S, systolic, D, Diastolic; [d]Cr, cardiac rate; [e]normal values, <22 mg/g in men and <31 mg/g in women; [f]GF, glomerular filtration; [g]EF, eye fundus; [h] MR, mild retinopathy; [i]AR, advanced retinopathy.

differences between ICH and non-ICH in gender (65.5% male vs 59.0% male, respectively, $p=0.55$), age (55.7 vs 57.44, $p=0.46$) or BMI (28.83 vs 28.86 kg/m^2, $p=0.97$). There were also no (statistically significant) differences in smoking status, alcoholism and physical exercise.

Clinic BP was higher for SH than for ICH ($152.51\pm13.22/89.55\pm9.39$ mmHg vs $149.88\pm7.20/86.34\pm8.01$ mmHg) although this difference was not statistically significant ($p=0.32$ systolic, $p=0.11$ diastolic). Differences in SBPM figures were statistically significant between ICH and SH ($147.89\pm12.55/88.95\pm9.95$ mmHg vs $128.17\pm15.45/79.77\pm10.45$ mmHg, $p<0.0001$). In the case of the ABPM figures, the differences were not statistically significant ($p=0.132$ for systolic and 0.79 for diastolic).

Fifteen hypertensive with SH (24.6%) and five hypertensive ICH (19.2%) showed LVH according to voltage criteria ($p=0.75$). There were no statistically significant differences in MA figures, both in means (4.49 vs 5.56 mg/g, $p=0.814$) and in the percentages of patients above normality (4.4% vs 5.6%, $p=0.852$); nor in GF computed using the two formulae. Hypertensive ICH patients presented lower EF damage than SH, although the differences were not statistically significant. In particular, any EF damage was 49.18% vs 46.15%; MR 39.94% vs 38.46%; exudates or haemorrhages 9.8% vs 7.7%; 37.77 % of SH hypertensive vs 38.88% of ICH hypertensive did not present any TOD; 37.77% vs 27.77% presented only (and exclusively) EF alteration; 8.88% vs 5.55% presented only (and exclusively) LVH; 11.1% of ICH hypertensive presented only (and exclusively) exudates or haemorrhages (data not shown).

Table III shows the results for different cut-off points in the definition of ICH. The multivariate logistic regression (Table IV) shows that being SH hypertensive increased the risk of an occurrence of any TOD in all the cut-off points, whereas BMI was negatively associated with this risk. Note also that, for ICH hypertensive, the risk of an occurrence of any TOD decreased with the cut-off points (Figure 1).

Discussion

Results from the first 135 patients included in the VAMPAHICA study show that the prevalence of ICH was 30.53%, presenting no differences for age, gender, BMI, smoking status, alcohol or physical exercise. Other studies, however, show that ICH patients were predominantly women, elderly, non-smokers, with a high BMI and lower ICH (28,29), although some authors report other results (30). The results of the current paper could be explained by

Table III. Variables according to the different cut-off points for isolated clinical hypertension.

	130/85 mmHg			130/80 mmHg			125/80 mmHg		
	SH	ICH	*p*-value	SH	ICH	*p*-value	SH	ICH	*p*-value
n (%)	70 (73.68)	20 (21.05)		74 (77.89)	16 (16.84)		83 (92.22)	7 (7.77)	
Men, *n* (%)	49 (57.10)	12 (60.0)	0.820	43 (58.10)	7 (43.80)	0.891	47 (56.6)	5 (71.5)	0.446
Age, years (TD[a])	57.27 (9.69)	53.93 (10.66)	0.240	57.19 (9.76)	53.58 (10.49)	0.246	56.9 (9.8)	53.7 (11.2)	0.445
BMI[b] (TD)	29.27 (4.25)	28.47 (3.36)	0.454	29.21 (4.15)	28.54 (3.72)	0.567	29.1 (4.1)	28.5 (3.7)	0.692
LVH, *n* (%)	10 (26.5)	2 (13.3)	0.377	19 (26.4)	1 (9.1)	0.251	20 (25.0)	0	0.282
Non-normal[c], MA, *n* (%)	3 (4.2)	0	0.476	3 (4.05)	0	0.344	3 (3.61)	0	0.053
EF[d] MR,[e] *n* (%)	29 (41.43)	4 (20.0)	0.079	30 (40.54)	3 (18.75)	0.101	33 (39.75)	0	**0.036**
EF AR,[f] *n* (%)	8 (11.43)	0	0.113	8 (10.81)	0	0.168	8 (9.64)	0	0.389
EF some damage, *n* (%)	37 (52.86)	4 (20.0)	**0.009**	38 (51.35)	3 (17.75)	**0.018**	41 (49.40)	0	**0.012**

In bold type, statistically significant to 95%. [a]TD, typical deviation; [b]BMI, body mass index; [c]normal values, <22 mg/g in men and <31 mg/g in women; [d]EF, eye fundus; [e]MR, mild retinopathy; [f]AR, advanced retinopathy.

some factors. First, the definition of ICH was based on SBPM and not on ABPM like in other studies; and second, the small sample size could have reduced the statistical power of this study.

There were no differences between SH and ICH groups in relation of the presence of TOD. It is accepted that SBPM presents a higher correlation with TOD (LVH by echocardiogram and by ECG, MA, intima-media thickness and alteration in EF than clinic BP) (3,31,32). However, there are no studies relating diagnosed ICH by SBPM with the occurrence of TOD, since all studies use ABPM instead. Results from this study show that there is no relationship between ICH and MA, although there were some differences in the presence of LVH by ECG and in the occurrence of EF, which were not statistically significant. These results coincide with those of Pose-Reino et al. (33) who, even using ABPM to define ICH, did not find differences in the presence of LVH and in EF damage between SH and ICH patients. This deserves further investigation in our study.

Table IV. Risk of showing some target organ damage (TOD).[a]

	RR (IC 95%)	*p*-value
Sex (men)	0.74 (0.04–21.07)	0.496
Age	0.99 (0.22–2.47)	0.315
BMI	**0.29 (0.07–1.26)**	**0.050**
Tobacco	1.48 (0.35–6.12)	0.291
Alcohol	0.66 (0.19–2.32)	0.261
Physical activity	0.93 (0.29–3.03)	0.457
SH (SBPM)	**3.98 (0.79–19.90)**	**0.045**

Reference category between brackets. In bold type, statistically significant to 95%. BMI, body mass index; SH, sustained hypertension; SBPM, self-blood pressure monitoring. [a]Left ventricular hypertrophy, microalbuminuria, eye fundus, any damage. Multivariate analysis (probability of a likelihood ratio test) of the risk of showing some TOD adjusted to sex, age, BMI, tobacco, physical activity and showing sustained hypertension (SH).

The frequency of the occurrence of TOD is very variable, however, the results of our study are comparable with those of others carried out with hypertensive patients of similar ages (46 years old) (33), with an LVH (by ECG) prevalence of 21.6% and any *retinopathy* of 45.1%. Other studies found a MR prevalence in the range 42.4–55% (34,35). Particularly noteworthy is the frequency of exudates or haemorrhages in this study (8.42%), which coincided with the results of a recent revision (36) (7–9.9%). The presence of these damages (exudates or haemorrhages) represents a very important increase in cardiovascular risk (37) and provides decision-making elements for the treatment of the HT. In fact, it shows the necessity of beginning pharmacological treatment, whether ICH or not, firmly to control the BP. A high percentage of ICH patients presented TOD (61.12%), either retinopathy of any degree or LVH. Therefore, it is necessary to make an initial assessment of all hypertensive patients, whether ICH or not. In particular, it would be convenient if this assessment included an EF test, since the presence of retinopathy with exudates or haemorrhages (8.42% of hypertensive, 7.7% of ICH) would identify a higher cardiovascular risk group.

The lack of differences in the prevalence of TOD between SH and ICH could be attributed to the fact that the situation of ICH is not as benign as was thought and that current figures would not be very discriminate for the ICH condition. Results of the current study show that a cut-off point of 135/85 mmHg does not discriminate for the presence of any TOD in SH patients. The cut-off point of 130/85 mmHg discriminates the presence of some EF damage and the cut-off point 125/80 mmHg puts all

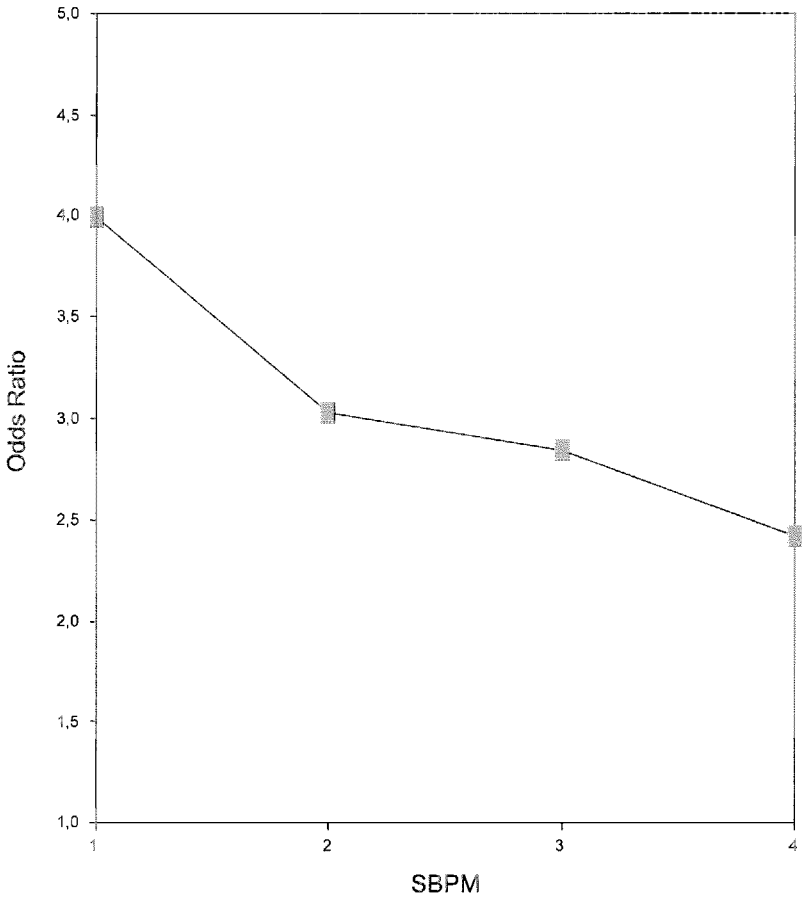

Figure 1. Risk of suffering some target organ damage (eye fundus, left ventricular hypertrophy and/or microalbuminuria) with respect to normotensive patients. Self-blood pressure monitoring (SBPM) 1=135/85; SBPM 2=130/85 mmHg; SBPM 3=130/80 mmHg; SBPM 4=125/80 mmHg.

TOD, including LVH, in the SH group. It is important to point out that severe EF damage, exudates or haemorrhages, were only present in SH patients with the 130/85 mmHg cut-off point.

Depending on the location of the cut-off point, sensitivity, specificity and predictive value would vary and directly influence the diagnosis of ICH. In fact, a preferable ICH definition would be based on the probability that the patients included in this group would not have a prevalence nor an incidence of TOD and a low incidence of cardiovascular disease. Recent results from the PAMELA study (38), using survival curves estimated by Kaplan–Meier, show cut-off points that are lower than those accepted nowadays (39): 122.5/76 mmHg for SBPM; 119/73.5 mmHg for 24-h ABPM; 124/78.5 mmHg for daily ABPM and 109/64.5 for nightly ABPM. This finding agrees with those of other authors (40) with reference to the possibility of revision of the cut-off points for normality of ambulatory BP.

The lower the cut-off point, the lower the sensitivity to detect ICH, and the higher the specificity. In other words, although the positive predictive value improves, the negative one decreases. The last WHO report (1) recommends a threshold of 125/80 mmHg, whereas the figures are 135/85 in the European (14) and the American Guidelines. This difference in the figures is due to the distinct method used to compute it in each case. The PAMELA study (41) used a regression of SBPM figures on clinical BP and obtained a 95% confidence interval of 124/79–130/83 mmHg. The upper figures of this interval were slightly different from those obtained by meta-analysis (42) of the 95th percentile figures (135/86 mmHg). Both methods have some limitations and more recent revisions recommend a threshold of 135/85 mmHg (29,37). It seems that figures below 130/80 mmHg correspond to normotension and figures above 135/85 mmHg to HT. Intermediate figures, 130–135/80–85 mmHg, are in a limit situation, leaving the decision of

diagnosis to the physician. The HOMED study, finishing in 2012, will provide information about the threshold of BP obtained by SBPM in order to begin pharmacological treatment against HT (43).

This current study has some limitations. First, the sample size is reduced as a consequence of the first step of the follow-up. Second, patients were included based on the detection of hypertensive patients in the physician's office or in the infirmary. This could lead to a selection bias. However, most of the population participating in the study are rural or semi-urban, and, therefore, most of them consult with their referring physician or nurse when they have health problems.

For a lot of physicians and patients, the ABPM is not a very accessible procedure, requiring skilled personnel and costly tools, whereas the SBPM is a simpler procedure, very easy for most primary healthcare physicians and less costly. If, as most of the studies show, SBPM is useful in the diagnosis of ICH and the predictive value of SBPM is similar to that of ABPM, SBPM could be generalized to all primary healthcare consultations, improving the diagnosis of hypertensive patients and the decision-making process concerning their care.

In conclusion, the VAMPAHICA is a cohort study, the results of which will provide information about the value of SBPM in the diagnosis of ICH, relating this diagnosis with the TOD and cardiovascular disease incidence and comparing it with normotensive and maintained hypertensive patients. The study will also determine if ABPM and SBPM have a similar predictive value. Results presented in this paper show the presence of TOD in both groups, in particular AR, which implies doing a careful initial assessment that would include EF exploration. This study shows that if TOD is accepted as a surrogate endpoint, the definition of ICH using the SBPM cut-off point proposed by the WHO (1), 125/80 mmHg, allows this group to be defined at lower cardiovascular risk, since they presented a lower TOD prevalence. All these results will define the role of SBPM in the decision-making process about hypertensive patients and, if the case, to implement measures that improve the access to this technique by healthcare professionals.

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