

Should Physicians Still Measure their Patients' Blood Pressure or Should Patients Measure their Own Blood Pressure at Home?

¿La presión arterial aún debe ser medida por el médico o debería ser medida por la propia persona en su hogar?

"... At first there are no sounds whatsoever. As the mercury in the manometer drops to a certain height, there appear the first short or faint tones, the appearance of which indicates that part of the pulse wave of the blood stream has passed under the sleeve.

Consequently, the reading on the manometer when the first sound appears corresponds to the maximum blood pressure. Finally all sounds disappear. The time of the disappearance of the sounds indicates the free passage or flow of the blood stream; in other words, at the moment of the disappearance or fading out of the sounds, the minimum blood pressure in the artery has surpassed the pressure in the sleeve. Consequently, the reading of the manometer at this time corresponds to the minimum blood pressure.."

NIKOLAI KOROTKOFF

On methods of studying blood pressure". 1905 (1)

INTRODUCTION

It was not until the beginning of the 20th century that the symbol of the physician measuring blood pressure (BP) by the auscultatory method in the physician's office appeared. In 1896, the Italian physician Riva-Rocci developed the indirect method for measuring BP by inflating a compressive rubber cuff wrapped around the patient's arm, although the method could only determine systolic BP (SBP) when the radial pulse could be felt. In 1905, the Russian physician Nikolai Korotkoff described for the first time, in less than one page, the auscultatory method for BP measurement, an indirect technique that could measure systolic and diastolic BP with the famous "Korotkoff sounds" (see the direct quotation from reference 1 in the epigraph). This method remained practically unmodified during the entire century for measuring the so called "casual" BP in the clinical setting and in other scenarios (pharmacy or primary care setting, among others). Since it was originally described, casual BP has been the gold standard in clinical practice, and in the investigation and development of antihypertensive drugs.

However, its extreme variability has always been known. In the 18th century, during his first direct measurement of BP in the horse, Steven Hale observed that the variability of BP was incidental and time-dependent. Forty-five years ago, Bevan et al. reported that 24-hour recording of direct BP in subjects during normal and unrestricted daily activities had marked variability and time-dependence. (2)

For these reasons, each guideline developed for the management of BP thoroughly recommends which methods should be followed for casual BP measurement and monitoring at the office or clinic. These procedures are intended to reduce spontaneous variability of BP and to increase the reliability and reproducibility of BP measurement. Yet, in daily practice, BP is seldom measured during a medical screening or in the clinical setting as recommended by guidelines, and concerns about accurate BP measurements are commonly unattended or ignored. The low adherence to the procedures for office blood pressure (OBP) control is still a serious challenge both in Argentina and worldwide.

One way of improving the quality of OBP "casual" BP information is by substantially increasing the number of BP measurements and hence, the cumulative information about BP across time. Since 1969, when Possey et al. developed the cuff-oscillometric which theoretically allows indirect mean BP measurement, the subsequent theoretical and technological improvements enhanced the development of an automatic method to determine SBP and diastolic BP (DBP). As a result, automatic devices for self-measurement of BP were rapidly developed and validated with the classic auscultation method of Korotkoff sounds.

Technological improvements led to the development of a device for monitoring and recording ambulatory BP (ABP) every 15 to 30 minutes for 24 hours, during unrestricted daily activities and providing the exact time of 50 to 100 BP measurements in the short period of a particular day

Self-measurement of blood pressure at home (HBP) with automatic oscillometric devices are less expensive and provide extended information about BP obtained in certain conditions at fixed hours of the day and during a long period of time. For example, if BP is measured once in the morning and once in the evening, 60 measurements will be obtained during a month. Average HBP measurements are stable and have high reproducibility in the short and long-term. (3)

Based on the advantages of HBP over ABP, the 2003 and 2011 Japanese Society of Hypertension (JSH) guidelines for self-monitoring of blood pressure at home (4, 5) emphasize the importance of HBP monitoring over ABP monitoring for the diagnosis and

treatment of hypertension. By the beginning of this century, over 35 million HBP monitoring units were distributed in Japanese homes, almost equivalent to the number of hypertensive patients in the country. (6) In 2005, a patient survey at Japanese pharmacies (n=8500) showed that 75% of hypertensive patients and 39% of those without hypertension owned these automatic devices. (7)

The recent European and American guidelines support the use of HBP monitoring for the management of hypertension in clinical practice and recommend its use in most patients with possible or treated hypertension. (8)

GENERAL CHARACTERISTICS OF HOME BLOOD PRESSURE

Advantages of self-monitoring blood pressure at home As HBP can be measured under standard conditions, its average values are less variable and more stable; therefore, the reproducibility of the readings is greater than that of OBP or ABP in the short- and long-term. Therefore, the highest reproducibility and reliability of HBP is overall superior compared with APB and OBP. Due to these characteristics, HBP can be used to determine small but significant changes in SBP and DBP.

The Ohasama study group has recently reported the outcomes of the Hypertension Objective Treatment based on Measurements by Electronic devices of Blood Pressure Study (HOME BP Study). This randomized, controlled and open-label study used automatic devices for HBP measurement with data collection through the internet (telemedicine). The trial involved 3,518 patients who were followed-up for 10 years (average 5.3 years) by 300 primary care physicians. (9) This study demonstrated that HBP could be easily used and was well accepted by physicians and patients.

Home BP is a highly available, useful, well tolerated and reliable method, and these qualities are recognized worldwide.

The method offers the possibility of obtaining multiple readings for a long period in standardized conditions, and is simple to repeat and track. Home BP monitoring is not adequate for repeated measurements in a short period of time.

It provides direct and immediate feedback about the diagnosis and treatment of hypertension.

Standardization of the measurement procedure is a favorable aspect of HBP monitoring, while ABP monitoring implies unrestricted daily activities. In this way, the reproducibility of HBP is higher than that of ABP. The Japanese Society of Hypertension (JSH) guidelines recommend that HBP should be measured daily over a long period, that is, life-long measurements.

Home BP monitoring is not only an instrument for decision-making in the diagnosis and treatment of hypertension; but also a tool for changing lifestyle or way

of life and for the self-management of hypertension.

Shortcomings and problems of self-monitoring blood pressure at home

Home BP monitoring could interfere with daily activities, but the extension of this interference is minimal compared with ABP and OBP. In Japan, BP monitoring is a usual practice and people do not perceive HBP as a problem.

Although a few subjects may feel anxious about BP measurement or overact measuring their BP repeatedly, the appropriate interaction between physicians and patients, including patient education, is generally helpful to overcome these difficulties rapidly.

The novelty effect that could alter BP is observed during the first days and stabilizes thereafter. Therefore, the effect of regression to the mean is minimal or absent in HBP compared with OBP or ABP measurements, suggesting that in HBP monitoring the placebo effect is absent or minimal.

It may happen that patients report to their physicians the highest or the lowest BP values for different reasons; if only the lowest values are reported, drugs will not be titrated, and if only the highest values are considered, the dose of antihypertensive drugs will be unnecessarily increased with the risk of inducing hypotension. To avoid selection biases, the guidelines recommend that BP should be measured 1 to 3 times in the morning and in the evening and all the readings should be documented. The Japanese guidelines emphasize that BP measurement should be taken once in the morning and in the evening for a long period to avoid reporting biases. Use of a device with an integrated memory circuit is useful to solve this problem.

Home BP monitoring was spontaneously introduced by patients themselves without being instructed by health care professionals. Most persons can use HBP devices without difficulty, as patients do not require training to use the current automatic devices. At least, the written instructions provided with the device seem to be enough to allow reliable HBP measurements.

A significant number of the new devices for HBP monitoring have an integrated memory circuit which allows data collection through a microcomputer. In this way, a large number of BP measurements is easily available and may be applied to telemedicine. These functions of HBP monitoring are not provided for ABP or OBP.

The JSH guidelines recommend instructing patients about how to manage drug treatment based on HBP. In the past years, different studies have recognized that self-titration of antihypertensive drugs is feasible by combining HBP monitoring with telemedicine.

PRACTICAL ASPECTS AND REASONS FOR PREFERRING SELF-MONITORING BLOOD PRESSURE AT HOME

The JSH guidelines recommend that HBP should be

measured in the morning within 1 h after waking, after micturition before drug ingestion, and before breakfast. In the evening, HBP should be measured just before going to bed. Home BP is lower in the evening than in the morning because of circadian variation due to lifestyle or workplace (Table 1).

Home BP monitoring with hypertension specifically observed in the morning can be a better predictor of stroke than evening hypertension, particularly among individuals using antihypertensive medication. (11)

The diagnosis of morning, evening or workplace hypertension can only be made when measurements are performed outside the clinical setting.

When hypertension is detected in any of these conditions but not in the clinical setting, it is defined as “masked hypertension”, which is related to poor prognosis of cardiovascular disease.

Home BP monitoring is also the most plausible method to diagnose “white-coat hypertension” or to define “white-coat effect”. Self-BP monitoring without the presence of a health care professional may possibly define normal levels of HBP and “white-coat hypertension”. Even though “white-coat hypertension” is a benign condition during short-term observation periods, its long-term effect is still unknown. The Ohasama study, where “white-coat hypertension” was defined based on HBP monitoring, demonstrated that this condition precedes true hypertension. Recently, the Italian PAMELA trial confirmed that the risk of developing true hypertension is higher in persons with “white-coat hypertension”. In persons with “white-coat hypertension”, HBP monitoring is the best tool to determine the long-term risk of this condition.

Non-dipper or inverted dipper circadian BP variation can be determined by ABP monitoring but not with HPB monitoring; yet, HBP monitoring can determine the first morning BP.

The morning surge of BP represents a mirror image of nocturnal dipping circadian variation. In the Ohasama study, morning hypertension is primarily mediated by nondipper or inverted dipper circadian BP variation.

“Masked hypertension” is mediated by non-dipper circadian BP variation, inverted dipper circadian BP variation and insufficient duration of action of the antihypertensive medication. Home BP measurement is the only practical method to determine the occurrence of morning hypertension.

Home BP measurements provide an index of drug action duration, i.e., the morning effect versus evening effect ratio (M/E ratio), which is comparable to the trough/peak (T/P) ratio obtained by ABP monitoring. The M/E ratio is more reliable than the T/P ratio, since the former is obtained by the average of multiple measurements of the M/E ratio.

Home BP monitoring can detect the short-term effects of withdrawing antihypertensive drugs (lack of adherence) and improves compliance to medication.

The use of HBP monitoring in clinical trials with

Table 1. Practical aspects of monitoring blood pressure at home (10)

The working groups make the following recommendations:

1. For home BP use, arm-cuff devices are recommended. They should be based on the cuff-oscillometric method, validated officially, and confirmed for accuracy in each individual.
2. BP should be measured in the upper arm. Finger-cuff devices and wrist-cuff devices should not be used.
3. Devices for home BP measurement should be validated for international standards. In addition, the difference between the BP measured by the auscultatory method and that measured using the device should be 5 mm Hg or less in each individual, before use and at regular intervals.
4. Home BP should be monitored under the following conditions:
Morning measurements:
 - within 1 hour after waking
 - after micturition
 - after 1 to 2 minutes of sitting at rest
 - before drug ingestion
 - before breakfast
 The evening measurements:
 - just before going to bed
 - after 1 to 2 minutes of sitting at rest
5. Home BP should be measured at least once in the morning and once in the evening.
6. All home BP measurements should be documented without selection or omission and include the date, time, and pulse rate. Use of a device with a printer or an integrated memory circuit is useful to avoid selection bias.
7. Home BP in the morning and that in the evening should be averaged separately for a certain period. The first measurement on each occasion should be used for totaling.
8. Home BP values that average 135/80 mm Hg and over, for a certain period, indicate hypertension. Average values of 135/85 mm Hg and over indicate definite hypertension. Normotension is defined as less than 125/80 mm Hg and definite normotension as less than 125/75 mm Hg.

NOTE: “At least once” means that more than one measurement during that occasion is also permissible and recommended. The first measurement would be considered a common denominator in all cases. If measurements are not repeated regularly, the average of the first measurement for a certain period is an important commonality for clinical decision making.

HBP: Home blood pressure. BP: Blood pressure.

drugs has demonstrated a reduction in the number of patients needed to detect the antihypertensive effects.

The possibility of multiple readings for a long period with self-measurement at home in standardized conditions makes HBP monitoring the most appropriate method to evaluate the efficacy of antihypertensive drugs.

The use of HBP monitoring on a regular basis can facilitate the evaluation of the effectiveness of BP control in patients taking medication, improving BP control and increasing the proportion of patients who achieve target BP.

The prognostic importance of visit-to-visit OBP variability is a novel topic, but unfortunately, it takes more than a year to obtain a visit-to-visit OBP variability index. However, HBP monitoring can provide information about BP variability in a short-term period.

Home BP monitoring demonstrated that day-by-day variability reflects the risk of stroke in the Ohasama study and the risk of cardiovascular events with HBP variability during the morning in the Finn-Home study.

It has been reported that HBP monitoring yields minimal alerting effects and novelty effects; these characteristics reflect the good reproducibility of BP levels, no regression to the mean and minimal placebo effect. Home BP monitoring can distinguish small but significant serial changes in BP. These aspects make HBP monitoring superior to ABP monitoring, as multiple BP measurements are impractical to determine the efficacy of antihypertensive drugs, and apparently it surpasses the information available by OBP.

The guidelines have defined hypertension as HBP of 135/85 mmHg on the basis of the Ohasama study and other international trials, while the 1999 WHO/International Society of Hypertension guidelines reported that HBP of 125/80 mm Hg was equivalent to OBP of 140/90 mm Hg, consistent with research studies as the Ohasama and PAMELA trials. In 2007, the European Society of Cardiology guidelines considered hypertension as HBP of 130-135/85 mm Hg, reflecting certain flexibility for SBP. Home BP values $\geq 125/80$ mm Hg and $< 135/85$ cannot be considered definite normal BP and should be recognized at least as high normal BP.

A meta-analysis of studies about HBP concluded that HBP levels $< 120/80$ mm Hg are optimal. (12)

The risk at 5 years is $< 5\%$ if systolic HBP was ≤ 131.6 mm Hg. (8) The HOME-BP study shows that adjusting antihypertensive treatment according to HBP is feasible and suggests that a SBP target of 130 mm Hg should be feasible and safe. (13)

The introduction of HBP monitoring for the management of hypertension allows health care professionals to obtain day-to-day BP levels in patients without frequent visits to the outpatient clinic and with the possibility of reducing health care costs. Home BP monitoring contributes to reduce the costs of identifying “white-coat hypertension” and “masked hypertension”.

Home BP monitoring should be considered the gold standard for the diagnosis of hypertension, as it is more effective and cost-effective compared with ABP and OBP.

As HBP can be used in populations without hy-

pertension, the use of HBP monitoring as an initial screening of persons with suspected hypertension or normal BP is promising. It also provides information about “white-coat hypertension” or “white-coat effect”, “masked hypertension” and “masked resistant hypertension”. These advantages of HBP are reinforced by its high reproducibility, reliability, practicality and low cost.

Home BP monitoring should not be assigned a supportive role but it should rather be the main actor in the management of hypertension.

REVIEW AND META ANALYSIS OF PROSPECTIVE STUDIES OF HOME BLOOD PRESSURE MONITORING AND CARDIOVASCULAR RISK ASSESSMENT

In 1998, the Ohasama (Japan) study demonstrated that the predictive value of HBP monitoring for cardiovascular morbidity and mortality was greater than that of OBP monitoring. In 2005, the Pressioni Arteriose Monitorate e Loro Associazioni (PAMELA) trial compared the prognostic value of HBP and OBP for all-cause mortality and cardiovascular mortality with a small number of events. (13)

In the same year, Fagard et al. demonstrated that the prognostic value of HBP measured by the medical team was better than that of OBP and was at least similar to ABP in older hypertensive patients in a primary care cohort. (14)

In 2010, the investigators of the Finn-Home study reported that after a 6.8-year follow-up period in 2,081 persons in Finland, HBP was more effective than OBP to predict cardiovascular events. (15)

The evidence supporting the predictive superiority of HBP has been increasing over the past years.

A recent meta-analysis which included prospective longitudinal studies, examined the prognostic value of HBP to predict cardiovascular risk in the general population or in patients with hypertension treatment, with or without cardiovascular disease.

Those studies that enrolled patients with previous conditions as chronic kidney failure or diabetes, or with a follow-up period < 12 months were excluded from the analysis. The primary outcomes were all-cause mortality, cardiovascular mortality and cardiovascular events. Home BP and OBP were adjusted between them and compared in some studies that provided the necessary data.

In total, eight studies including 17,698 participants were eligible: three studies were from Japan and the remaining five studies were from France, Belgium, Italian, Greece and Finland. Four studies were based on the general population, two included hypertensive population, one study was performed in the primary care setting and one study included an unselected national sample. The studies excluded patients with history of stroke or myocardial infarction (MI). Average age ranged from 54 to 74 years, and female sex was more prevalent in all the studies, except for one. The follow-up period varied between 3.5 and 10.9 years.

The number of initial BP measurements ranged between 2 and 6 for OBP and from 1 to 28 for HBP. (16)

All-cause mortality

All-cause mortality was reported in five studies but one of them did not report OBP.

In 12,046 persons with 747 deaths, a HR of 1.14 (95% CI 1.01-1.29) per 10 mmHg increase in SBP was found for HBP, compared to 10,860 persons and 61 deaths with a HR of 1.07 (0.91-1.26) per 10 mmHg increase in SBP for OBP.

For HBP, the HR was 1.10 (95% CI 1.02-1.19) per 5 mmHg increase in DBP, compared to a HR of 1.02 (95% CI 0.92-1.12) for OBP.

Cardiovascular mortality

Three studies published the results for cardiovascular mortality in 8,779 persons with 193 cardiovascular deaths, with a HR of 1.29 (95% CI 1.02-1.64) per 10 mmHg increase in SBP for HBP, compared to a HR of 1.15 (95% CI 0.91-1.46) per 10 mmHg increase in SBP for OBP.

For HBP, the HR was 1.17 (95% CI 1.03-1.32) per 5 mmHg increase in DBP compared to a HR of 1.07 (95% CI 0.92-1.25) for OBP.

Cardiovascular events

Five studies published the results for cardiovascular mortality in 12,669 persons with 699 events, with a HR of 1.14 (95% CI 1.09-1.20) per 10 mmHg increase in SBP for HBP compared to a HR of 1.10 (95% CI 1.06-1.15) per 10 mmHg increase in SBP for OBP.

For HBP, the HR was 1.13 (95% CI 1.08-1.18) per 5 mmHg increase in DBP compared to a HR of 1.07 (95% CI 0.99-1.16) for OBP.

The hazard ratios (HR) associated with SBP and DBP for HBP were stronger than those associated with OBP across all the studies of all-cause mortality and cardiovascular mortality. The same situation was observed for three of five studies of a certain cardiovascular event for SBP and for three of the four studies for DBP.

Three studies provide information about the outcomes that allow the use of models to adjust for HBP and OBP. They constitute a sample of 4,261 persons with 300 events (52 cardiovascular deaths and 248 cardiovascular events) with a HR of 1.20 (95% CI 1.11-1.30) per 10 mmHg increase in SBP for HBP adjusted for OBP compared to 0.99 (95% CI 0.93-1.07) per 10 mmHg increase in SBP for OBP adjusted for HBP. For DBP, the HR was 1.16 (95% CI 1.08-1.25) per 5 mmHg increase in DBP for HBP adjusted for OBP, compared to a HR of 1.00 (0.92-1.10) per 5 mmHg increase in DBP for OBP adjusted for HBP.

This meta-analysis strongly suggests that HBP remains a significant predictor after adjusting for OBP, but OBP does not have predictive value after adjust-

ing for HBP. Thus, the role of measuring BP in the office to determine treatment and prognosis is clearly limited.

These results are in line with the guidelines of the European Society of Hypertension, the American Society of Hypertension and the Preventive Cardiovascular Nurses Association guidelines for HBP monitoring, which recommend that the available evidence supports the rationale for considering the prognostic value of HBP similar to or greater than that of OBP.

In conclusion, the results of this meta-analysis demonstrate that HBP, but not OBP, significantly predicts all-cause mortality and cardiovascular mortality. The results are similar for SBP and DBP. After adjusting for OBP, HBP (systolic and diastolic) remains a significant predictor of mortality and cardiovascular events, suggesting that its importance as a prognostic variable exceeds the importance of OBP.

MAY HOME BLOOD PRESSURE MONITORING REALLY MAKE OFFICE MEASUREMENTS OBSOLETE?

The conventional measurement of BP in the office or clinic has been the cornerstone and almost the only technique for hypertension management for decades. However, because of white-coat and the masked hypertension phenomena, out-of-office BP monitoring with ambulatory or home measurements is often required. (17)

The ultimate criterion to identify a useful method for the assessment of cardiovascular risk in clinical practice is its actual ability to predict future cardiovascular events. This criterion should be used when considering which of the different methods now available for BP measurement is better. The meta-analysis by Ward et al., (16) which we have just considered, summarizes the available evidence from eight prospective studies and 17,688 patients followed-up for 3.2–10.9 years, which results in accessible information based on almost 100,000 person-years of follow-up, and shows that after adjustment the prognostic value of HBP is superior to OBP. On the contrary, OBP loses its significance after adjusting for HBP, so measurement of HBP makes OBP unnecessary.

In 2007, Pickering et al. (18) questioned the usefulness of conventional BP measurements taken by the doctor in the office. Given that office measurements often induce white-coat syndrome, it was suggested that a diagnosis of hypertension based on elevated office BP would require confirmation by out-of-office measurements. However, because of the masked hypertension phenomenon, the finding of normal or low office BP would also require confirmation by out-of-office measurement.

The practical interpretation of these data, even with the influence of the long tradition with classic office measurements, led to the straightforward conclusion that, once reliable out-of-office BP measurements were available, the classic office measurements should become obsolete.

Over the past years, the British National Institute for Health and Clinical Excellence (NICE) guidelines have suggested that the diagnosis and treatment decision in hypertension should no longer be based on office measurements alone, and that confirmation by out-of-office measurements should be mandatory (19)

When Pickering (18) posed the question "Should doctors still measure blood pressure?", he came to the conclusion that "the best established technique for out-of-office BP measurement is ambulatory monitoring, and home monitoring may also be applicable in the future". His conclusion was supported by the fact that the role of ABP had been investigated almost one decade before HBP, in line with the 2011 UK NICE guidelines.

These conclusions are based on the possibility of detecting white-coat hypertension and particularly the masked hypertension phenomenon, which is more difficult to detect by APB as it would be harder to define the population at risk requiring screening, although it would undoubtedly be larger than the population with elevated blood pressure in the office.

The most recent evidence about the prognostic value of HBP suggests that this method should not be considered any more a screening test requiring subsequent confirmation by ABP but as a highly reliable tool and an alternative to ABP that should be only combined when its clinical relevance is considered.

Self-monitoring BP at home is a method easily available and widely used, strongly supported by the evidence of its prognostic relevance. Therefore, this is the right time for physicians to take the control of this popular instrument which is being increasingly used for the management of hypertension, supervising the technique as recommended by the current guidelines to achieve the best BP target, increase patients' adherence to treatment and, above all, improve their long-term prognosis.

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