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PROPOSAL FOR A SYSTEM OF ASSESSMENT AND DIAGNOSIS OF ESSENTIAL HYPERTENSION IN PRIMARY HEALTH SERVICES

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Psychological treatment for essential hypertension (HT) currently relies on standardised guidelines for evaluation and diagnosis used in primary health care. These guidelines allow the diagnosis of HT according to three abnormally high measurements of blood pressure taken in the clinic. Around 20-30% of HT-diagnosed patients do not exhibit high pressure outside the clinic (isolated clinic HT), and may thus receive unnecessary treatment. A system for the evaluation and diagnosis of mild HT is suggested, based on a combination of clinic and non-clinic blood-pressure measurements. By distinguishing between sustained HT and isolated clinic HT with different levels of cardiovascular risk, this system allows more rational planning of monitoring and treatment. After reviewing its advantages and limitations, self-measurement by an automatic electronic sphygmomanometer is suggested as the best choice to obtain non-clinic blood-pressure measurements in the primary health care context.

El tratamiento psicológico de la hipertensión arterial (HTA) esencial descansa actualmente en los protocolos estandarizados de evaluación y diagnóstico seguidos en atención primaria. Con ellos se diagnostica la HTA atendiendo a tres medidas de presión arterial anormalmente altas obtenidas en la consulta. El 20-30% de los pacientes con HTA así diagnosticada no muestran presiones altas fuera de la consulta (HTA clínica aislada) y pueden recibir un tratamiento innecesario. Se propone un sistema de evaluación y diagnóstico de la HTA leve basado en la combinación de medidas clínicas y no clínicas de presión arterial que permite programar más racionalmente las actuaciones de vigilancia y de intervención al distinguir entre HTA mantenida y HTA clínica aislada con distintos niveles de riesgo cardiovascular. Tras revisar sus ventajas y limitaciones, se sugiere que la mejor opción para obtener las medidas no clínicas en atención primaría es la automedición mediante un esfigmomanómetro electrónico automático.

INTRODUCTION

In Spain, as in many other Western countries, arterial hypertension (HT) represents the most frequent reason for consulting a doctor of all chronic pathologies dealt with by the primary health services (Pardell, 1984). The sociosanitary importance of HT is based fundamentally on two facts: (1) its role as a risk factor for the appearance of cardiovascular disorders, disorders that represent the main cause of death in the developed countries (for example, the risks of congestive heart failure and cerebral ateriothrombosis are, respectively, six and ten times higher in persons with HT than in those with normotension; García-Vera and Sanz, 2000), and (2) its high frequency in the population (it is calculated that 20-30% of Spain's adult population suffers from hypertension; Pardell, 1988).

In 90-95% persons suffering from HT, their high blood pressure cannot be directly attributed to any organic anomaly or dysfunction. In these cases we can speak of *essential hypertension*, and there are sufficient data to affirm that psychological factors play an important role in its development, either through behaviours associated with certain physical factors related to HT, such as obesity, lack of physical exercise, alcohol abuse and the excessive consumption of salt in the diet (see Blanchard, Martin and Dubbert, 1988), or through the effects of stress on the cardiovascular system (see Stainbrook, 1988). Thus, people's behaviour and their response to different life situations lead to increases in blood pressure which, as a function of individual predispositional variables, may persist over time, resulting in essential

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HT. These data help to explain the interest aroused by this disorder among clinical and health psychologists. However, another fact that has fomented this interest is that the use of pharmacological treatments for patients with mild essential HT is being questioned, since the trade-off between costs, risks and benefits does not fully justify such a policy, in contrast to the case of patients with moderate, severe or very severe essential HT (Schechter, 1990). For example, the UK's Medical Research Council (MRC, 1981, 1985) carried out a study in which 18,000 hypertension patients with diastolic pressure levels between 90 and 109 mmHg (mild HT) were randomly assigned to treatment with drugs or with placebo. The results were disappointing. The antihypertensive medication had no positive effect on the incidence of coronary conditions, and only slightly reduced the risk of cerebral ateriothrombosis (it was calculated that 850 patients would have to receive treatment for a year to prevent a single case of thrombosis). Moreover, apart from the high financial cost of the medication, this type of treatment had serious negative consequences for the participants: 20% of patients receiving pharmacological treatment suffered side-effects, such as impotence, lethargy or vertigo, and a greater number of women died in the group of patients that took the antihypertensive drug than in the placebo group (MRC, 1981).

In sum, the presence of behavioural elements in the etiology of essential HT, as well as doubts about the appropriateness of administering antihypertensive medication to patients with mild essential HT (who represent 67-81% of all cases of HT; García-Vera and Sanz, 2000), explain why many professionals and researchers from the fields of clinical and health psychology have devoted their efforts to the evaluation and treatment of this disorder.

STANDARD PROCEDURE OF BLOOD-PRESSURE MEASUREMENT FOR THE DIAGNOSIS OF ESSENTIAL HYPERTENSION

In Spain, several studies have been published on the antihypertensive effectiveness of different psychological interventions, especially the cognitive-behavioural type (Amigo, Buceta, Becoña and Bueno, 1991; Amigo, González and Herrera, 1997; García-Vera, Labrador and Sanz, 1997; Germán et al., 1994; González and Amigo, 1993; Grzib, Fernández-Trespalacios, Ortega and Brengelmann, 1989; Miguel-Tobal, Cano, Casado and Escalona, 1994). In all of these studies, the therapeutic decision on essential HT was taken according to the diagnostic protocols currently applicable in the primary health care services. These protocols are based on the normality or abnormality of at least three blood-pressure averages, these being obtained from measurements carried out in a clinic context by a doctor or nurse on three separate occasions over a period of between two and three months, and in accordance, if possible, with a standard procedure that consists in taking "two readings [of blood pressure] and averaging the values if the difference between the two does not exceed 5 mmHg; if the difference is in excess of this figure, a third reading is taken after a few minutes and the average of the measures calculated" (Ministry of Health and Consumer Affairs, 1990, p. 29). The reason why these averages serve as diagnostic criteria is that they are supposedly representative of the patient's blood-pressure level in any other situation and at all times. If the figures are high it is inferred that the individual's usual blood-pressure level is high and, consequently, treatment is administered to reduce it. Specifically, the most widely-accepted criterion in the case of adults is that when blood-pressure levels recorded in the clinic situation are lower than 140/90 mmHg, the diagnosis is *normotension*; in the contrary case *hypertension* is diagnosed, and therapeutic intervention prescribed (see Table 1).

However, more and more research results (cf. the reviews by Pickering, 1991, 1995; see also Table 2)

TABLE 1
Diagnosis of hypertension according to clinic blood-pressure values in persons over 18 years of age

Diagnosis	Systolic pressure (mmHg)		Diastolic pressure (mmHg)
JNC-VI (1997, p. 11)			
Optimum	< 120	and	< 80
Normal	< 130	and	< 85
Normal high	130-139	or	85-89
Hypertension			
Stage 1 (mild)	140-159	or	90-99
Stage 2 (moderate)	160-179	or	100-109
Stage 3 (severe)	≥ 180	or	≥ 110
WHO/ISH (1993, p. 909)			
Normotension	< 140	and	< 90
Mild hypertension	140-180	and/or	90-105
Subgroup: Borderline hypertension	140-160	and/or	90-95
Moderate and severe hypertension	≥ 180	and/or	≥ 105
Isolated systolic hypertension (ISH)	≥ 140	and	< 90
Subgroup: borderline ISH	140-160	and	< 90

Note: JNC-VI: Sixth Report of the Joint National Committee on the Detection, Evaluation and Treatment of High Blood Pressure (USA); WHO/ISH: World Health Organisation/International Society of Hypertension.

coincide in indicating that, given the variability inherent in blood-pressure levels, the standard procedure for the measurement and diagnosis of HT leads to a large number of diagnostic errors. In fact, blood pressure is in continual variation, due to the presence of intrinsic rhythms related to the functioning of bodily systems (e.g., breathing, sleep cycles, seasonal cycles), on which are superimposed changes linked to an enormous number of factors linked to people's physical and mental activity, and which affect blood pressure in the short, medium and long term (e.g., posture, exercise, mood, ingestion of food and drink, smoking, or external stimuli). Consequently, the measurement of blood pressure is an attempt to estimate a person's usual or "true" pressure, that is, "the mean pressure level (a person presents) over a long period of time, around which short-term fluctuations occur" (Pickering, 1991, p. 17).

Empirical studies indicate that, probably due to this spontaneous variability of the blood pressure and to the peculiar physical and psychological circumstances involved in medical consultation, blood-pressure readings taken in the clinic context are not as representative of a person's "true" blood pressure as we might expect. By way of an example, it is sufficient to cite the study carried out by Pickering, James, Boddie, Harshfield, Blank and Laragh (1988), with 292 patients that had been diagnosed as borderline essential HT cases (diastolic pressures between 90 and 104 mmHg) using the standard clinical procedure. The blood pressure of these people was measured over a 24-hour period in different home and work situations using automated ambulatory devices that took readings every 15-30 minutes. After calculation of the average of these readings it was found that 21% of the patients presented diastolic and systolic blood pressures recorded over the 24 hours that were well below the value set by these researchers as the boundary between hypertension and normotension (134/90 mmHg, a value corresponding to percentile 90 of the diurnal pressures obtained in a group of 37 normal volunteers). This condition of discrepancy between a normal blood-pressure average calculated from measures taken outside the clinic and an abnormally high average obtained from multiple readings taken in the clinic context is called *white coat hypertension*. As Table 2

TABLE 2
Prevalence of isolated clinic hypertension (IC-HT) according to different diagnostic criteria among the population with clinically-diagnosed hypertension

Study	N	Criterion of hypertension for clinic blood pressure (SBP/DBP in mm/Hg)	Criterion of normotension for non-clinic blood pressure (SBP/DBP in mm/Hg)	Prevalence of IC-HT (%)
International				
Floras et al. (1981)	59	>140/90	>140/90	34
Waeber et al. (1984)	245	DBP > 90	DBP > 90	61
Pickering et al. (1988)	292	90 < DBP < 104	< 134/90	21
Zachariach et al. (1988)	168	DBP > 90	DBP > 90	35
Krakoff et al. (1988)	60	140/90 < BP < 180/104	< 130/85	38
Siegel et al. (1990)	83	140/90 < BP < 180/104	< 130/85	24
Khoury et al. (1992)	131	DBP > 90	DBP < 85	34
Hoegholm et al. (1992)	159	DBP > 90	DBP > 90	25
Gosse et al. (1994)	229	SBP ≥ 140	SBP < 135	28
		DBP ≥ 90	DBP < 85	14
Verdecchia et al. (1992)	346	DBP ≥ 90	< 136/87 M; < 131/86 F	12
			< 134/90	16
Palatini et al. (1997)	942	140/90 < BP < 159/99	< 130/80	16
			< 135/85	35
Spain				
Mora y Ocón (1991)	95	DBP > 90	DBP > 90	38
Hernández et al. (1995)	106	90 < DBP < 104	<134/90	46
Vinyoles y de la Figuera (1995)	164	≥ 149/90	< 135/85	23
Márquez et al. (1996)	102	140/90 < BP < 180/109	< 135/85	36
Mayoral et al. (1996)	91	≥ 140/90	< 135/85	30
López et al. (1997)	331	> 140/90	< 135/85	23
Llisterri et al. (1997)	60	≥ 140/90	< 130/80*	8
Pascual et al. (1997)	115	≥ 140/90	< 140/90*	41

Note: All studies used automated ambulatory devices for monitoring blood pressure over 24 hours (without taking into account the values obtained during the night), except for those marked with an asterisk, which used self-measurement procedures. M = males; F = females.

shows, this is a phenomenon invariably found in research on HT comparing clinic and non-clinic measures of blood pressure, and whose prevalence ranges between 8% and 61% of patients with essential HT (mean 29%). Although the term *white coat hypertension* is the most frequent in the scientific literature and in professional practice, recently several researchers (e.g., Mancia and Zanchetti, 1996) and the World Health Organisation (WHO) (1996) itself have proposed the term *isolated clinic hypertension* (IC-HT), in an attempt to highlight the fact that the precise etiology of the phenomenon is not known, and to distinguish it from another quite similar condition, the *white coat effect*. It is the intention of the present work to reflect the authors' support for these initiatives.

Measurement of the blood pressure carried out by medical personnel in a clinic context can trigger an alerting reaction in the patient that results in transitory increases in both blood pressure and heart rate (Mancia et al., 1983, 1987). This transitory increase in blood pressure in the clinic measurement situation is known as the *white coat effect*. The phenomenon is related to the individual's patterns of orientation and defence, and appears with reasonable frequency both in people with normotension and those with hypertension. Blood pressure rises to a peak during the first 4 minutes of the consultation, usually maintains that level for some 10 minutes, and falls in successive readings as the patient becomes accustomed to the measurement procedure and the clinic context itself (Mancia et al., 1983, 1987).

The confusion between IC-HT and white coat effect is due to at least two factors. The first is that many researchers consider IC-HT to be a special case of white coat effect in which the increased-blood-pressure response does not disappear (i.e., the subject does not become accustomed to the situation), persisting despite numerous repetitions of the clinic measurement (and at different times) following the standard protocols of HT diagnosis referred to above. This lack of habituation, which could be explained in terms of classical conditioning and incubation theory, would be reflected in a discrepancy between clinic and non-clinic measures of blood pressure, and hence the term white coat hypertension (Amigo, 1994; Pickering, 1991; Pickering and Friedman, 1991). Although it is likely that this is one of the causes of differences between clinic and non-clinic blood-pressure measures, various studies have suggested that other factors related to the mechanisms determining usual levels of blood pressure are involved, so that the term IC-HT does more justice to the current state of knowledge about the causal mechanisms of these differences (Parati et al., 1998). The second reason is that the difference between clinic and non-clinic measures of blood pressure is frequently used as an indicator of white coat effect (for example, a difference between clinic blood pressure and diurnal pressure obtained with ambulatory device of at least 20 mmHg in systolic pressure and/or 10 mmHg in diastolic pressure; Myers, Oh and Reeves, 1991), though it is not clear that this index accurately reflects the pressure-increase alarm response induced in the patient by clinic measurement, since, for example, it never appears associated with a systematic difference between clinic and non-clinic readings of heart rate (Mancia and Zanchetti, 1996; Parati et al., 1998).

The clinical importance of IC-HT lies in the fact that its sufferers appear to have lower cardiovascular morbidity and mortality rates than patients with *sustained hypertension* (patients that present both blood-pressure averages, clinic and non-clinic, over the limit considered as normal), and are therefore, at risk of receiving unnecessary treatment that may involve considerable side-effects. Thus, for example, Pickering's research team, after observing a group of 739 patients with HT for an average period of 5 years, found a cardiovascular morbidity of only 2.1% in patients with IC-HT, as against the 4.4% observed in the patients with sustained HT (Pickering, 1991). Likewise, other studies have shown that IC-HT patients: (1) present, in the long-term, a cardiovascular morbidity similar to that of people with normotension and lower than that of patients with high diurnal ambulatory pressures (Verdecchia et al., 1994), and (2) do not present structural or functional organic disorders related to HT (White et al., 1989; Verdecchia et al., 1994). Nevertheless, with respect to this last point, the scientific literature also includes some studies demonstrating that IC-HT patients present certain initial signs and symptoms of organic disorders, as well as other cardiovascular risk factors, that make their risk profile closer to that of patients with sustained HT than to that of persons with normotension (Julius et al., 1990; Hoegholm et al., 1994). This disparity of results is due in part to the choice of different limits of normality for non-clinic blood-pressure values (the higher the limit, the greater the probability of including, among patients with IC-HT, patients with organic disorders due to HT, and vice-versa). Using the limits currently most frequently accepted (around 135/85 mmHg; we shall subsequently explain the reasons for this figure), the results of the most

methodologically correct studies (i.e., those that have compared simultaneously IC-HT and sustained HT patients with persons presenting normotension, using sufficiently large samples and appropriate clinic and non-clinic measurement procedures) appear to indicate that, in general, although IC-HT patients may have a higher level of hypertensive complications than people with normotension, they nevertheless present fewer organic disorders than patients with sustained HT (e.g., Palatini et al., 1997). These results, moreover, coincide with those of the few existing prospective studies, which, as mentioned above, indicate lower cardiovascular morbidity among IC-HT patients than among those with sustained HT (Pickering, 1991; Verdecchia et al., 1994).

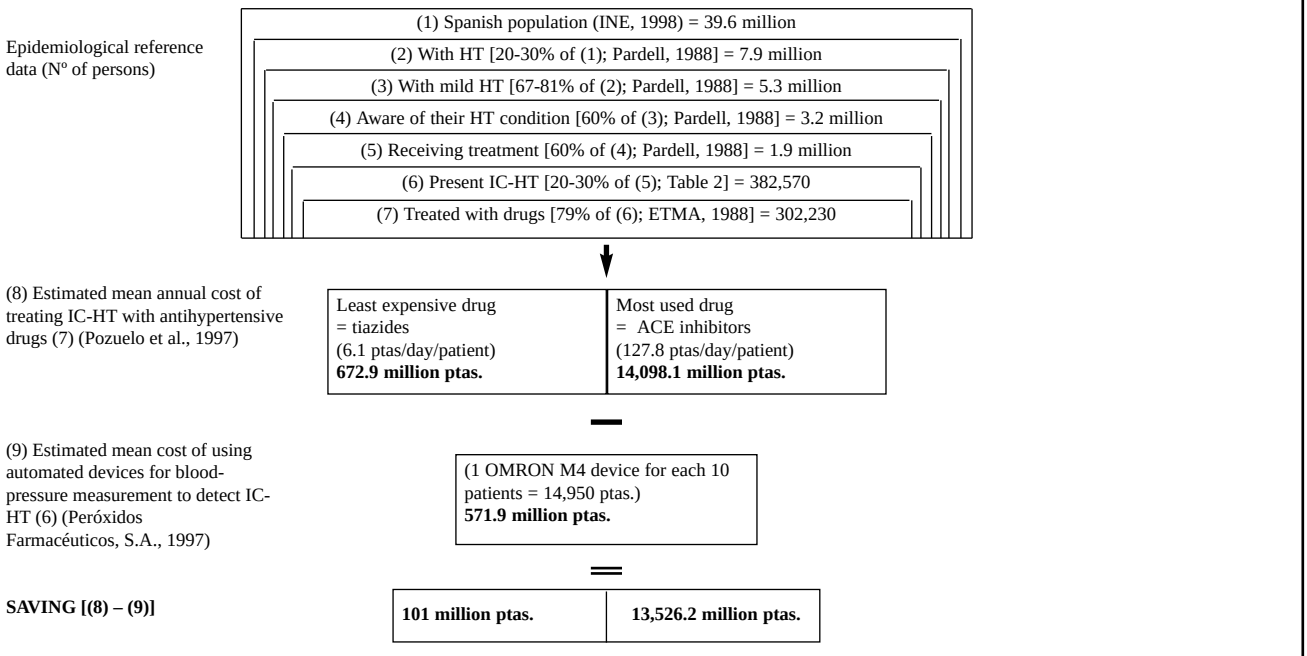
In sum, although the prevalence of IC-HT varies according to the criteria used to define the clinic and non-clinic limits of blood-pressure normality, from the data in Table 2 it can be seen that both in Spain and in other Western countries there are 20-30% of patients diagnosed as mild or stage 1 HT in whom the clinic readings of blood pressure are not representative of their blood pressure in other everyday-life situations, which is below the limit that defines HT for non-clinic measurements. These persons are not in a cardiovascular morbidity/mortality high-risk group, but in the majority of cases they are receiving unnecessary long-term treatment chronic that has serious side-effects and is very costly (see Figure 1).

PROPOSAL FOR A PROCEDURE OF BLOOD-PRESSURE MEASUREMENT IN PRIMARY HEALTH CARE

Given that the problem of the representativeness of clinic blood-pressure readings is a key factor in the diagnosis of essential HT, in the present work we propose some changes in the system of blood-pressure measurement and in the diagnosis of HT, with the intention of improving the standard procedure used in primary health care, that is, the procedure used at the health service level at which essential HT is detected and at which the majority of, if not all, persons with HT receive attention. This procedure is based on the combined use of clinic and non-clinic blood-pressure measurement, and it is proposed that the latter be obtained through a measurement by the patients themselves (self-measurement), reserving measurement procedures using automated ambulatory devices for the specialised health services.

FIGURE 1

Estimation of pharmacological saving attainable in Spain in a single year through the use of self-measurement of the blood pressure to detect, among patients initially diagnosed as mild (stage 1) hypertensives by the standard clinical procedure, cases of isolated clinic hypertension (IC-HT), which in principle do not require pharmacological treatment.



The renunciation of these last-mentioned procedures is attributable, in the first place, to questions of viability: their cost in terms of equipment –each device may cost between 500,000 and 1 million pesetas–, qualified technical personnel and time is far in excess of what primary health care centres can currently bear. Secondly, these procedures are not exempt from criticism in terms of their validity for representing a person's usual or "true" blood pressure. Automated ambulatory devices taking readings over 24 hours provide a blood-pressure average calculated from 48-72 readings taken in a single day, an average which *a priori* is a good indicator of the person's usual blood-pressure. However, there remains the possibility that sometimes the average is the result of pressures that are continually changing due to certain stimuli and situations that generate significant fluctuations in blood pressure on the day of measurement. If such fluctuations go unperceived, the average obtained will not be representative of the average that would be obtained on any other day, and therefore, these fluctuations will have affected the estimation of the individual's "true" blood-pressure. A large number of readings will count for little if we do not know what they represent. Consequently, in order to safeguard the construct validity of the measurement procedure, it is important to use self-records of the activities carried out by the subject while attached to the ambulatory device, so that we can discriminate between when the measurement represents a stable average and when it represents the response of blood pressure to one or more specific situations.

The problems caused by this lack of control have been demonstrated in a number of studies. For example, Pickering, Harshfield, Kleinert et al. (1982) automated ambulatory devices to take readings over a 24-hour period and compare, in a group of patients with essential HT, the blood-pressure measures taken at home with those taken in the workplace. The results showed the readings taken at work to be considerably higher than those taken in the home, with approximately 5/4 mmHg of difference between them, so that they could not be used for estimating the subject's baseline blood-pressure level. It was hypothesised that the workplace pressures were the result of a continual stress response, and the changes were attributed to emotional factors. Nevertheless, subsequent research on the roles played separately by "place" (work) and "physical activity" (posture) showed that the majority of the variance in blood pressure was attributable to the "physical activity" –specifically to the posture (standing up). By controlling posture, the difference between the home and work situations was reduced to just 2/2 mmHg (Pieper, 1990, cited in Pickering, 1991). Various studies have supported the hypothesis that posture can increase differences between the averages of different situations, such as home and work, when readings –taken over 24 hours– from automated ambulatory devices are compared (Gellman et al., 1990; Llabre, Ironson, Spitzer, Gellman, Weidler and Schneiderman, 1988). For this reason researchers stress the need to control for behaviours that cause transitory increases in blood pressure, especially posture and activity level. Given the above considerations, blood-pressure averages over 24 hours are to be taken from those times when the subject is at rest, thus avoiding variability due to physical activity or other behaviours. Reducing the effects of these interferences contributes to improving the construct validity of this form of blood-pressure measurement. In this same line, some recent studies have suggested that to obtain a representative measure of a subject's usual blood pressure it is more appropriate to take fewer readings over longer periods than more readings over short periods (Pickering, 1991; Llabre et al., 1988). Thus, the use of automated ambulatory devices could be optimised by reducing the 24-hour periods but extending the monitoring over a number of days or weeks. In view of the above arguments, it would appear obvious that the self-measurement of blood pressure represents the best option in practice, since it greatly facilitates the sampling of a larger number of situations over several days or even weeks. Apart from this *a priori* advantage of self-measurement as opposed to clinic measurement or 24-hour automated ambulatory devices, several other advantages have been identified in the empirical literature, and we shall continue by considering some of these.

Advantages of self-measurement of the blood pressure

1. *Greater reliability than clinic measures*. Given that self-measurement allows us to obtain a greater number of readings, and that these are not affected by the errors and biases inherent in the standard clinical procedure (mainly those related to the white coat effect), blood-pressure readings obtained through self-measurement tend to present greater temporal reliability and reproducibility than those obtained in the clinic or surgery. For example, García-Vera, Labrador and Sanz (in press) obtained three clinic

readings using the standard clinical procedure from a group of 43 patients with essential hypertension who were also asked to self-measure their blood pressure three times a day (twice at home and once at work), over 16 days, by means of an oscillometric device. With the same number of self-measurements as clinic ones (in both cases 6-9 readings), the reliability of the former was higher than that of the latter, both in terms of test-retest correlations at 2 months (self-measurements =.83/.87; clinic measurements = .62/.32) and in terms of intra-category reproducibility coefficients in multiple readings (self-measurements = .74/.78; clinic measurements = .37/.52). Moreover, these differences were evident both among patients with sustained HT and among those with IC-HT. Similarly, Sakuma, Imai, Nagai et al. (1997) found, in a group taken from the general population, that the reliability of self-measurements was greater than that of clinic measurements, as indicated by higher test-retest correlations at one year (self-measurements =.84/.83; clinic measurements = .69/.57) and by lower standard deviations of the differences between measurements over the same period (self-measurements = 7.66/5.53; clinic measurements = 13.84/10.24).

Furthermore, there are data indicating that self-measurements of blood pressure are more reliable than clinic ones in terms of concordance with direct readings taken by means of intra-arterial procedures (e.g., Kjeldsen, Moan, Petrin, Weder, Zweifler and Julius, 1993).

2. *Greater validity than clinic measures*. With self-measurement it is possible to obtain a greater number of blood-pressure readings in more varied and representative conditions of a patient's everyday life than with the standard procedure carried out in the clinic or surgery context; it would therefore seem logical to expect self-measured readings to be more valid for evaluating a person's usual or "true" blood pressure. In this respect, empirical research has indeed shown self-measured pressures to present higher indices of criterion validity (both concurrent and predictive) and convergent validity than those of clinic readings.
3. *Better concurrent criterion validity*. Several studies have indicated that self-measurements more closely reflect the effects of HT on the organs than clinic measurements (Ibrahim et al., 1977; Kleinert et al., 1984; Verdecchia et al., 1985). Likewise, research that has examined predictive criterion validity shows that self-measurements are more closely related to future risk of sustained HT (Nesbitt et al., 1997), of thrombosis mortality (Sakuma, Imai, Tsuji et al., 1997), and of general mortality (Tsuji et al., 1997). Finally, the studies by Comas et al. (1998) or Kleinert et al. (1984), to cite just two examples, coincide in indicating that self-measurements of blood pressure present high and statistically significant correlation and concordance indices with respect to measures obtained by means of automated ambulatory devices (24-hour monitoring), and that these indices are higher than those presented by clinic measures, thus lending empirical support to the greater convergent validity of self-measurements.
4. *Facilitates assessment of treatment effectiveness*. This is the case not only because self-measurement permits us to obtain, as we have seen, more reliable and valid readings than those obtained with clinic measurement, but also because measurement can be repeated more easily at different points in the day over long periods (e.g., 3-8 weeks), which represents a clear advantage for therapeutic monitoring, even by comparison with procedures that use ambulatory instruments taking automatic readings over 24 hours. Thus, from the point of view of drug treatments, self-measurement makes it possible: (a) to gauge the initial dose more easily, which helps to avoid negative effects of overdoses, and (b) to estimate the duration of the effects of different drugs, and therefore to customise the treatment, and even to determine the most appropriate time for its administration (Ménard, Chatellier; Day and Vaur; 1994; Mengden, Weisser and Vetter, 1994). Although in the case of cognitive-behavioural treatments there are no empirical data to support the advantages of self-measurement, it seems logical to assume that it is the most appropriate procedure for evaluating the generalisation to different moments and situations of the abilities learned during the therapy.
5. *Improves adherence to treatment by the patient*. Self-measurement of the blood pressure, as in general all self-monitoring procedures (Meichenbaum and Turk, 1991), not only encourages patients to participate more directly in the control of their disorder and increases their level of autonomy with respect to health services –it also increases patients' level of fulfilment of therapeutic prescriptions. If adherence to such requirements is problematic in view of the

disorder itself, it becomes even more so when these involve inconvenient preventive measures. It is unsurprising, therefore, that in a disorder such as HT, in which the high blood pressures are not accompanied by specific symptoms except when it develops into a chronic and severe condition, non-fulfilment of therapeutic regimes (e.g., failure to attend consultations, to comply with dietary recommendations or physical exercise programmes, to take the prescribed medication or observe correct dosage/frequency, to participate in health education programmes, or to carry out in-home tasks required by cognitive-behavioural programmes) is considered the norm rather than the exception. It is estimated that 50% of HT patients fail to adhere to their doctor's advice, and that over 50% cease to take health precautions within the year (Vetter, Ramsey, Luscher, Schrey and Vetter, 1985). Given the magnitude of the problem, any procedure that improves adherence to antihypertensive therapy is of incalculable value. In this regard, there are data confirming that the self-measurement of blood pressure not only increases adherence to treatment requirements, but that it is far more effective in this respect than doctor-patient conversations about the details of the treatment regime. Magometschnigg and Hitzenberger (1997), on comparing the two procedures in a sample of 301 patients with HT, found that 80% of the patients that had self-measured their blood pressure presented a level of adherence to the prescribed treatment regime of 80% or higher, whilst this degree of fulfilment was achieved by only 40% of the patients that had simply had a conversation with their doctor about the treatment requirements. It should be pointed out that 80% adherence to a pharmacological treatment regime is considered as a minimum for effective normalisation of blood pressure (Luscher, Vetter, Siegenthaler and Vetter, 1985).

6. *Reduces health costs*. Self-measurement of the blood pressure permits the detection of patients with IC-HT, thus avoiding unnecessary pharmacological treatment. As shown in Figure 1, the saving to health services implied amounts, in the case of Spain, to an estimated figure of between 101 and 13,500 million pesetas per year, even on the basis of the cheapest brand and the minimum dose for each group of drugs (tiazides and ACE inhibitors). Moreover, this saving should increase in successive years, given the fact that it would not be necessary to buy new self-measurement devices, but only to recalibrate them or, at most, repair them.

Furthermore, there are empirical data to suggest that the savings represented by self-measurement of the blood pressure are not confined to those achieved by avoiding the unnecessary prescription of treatment. Soghikian et al. (1992) randomly assigned 200 HT patients to two groups: the first underwent the standard procedure for evaluation and monitoring of HT, whilst the second, in addition to receiving the standard procedure, used self-measurement of the blood pressure. After one year, the two groups presented similar levels of improvement in their HT condition, but the medical costs, in terms of consultations with the doctor, telephone calls and laboratory tests, were 29% lower in the group that had used self-measurement.

Self-measurement in the 1990s: former limitations overcome

Despite these advantages, and the fact that it has been used in research since the 1940s, (e.g., Ayman and Goldshine, 1940), self- measurement of blood pressure is very little used in professional practice. This is hardly surprising given that until six or seven years ago there was great mistrust towards it among the vast majority of researchers and professionals in the field of HT. Thus, for example, as recently as 1993, the official posture of the American College of Physicians with respect to the use of self-measurement for the diagnosis and management of HT was one of considerable scepticism, questioning the accuracy of the available instruments and raising serious doubts as to the extent to which self-measured readings represented the usual blood-pressure levels of an individual (American College of Physicians, 1993; similar criticisms came from the US National High Blood Pressure Education Program –Hunt, Frohlich, Moser, Roccella and Keighley, 1985). Nevertheless, in 1996 and 1997, reports from two such prestigious American institutions as the American Society of Hypertension (Pickering, on behalf of an Ad Hoc Panel of the American Society of Hypertension, 1996) and the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure (JNC-VI, 1991) unreservedly recommended the use of self-measurement of blood pressure as a technique for the initial assessment of patients with HT and for monitoring their response to treatment. This recommendation undoubtedly stems from the fact that the earlier limitations and criticisms of self-measurement had been answered by technological

advances and empirical data from recent research. Specifically, the former limitations and criticisms referred to the following main points:

1. *The measurements are not very precise because it is difficult for patients to learn the technique of blood-pressure measurement.* When the best alternative for self-measurement of blood pressure was the auscultatory method using a stethoscope and a mercury or aneroid sphygmomanometer, it was possible that patients obtained erroneous readings due to the intrinsic difficulties of the method itself, since it required, among other things, familiarisation with the sound of the stethoscope, sufficiently acute hearing to discriminate the different Korotkoff noises, proper positioning of the stethoscope and cuff, a correct rate of inflation and deflation of the cuff, and appropriate selection of maximum inflation level. Nevertheless, and in spite of such difficulties, in the study by Tecumseh, carried out with 608 people from the general population that had used aneroid sphygmomanometers with stethoscopes incorporated for self-measurement of blood pressure, correlations of 0.99 were obtained between self-measurements and measurements carried out simultaneously by a qualified nurse (Mejia, Julius, Jones, Schork and Kneisley, 1990).

   Without entering into the question of how far these results can be generalised, what appears obvious is that a large part of the previous difficulties have been resolved through the use of the currently-available electronic manometers for domestic use, and that these, therefore, tend to be the best option for self-measurement of blood pressure. The majority of these instruments use the oscillometric method of measurement and provide digital readings of systolic and diastolic pressure (and of heart rate), thus avoiding the difficulties and biases of patients on detecting Korotkoff noises or on reading pressure levels from the spheres or the mercury columns of traditional sphygmomanometers. Moreover, some electronic manometers incorporate automatic systems for inflating and deflating the cuff, so that another source of errors is ruled out –that which originates from the act of inflating the cuff, as well as errors related to an inappropriate inflation-deflation rate (the muscular activity involved in inflating the cuff produces a momentary increase in blood-pressure of 12 mmHg which, though lasting only 10 seconds, may distort the reading if the cuff is inflated to a level close to that of expected systolic pressure or if is deflated rapidly; Veerman, Van Montfrans and Wieling, 1990). Likewise, the most modern instruments include switches for pre-selection of the pressure that allow a constant inflation pressure setting at a value higher than the systolic value, or are even equipped with intelligent control systems (such as the "fuzzy logic" of the OMRON Matsusaka Co., Japan) that permit the apparatus to detect automatically the correct value of inflation pressure.
2. *Measurements are not very precise because electronic manometers are inaccurate*. During the 1980s various studies were carried out to assess the accuracy of different domestic instruments for measuring blood pressure, comparing their readings with those obtained simultaneously through intra-arterial or auscultatory procedures that acted as reference criteria (Evans, Haynes, Goldsmith and Hewson, 1989; Imai et al., 1989; O'Brien, Mee, Atkins and O'Malley, 1990; Pickering, Cvetkovski and James, 1986; van Egmond, Lenders, Weernink and Thien, 1993). In general, the majority of these devices were found to be inaccurate, providing readings that consistently presented errors of more than 5 mmHg in comparison to the reference values. However, in recent years various electronic instruments have fulfilled the precision criteria proposed by the Association for the Advancement of Medical Instrumentation (AAMI, 1985), in the USA, and by the British Hypertension Society (O'Brien et al., 1990). Several of these instruments are commercially available in Spain. For example, Imai et al. (1989) reported that the main difference between the blood-pressure values obtained with the OMRON HEM-401C (OMRON Matsusaka Co., Japan) apparatus and those obtained with a mercury sphygmomanometer (for reference) only differed by 1.6 ± 6.7 mmHg for systolic and by 2.4 ± 6.1 mmHg for diastolic pressure. This semi-automatic device is currently available in Spain under the name OMRON M1 (Peróxidos Farmacéuticos, Barcelona). Moreover, O'Brien, Mee, Atkins and Thomas (1996) and Foster, McKinlay, Cruickshank and Coats (1994) have confirmed that the automatic devices OMRON HEM-705CP and OMRON HEM-706 –the latter sold in Spain as OMRON HEM-711– also obtain accuracies superior to $\pm$ 5 mmHg, thus meeting the highest standards set by the BHS and AAMI, whilst Córdoba et al. (1997) reached similar

conclusions with regard to the OMRON HEM-722C –currently available in Spain as OMRON M4.

3. *Patients distort the data*. There is a degree of suspicion among professionals and researchers in HT that some patients may note down in their self-records blood-pressure values that differ from those actually obtained with their measuring instruments. Although there are no empirical data available, this appears to be a possibility on the basis of research on the accuracy of self-reports of adherence to therapy (see Meichenbaum and Turk, 1991). For example, Taylor, Agras, Schneider and Allen (1983) studied, in a group of patients with HT, adherence to the daily practice of relaxation exercises through a microelectronic system that surreptitiously recorded the amount of time they had used a relaxation belt provided to them for this purpose. Despite the fact that 70% of the patients reported having performed the relaxation exercises daily, the microelectronic measure indicated that only 40% of them had in fact done so. Equally illustrative is a study with diabetic patients that self-measured their blood glucose levels using an electronic device that included a memory chip for recording the readings without the patient's knowledge (Mazze et al., 1984). Through this procedure, researchers found a certain tendency among the patients to report values lower than those actually provided by the instrument.

   Of course, in professional practice the use of concealed measures makes no sense, and may undermine the therapeutic relationship between the patient and the health professional. However, the use of electronic devices for the measurement of blood pressure with printers (e.g., the OMRON HEM-705CP) offers, with full knowledge on the part of patients, an assurance that subjects do not distort the figures provided by the instrument; likewise, the use of electronic devices with memory chips also guarantees the absence of biases. In this case, patients should always be informed of the presence of this chip, which should be presented not as a means of "controlling" them, but rather as, for example, a device that facilitates the statistical treatment of the data by means of a computer (e.g., the OMRON IC can record up to 350 blood-pressure readings, which can subsequently be edited and analysed through a computer program; the OMRON M4 also includes a memory function, but in this case it is the patients that must activate it each time they wish to record a reading).

4. *Patients do not co-operate, and usually fail to carry out the self-measurements*. The majority of empirical studies confute this criticism, finding that the observance of self-measurement tends to be high, both in patients with hypertension and in subjects from the general population. For example, in our research we usually ask patients to measure their own blood pressure three times a day, over 16 consecutive days, in both pre-treatment and post-treatment, which requires them to make 48 blood-pressure readings in each phase of the study. Despite the demands of this request, the mean percentage of readings carried out by a group of 43 patients with essential HT that participated in a controlled therapeutic trial was 99%, with a range of 87 to 100% (García-Vera and Sanz, 1999).

   While the above results may be attributable to the special context of high motivation and close clinical monitoring that tend to be a feature of research carried out with small samples and few professionals (who are usually also the researchers), other studies present data on fulfilment of self-measurement requirements that can much more readily be generalised to normal professional practice, and which also indicate that this procedure for blood-pressure measurement is viable. Chatellier et al. (1996) carried out a study with 1,710 patients recruited by 694 GPs in order to test the therapeutic effectiveness of a drug. In that study neither doctors nor patients were previously familiar with self-measurement of blood pressure, so that the researchers could also check the viability of the procedure in primary health care. After discarding data from the first day of self-measurement (which was considered as a test day, since patients had received no specific training), the researchers' objective in the pre-treatment assessment was for patients to make a series of three consecutive blood-pressure readings in the morning and another series of three consecutive readings in the afternoon/evening over three days (that is, six series with a total of 18 readings).

(1) **Footnote:** An exception to this reticence was the case of the World Hypertension League, which in 1988 suggested that the limit of normality for self-measured blood pressures could be 140/90 mmHg (World Hypertension League, 1988), a value that, in view of the differences between clinic and self-measured pressures, does not appear reasonable.

The results of the study showed that 36% achieved this objective (100% of readings required), and that a further 29% carried out at least two series of readings in the morning and two in the afternoon/evening that included at least one reading (between 22 and 94% of the readings required). That is, without any prior training, more than 60% of patients carried out 4 or more blood-pressure readings, a figure with which reliability coefficients of 0.77-0.78 (García-Vera and Sanz, 1999) can be achieved, and which would probably have improved had the patients received specific instructions from the doctors about how to carry out a proper self-measurement. Indeed, these researchers found that, after receiving a one-hour course on blood-pressure self-measurement, 71% of the patients of a hospital service specialising in HT succeeded in carrying out 80% of the required readings (Chatellier et al., 1996).

5. *There is no agreement as regards what is considered normotension and hypertension for blood-pressure levels obtained through self-measurement*. The literature has confirmed, unanimously and repeatedly, that blood-pressure levels obtained outside the clinic, either by self-measurement or by automated ambulatory devices taking readings over 24 hours, are much lower than values obtained in the clinic using the standard procedure (see the reviews by Pickering, 1991). In patients with essential HT, it is possible to find discrepancies between self-measurements and clinic readings of up to 20/15 mmHg (García-Vera, Labrador and Sanz, 1999) or 32/16 mmHg (Ibrahim, Tarazi, Dustan and Giffort, 1977), though the mean difference can be estimated at around 12/6 mmHg (see the review of the studies in Gaudemaris, Chau and Maillon, 1994). In persons with normotension the differences between self-measured and clinic values are smaller, but still significant. Table 3 shows the normative clinic and self-measured pressures found in various large-scale studies with samples of volunteers from the general population. The total number of people participating in these studies was 4,023, from a variety of countries (Germany, USA, France, Italy, Japan). After weighting (according to number of participants) the differences between the means of the clinic pressures and those of the self-measured pressures, it can be calculated that the clinic systolic/diastolic values are on average 6/5 mmHg higher than the respective values obtained through self-measurement.

The consistency and magnitude of these differences have led researchers to the conclusion that the boundaries of normotension/hypertension established for clinic measures of blood pressure (see Table 1) can in no way be applied to self-measurements. However, for many years the lack of sufficient data and the failure to reach an agreement have impeded the establishment of a reasonable normative limit for self-measured blood pressures. Indeed, until 1996, none of the reports on self-measurement of the blood pressure drawn up by the most influential scientific associations in the field of HT (WHO, JNC, the American, British and International Hypertension Societies, the American College of Physicians) had proposed any specific normative criterion[1]. In that year, Pickering, in a report on behalf of an Ad Hoc Panel of the American Society of Hypertension (1996), proposed as a criterion of HT a self-measured pressure equal to or in excess of 135/85 mmHg, a criterion with which the JNC-VI (1997) coincided the following year, though in neither case are any reasons adduced to justify such proposals.

We believe, however, that there are reasons and data to support the value of 135/85 mmHg as the boundary between hypertension and normotension for readings obtained by self-measurement, and that, therefore, the problem of the lack of an agreed criterion is now resol-

TABLE 3
Studies carried out with samples from the general population to determine normotension values for adults in the self-measurement of blood pressure

	PAMELA	Dübendorf	Tecumseh	Ohasama	French Society of Hypertension
Reference	Mancia et al. (1995)	Weisser et al. (1994)	Mejia et al. (1994)	Imai et al. (1994)	Gaudamaris et al. (1994)
Nº of participants	1651	503	608	871	390
Age (years)	25-64	Mean = 45	Mean = 32	Mean = 46	20-59
Self-measurement period	12 days	14 days	7 days	28 days	3 days
Device	Philips	Sphygmomanometer	Marshall	OMRON HEM-401C	Tensiopuls UA516
Clinic BP (mmHg)	127/82	130 ± 17/82 ± 11	115 ± 12/77 ± 10	126 ± 19/72 ± 13	122/77
Self-measured BP (mmHg)	119/75	123 ± 15/78 ± 11	116 ± 11/73 ± 9	117 ± 12/69 ± 10	114 ± 14/73 ± 11

ved. Weighting the statistics of Table 3, it can be estimated that the mean (± standard deviation) of self-measured blood-pressure values in the general population would be around 118/73 mmHg (± 13/10 mmHg). Assuming as a normative limit of self-recorded blood pressure one standard deviation above the mean (approximately percentile 84), we could establish as a criterion of hypertension those blood-pressure values equal to or in excess of 131/83 mmHg. As regards ambulatory measures from instruments recording over 24 hours, the percentile 90 is usually adopted (Pickering 1995). Given that the distribution of self-recorded blood-pressure values fits the normal curve, from the previous data it can be deduced that percentile 90 would correspond to 135/86, a value that practically coincides with that proposed by the JNC-VI and the American Society of Hypertension. It could be argued that the best response to the problem of setting a limit for hypertension would result from considering the predictive value of the reference criteria. In order to do so it would be necessary to carry out longitudinal studies analysing the morbidity and mortality risks associated with different self-measured levels of blood pressure. Up to now there has been only one study of this type: Tsuji et al. (1997) obtained self-measured blood-pressure readings from 1,913 people over 40 in a Japanese rural community and evaluated their death rate after five years. On the basis of these data the researchers proposed a value of 137/84 mmHg as a criterion for hypertension, a figure sufficiently close to that proposed by the JNC-VI and the American Society of Hypertension to consider the latters' as a more than acceptable consensus criterion.

Protocol for the self-measurement of blood pressure in primary health care

In conclusion, taking into account its advantages and the fact that its previous limitations have been overcome, and bearing in mind the available health service resources, we recommend that the clinical procedure of blood-pressure measurement be complemented with self-measurement by means of some type of portable electronic instrument. The following steps are suggested:

1. Explain to the patient the need for self-measurement, given the inherent variability in blood-pressure levels.
2. Set a minimum number of blood-pressure readings and reach an agreement with the patient, according to his/her occupation and daily routine, about the days and times when they are to be carried out.

The number of readings established should ensure that the reliability of the self-measurements is acceptable; however, up to now there have been no empirical criteria on which to base the decision about this figure. Recently, through the application of the theory of generalisability to 48 readings obtained using self-measurement by 43 patients with HT during the pre-treatment assessment in a clinical trial, we obtained the generalisability coefficients (G*) for different combinations of number of readings and number of situations, including among the latter self-measurements at home in the morning and at night and self-measurements in the workplace (García-Vera and Sanz, 1999). These coefficients G*, which are equivalent to the reliability coefficients of classical tests theory, permit the researcher to decide the number of readings to be taken, and in what situa-

TABLE 4
Coefficients G* for a design of Person x Situation x Day generalisability obtained from self-measurements carried out by 43 HT patients over 16 days making 3 readings per day (one at home in the morning, another at work and the last one at home in the evening) –taken from García-Vera and Sanz, 1999.

Number of days	Coefficients G*					
	Systolic blood pressure			Diastolic blood pressure		
	1 Situation	2 Situations	3 Situations	1 Situation	2 Situations	3 Situations
1	.45	.68	.75	.52	.65	.71
2	.66	.78	.83	.65	.77	.81
3	.71	.82	.86	.71	.82	.86
4	.74	.84	.88	.75	.84	.88
5	.75	.85	.89	.77	.86	.89
6	.77	.86	.90	.79	.87	.90
7	.78	.87	.91	.80	.88	.91
8	.78	.87	.91	.81	.89	.92
12	.80	.89	.92	.83	.90	.93

tions, in order to then generalise to the universe of possible readings (see Table 4).

Various researchers have suggested a reliability coefficient of .80 as the minimum value necessary for obtaining reliable blood-pressure readings (Shepard, 1981; Llabre et al., 1988). As can be seen in Table 4, it is sufficient to ask the patient to take two readings in each of the three situations mentioned above (6 readings in total over two days) in order to attain this standard for both systolic pressure (coefficient G* = .83) and diastolic pressure (coefficient G* = .81). However, we concur with Yela (1984) in that this criterion may be appropriate for studies working with large samples and attempting to test certain theoretical hypotheses, but when an instrument is applied for making individual diagnoses and predictions its measurement error should be as low as possible, and therefore the reliability coefficient should be at least equal to 0.90. The data in Table 4 indicate that patients with HT should continue self-measurement for at least *six days, at a rate of three readings per day, one in each of the three situations*, in order to attain a generalisability coefficient of 0.90 for systolic and diastolic pressure. Moreover, the results presented in García-Vera and Sanz (1999) suggest that the number of readings should be slightly increased in more elderly patients and in those that present high levels of blood pressure in the self-measurements.

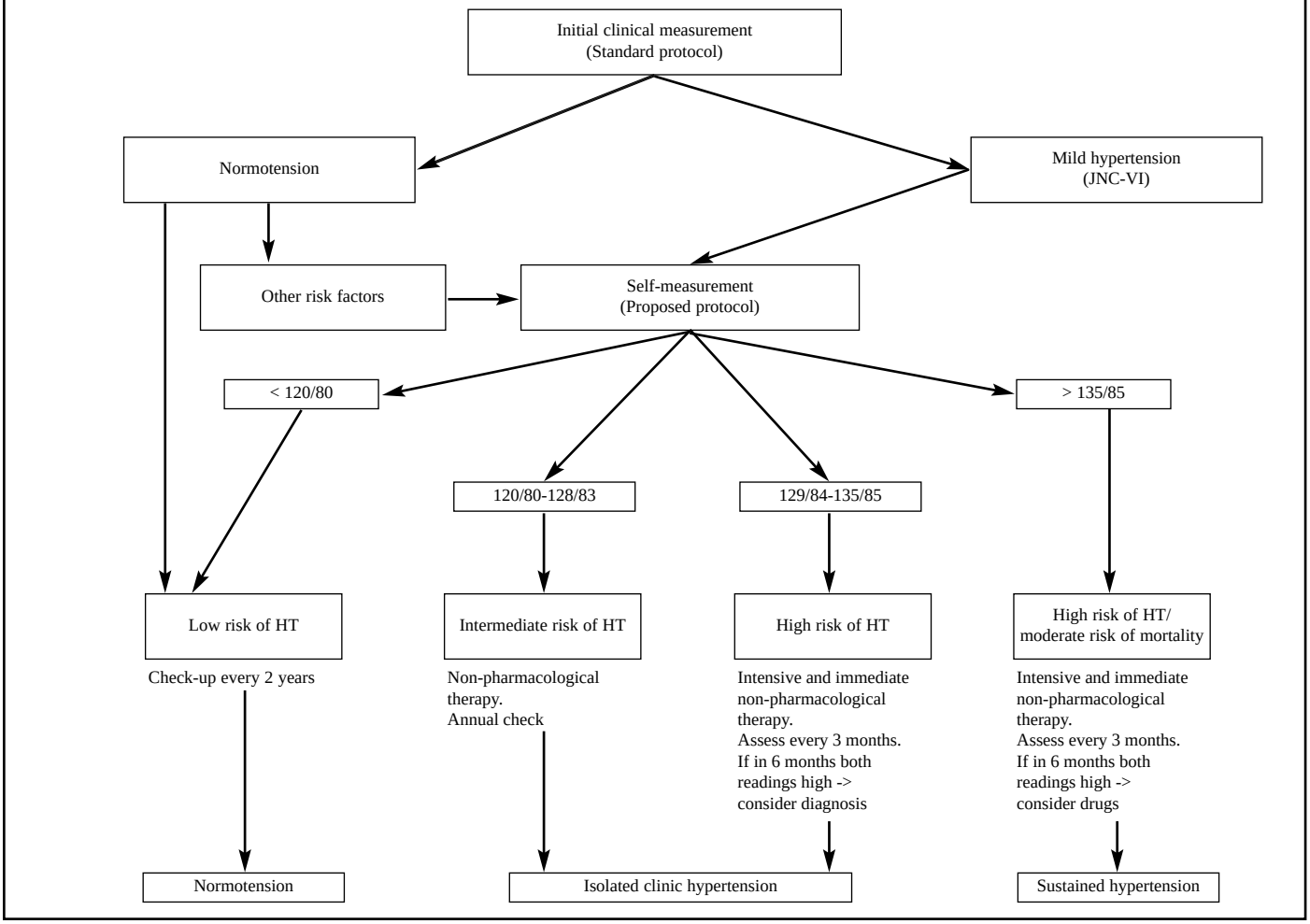
As far as weekends are concerned, measurements should be carried out in as similar a way as possible to the other days of the week, especially in terms of activity level and time of day, and this period of 6 days of self-measurements should be repeated in each of the periodic check-ups attended by the HT patients.

3. Choose an electronic device for blood-pressure measurement that has been validated by independent researchers in accordance with a standardised protocol, such as those of the Association for the Advancement of Medical Instrumentation (AAMI, 1985) and the British Hypertension Society (O'Brien et al., 1990), and have its accuracy checked annually, either by the technicians of its distributors or by means of comparison of its readings with those of a mercury sphygmomanometer calibrated with a Y-tube. If the error is greater than 4 mmHg the device should be recalibrated (Nash, 1994). Instruments should be equipped with a cuff of a size appropriate for the circumference of the patient's arm, and where this is not possible, large cuffs (14-15 cm wide x 31-39 long) should be used (Pickering, 1991). For the reasons stated earlier, it is preferable for the device to have automatic inflation and deflation of the cuff, as well as a printer or memory function.
4. Design a self-record procedure whereby the patient keeps records of blood-pressure and heart-rate readings and the most relevant circumstances at the moment of measurement. Additionally, patients may be required to include in these self-records information on aspects related to the treatment they are following, such as dose and time of taking medication or, in the case of cognitive-behavioural treatment, information on any variable relevant to a functional analysis of the case, such as stress level or mood just before the self-measurement.
5. Explain to the patient the norms to follow before self-measuring the blood pressure, in order to ensure that measurements are made correctly: no smoking, eating or ingestion of products containing caffeine in the 30 minutes prior to measurement; avoid anxiety-inducing thoughts; avoid exercise or activities involving muscular tension in the 30 minutes prior to measurement; urinate before measurement.
6. Teach the patient how to use the electronic device for blood-pressure measurement and how to keep the self-record. This teaching should include several trials in the presence of the health professional so that he/she can confirm that (1) the device is used correctly, and (2) the patient adopts the correct posture (relaxed and comfortable position, arm on a flat surface at the level of the heart, no speaking). On completion of the trials, the professional should take the patient's blood pressure at the same time as the latter makes a self-measurement, until a difference of less than 5 mmHg between the two readings is attained in two consecutive measurements. It is essential to insist on correctness of posture, as patients tend to forget or underestimate the importance of this factor (Stergiou, Malakos, Voutsa, Achimastos and Mountokalakis, 1996). Likewise, it is important to underline the need for the self-record and the drawing of the graphs that permit the patient to observe his/her progress; this aids motivational and therapeutic aspects of the self-record procedure. A session of 30-45 minutes is sufficient to ensure the achievement of all of these teaching objectives (Armstrong, Barrack and Gordon, 1995; Kjeldsen et al., 1993; Stergiou,

Voutsa, Achimastos and Mountokalakis, 1997); at the end of the session the patient should be provided with all the necessary written instructions. It is advisable for the basic guidelines for using the measuring equipment and the proper conditions for correct blood-pressure measurement to be clearly visible in the self-record book (an example of a self-record can be found in García-Vera, Labrador, Sanz, Arribas and Fernández-Alba, 2000).

7. Warn patients that normal values for clinic blood-pressure measures are higher than those for self-measurements, and that therefore they should under no circumstances make decisions about compliance with their prescribed treatment on the basis of the readings they obtain and without first consulting the health professional responsible for their case. In this regard, it is highly illustrative that some patients with mild HT only take the medication when they estimate their blood pressure to be high, such estimations being based on certain symptoms they claim to notice, such as headaches or tension, when at these levels hypertension is obviously an asymptomatic disorder (Leventhal and Nerenz, 1983).
8. Finally, professionals should bear in mind that self-measurement may be inappropriate in patients with irregular heart rate or severe overweight, or who present a high degree of anxiety in relation to their HT problem (Pickering, 1996). In this last case it should be pointed out, nevertheless, that the majority of patients find self-measurement to have a calming effect. This was so, for example, in 70% of the patients that participated in a study by Burns-Cox, Russell and Wilson (1975).

FIGURE 2
System for diagnosis of mild or stage 1 hypertension based on the combination of clinic and self-measurements of blood pressure with the objective of a more rational use of monitoring measures and of pharmacological and non-pharmacological therapies.



PROPOSAL FOR A SYSTEM FOR THE DIAGNOSIS OF ESSENTIAL HYPERTENSION IN PRIMARY HEALTH CARE

Having obtained self-measurements of blood pressure following the protocol proposed, it is possible to make more correct therapeutic decisions according to the different levels of cardiovascular risk in the groups defined by the joint consideration of their clinic and non-clinic blood-pressure measurements. We therefore propose a system of diagnosis, with its consequent therapeutic implications, based on the empirical data currently available on the risk of cardiovascular and mortality in these groups (see Figure 2). This system is an adaptation of the diagnostic scheme proposed by Nesbitt et al. (1997), with certain modifications to allow the inclusion of risk data found by Tsuji et al. (1997) and Sakuma, Imai, Tsuji et al. (1997) and the therapeutic recommendations of the JNC-VI (1997). The starting point of the system represented in Figure 2 is the diagnosis, in accordance with the standard clinical procedure, of mild or stage 1 HT –this group being the most controversial as regards therapeutic decision (see Introduction)– without organic disorders, clinical cardiovascular illness or diabetes (the presence of any of these maximum risk factors would require the immediate implementation of pharmacological therapy in conjunction with the non-pharmacological treatment; JNC-VI, 1997).

It is assumed, on the basis of the empirical data available, that the simultaneous presence of abnormally high self-measured blood pressures (> 135/85) implies a high risk of HT (Nesbitt et al., 1997) and moderate levels of risk of thrombosis mortality (Sakuma, Imai, Tsuji et al., 1997) and mortality in general (Tsuji et al., 1997). Thus, we consider that people with high clinic and non-clinic pressures –sustained HT– would be in risk group B according to the categorisation of cardiovascular risk proposed by the JNC-VI (clinic pressures of 140-159/90-99 mmHg, presence of at least one additional risk factor, but absence of maximum risk factors), so that the therapeutic recommendations of the JNC-VI itself would be applicable to them. Below the self-measured value of 135/85 mmHg we would find those with IC-HT, whose therapeutic regime could be tuned up even more, in view of the fact that Nesbitt et al. (1997) found increased risk of HT from self-measured readings above 128/83 mmHg, and Sakuma, Imai, Tsuji et al. (1997) discovered increased risk of thrombosis from self-measurements of over 133/81 mmHg. Therefore, we consider that these patients, despite being categorisable in risk group A of the JNC-VI, require closer monitoring than that proposed by the JNC-VI for group A, which involves only an annual check-up. This latter type of monitoring would be appropriate for IC-HT patients with self-measured pressure between 120/80 and 128/83 mmHg, whilst those with even lower levels would require no type of special monitoring, since they are unlikely in the near future to develop HT or any of its related problems.

Following Nesbitt et al. (1997), our diagnostic scheme does not stipulate which type of non-pharmacological treatment is most appropriate, since we believe this decision should be subject to a more comprehensive and detailed evaluation of each patient individually; however, we do make a distinction between "intensive" and "non-intensive" treatment, the former referring to a system of activities supervised by specialised professionals (e.g., psychologists; specialists in nutrition and physical exercise) and the latter to the advice and regular monitoring usually provided by the GP.

The diagnostic system proposed here has some limitations. For example, it makes no mention of the possibility of a patient presenting high self-measured blood pressure but normal clinic measures. Such a possibility certainly exists: there are studies that have found that between 10% and 16% of those considered as having normotension according to their clinic pressures present non-clinic measures within the hypertensive range (Palatini and Mormino, 1998). Nevertheless, we know of no study that has examined the risk of cardiovascular morbidity and mortality associated with this condition, which could be called "clinic pseudonormotension". Thus, while it would not seem reasonable to propose, as a general rule, the self-measurement of blood pressure in all persons with normotension, it may be recommended in those that present some additional cardiovascular risk factor (e.g., overweight, smoking, family history of cardiovascular illness).

Finally, it should be made clear that, since this system for the evaluation and diagnosis of essential HT has not yet been used in primary health services, there are obviously still no data available to support the relationship between diagnostic group and risk of cardiovascular morbidity proposed here. It should also be stressed that the system is not exempt from criticism (some of which have been mentioned here), and could be improved; nevertheless, it represents a qualitative change in the evaluation of HT, and may serve as a starting point for future research which, using longitudinal designs, might clarify with more precision the relationship between essential HT and risk of cardiovascular morbidity.

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