Hypertension Research (2013) 36, 661–672

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REVIEW

The reason why home blood pressure measurements are preferred over clinic or ambulatory blood pressure in Japan

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Data regarding ambulatory blood pressure (ABP) or self-BP measurements at home (HBP) have been accumulated. The difference between ABP and HBP is that ABP monitoring (ABPM) provides BP information at many time points on a particular day during unrestricted routine daily activities, whereas HBP provides extensive amounts of BP information obtained under fixed times and conditions over a long period of time; thus, the mean values of HBP are stable, and the reproducibility are high. The high reproducibility of HBP is the rationale for its overall superiority over HBP compared with ABP and clinic BP (CBP). The higher practicality of HBPM over ABPM is definitely recognized. HBPM allows for ongoing disease monitoring by patients and can provide health-care providers with timely clinical data and direct and immediate feedback regarding the diagnosis and treatment of hypertension. HBP is better able than CBP to predict hypertensive target organ damage and a prognosis of cardiovascular disease. Unlike CBPM, HBPM provides BP information in relation to time, that is, BP in the morning, in the evening and at night during sleep. HBPM is an essential tool for the diagnosis of white-coat hypertension and masked hypertension. Day-to-day variability of HBP has clinical significance. HBPM yields minimal alerting effects and placebo effects. HBPM can distinguish small but significant serial changes in BP and is the most practical way to monitor BP in the day-by-day management of hypertension. HBPM improves compliance with antihypertensive medication. The operational threshold of HBP has been established. HBPM is suspected to have a great effect on the medical economy. The superiority of HBPM over ABPM and CBPM is apparent from almost all practical and clinical research perspectives. These characteristics of HBPM indicate that this method is ideal for the diagnosis and treatment of hypertension in daily practice.
Hypertension Research (2013) **36,** 661–672; doi:10.1038/hr.2013.38; published online 18 April 2013

Keywords: diagnosis; home blood pressure; practicability; reproducibility; treatment

INTRODUCTION

The practice and research of hypertension depends on blood pressure (BP) information obtained in the medical environment (clinic BP/BP at a health examination (CBP)), resulting in the accumulation of a great quantity of data about CBP. CBP remains the gold standard for the diagnosis and treatment of hypertension. However, data regarding ambulatory BP (ABP) or self-BP measurements at home (home BP (HBP)) have been accumulating for the past 30 years. The most important difference between ABP and HBP is that ABP monitoring (ABPM) provides BP information at many points on a particular day during unrestricted routine daily activities, whereas HBP provides extensive BP information obtained under fixed conditions and at nearly fixed hours of the day over a long period of time. The mean values of HBP are stable, and the short- and long-term reproducibility is high.

Based on the advantages of HBP over ABP, the Japanese Society of Hypertension (JSH) 2009 Guidelines[1] and JSH Guidelines for HBPM 2003 and 2011[2,3] emphasize the importance of HBPM rather than ABPM for the diagnosis and treatment of hypertension. At present, >35 million units for HBPM have been distributed to Japanese households,[4] which is almost equivalent to the hypertensive population of Japan. In 2005, a patient survey at a pharmacy in Japan ($n = 8500$) showed that 77% of hypertensive patients and 39% of non-hypertensive patients owned these units.[5]

In a 2005 survey of doctors' awareness and practice of BP measurements in Japan ($n = 2000$), 90% of responding general practitioners indicated that they valued HBP as much or more than CBP, and almost all of them recommended measurements of HBPM for their patients.[6]

Recent European and American guidelines endorsed the application of HBPM in the management of hypertension in clinical practice and recommended its use in most patients with possible or treated hypertension.[7–10] The British Hypertension Guidelines (National

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Received 19 December 2012; revised 17 January 2013; accepted 18 January 2013; published online 18 April 2013

Institute for Health and Clinical Excellence: NICE clinical guideline 127) suggested that the diagnosis and treatment of hypertension should no longer be based on CBP alone and that incorporation of out-of-office measurements should be mandatory.[11] The NICE guidelines stated that if the CBP is ⩾140/90 mm Hg, ABPM should be offered to confirm the diagnosis of hypertension. Many practitioners do not or cannot follow this recommendation.

Evidence on the use of HBPM in clinical practice and research has been documented in several reviews and guidelines (see w-1 in Supplementary Information). In this review, we focus on the rationale for HBPM being the preferred method for the diagnosis and treatment of hypertension and hypertension research in Japan.

1. GENERAL CHARACTERISTICS OF CBP, HBP AND ABP

The common feature of HBPM and ABPM is that the measurement frequency of these methods is greater than CBPM (Table 1). Because HBP can be measured under standardized conditions, its mean values are stable, and the reproducibility of the short- and long-term readings are higher than those of CBP and ABP (see w-2 in Supplementary Information). The higher reproducibility and reliability of HBP is the rationale for its overall superiority over HBP compared with ABP and CBP. These characteristics of HBP allow it to be used to determine small but significant serial changes in systolic and diastolic BP.[12,13]

Practicality

The most remarkable difference between ABPM and HBPM is practicality. More than 35 million HBPM devices have been distributed in Japan, whereas only 20 000 ABPM devices are in use.[4]

The high number of available HBPM devices means that non-hypertensive as well as hypertensive subjects can obtain these devices. The reason for this wide distribution is that Japanese people are well aware of the serious risk associated with hypertension and are anxious to monitor their BP levels; this finding is reflective of the Japanese mentality. The self-measurement of BP at home in Japan is traditional. At the end of the 1950s, conventional mercury sphygmomanometers used with stethoscopes were sold in pharmacies and by mail order. This method was not followed because of the complex procedure involved. At the end of the 1960s, aneroid sphygmomanometers with a microphone in the upper arm cuff were released to the market. In the beginning of the 1970s, aneroid sphygmomanometers had been replaced by electrical strain gauge manometers. These devices frequently suffered from mechanical trouble and were expensive. At the end of the 1970s, semiautomatic electrical devices for HBPM based on the cuff-oscillometric principle were introduced in Japan. Subsequently, automatic devices for HBPM spread extensively. This trend has become common worldwide.[7,8]

Table 1 Comparison of general characteristics of the three BP measurement methods

	CBP	*ABP*	*HBP*
Measurement frequency	Low	High	High
Standardization	Low	Low	High
Reproducibility/reliability	Low	Medium	High
Sensitivity to BP change	Low	Possibly high	Hgh
Practicability			
Availability	Low	Low	High
Feasibility	Low	Low	High
Utility	High	Low	High
Acceptability, tolerability	Moderate	Low	High
Trackability	Moderate	Low	High
Quick feedback	High	Low	High
Repeatability	Moderate	Low	High
Cost for measurements	Low	High	Moderate
Labor for patients	Low	High	Moderate
Labor for doctor	High	High	Low

Abbreviations: ABP, ambulatory blood pressure; CBP, clinic blood pressure; HBP, home blood pressure.

Acceptability/tolerability

Japanese people are very tolerant of HBP automatic measurements and accept them as a daily activity to track their own health.[5] ABPM has been shown to be less accepted than CBPM or HBPM, largely owing to the discomfort, disturbance of life and sleep, high cost and need for medical staff (see w-3 in Supplementary Information). The high availability, feasibility, utility and tolerability of HBPM are acknowledged worldwide (see w-4 in Supplementary Information). The Ohasama study, which began in 1986, introduced ABPM and HBPM for obtaining BP information.[14,15] Thereafter, HBPM was performed for 26 years, and in total, 6000 Ohasama residents continued HBPM using automatic HBPM devices primarily purchased by the inhabitants of Ohasama. The ABPM project was discontinued in 2006 because of the excess labor required for medical staff and the high burden placed on the study subjects. The Ohasama study supports the higher acceptability, availability, feasibility and utility of HBPM over ABPM.

Recently, the Ohasama study group reported the results of the Hypertension Objective Treatment based on Measurement by Electrical devices of Blood Pressure Study (HOMED BP Study), a randomized, controlled, open trial using automatic HBPM devices and the Internet (telemedicine). In the study, 3518 hypertensive subjects were followed for up to 10 years (mean 5.3 years) by 300 general practitioners.[16] This study showed that HBPM was used without difficulty and was readily accepted by practitioners and patients.

Easy to repeat, easy to standardize, easy to track

HBPM offers the possibility of obtaining multiple readings over the long term under standardized conditions, and it is simple to repeat and track. ABPM is not suitable for repeated measurements.[17]

HBPM allows for ongoing disease monitoring by patients, can provide health-care providers with timely and relevant clinical data and can provide direct and immediate feedback regarding the diagnosis and treatment of hypertension.[18–21] HBPM can provide direct feedback as to the diagnosis of hypertension and BP control,[19–21] whereas there is a time lag in ABPM for feedback on the diagnosis and treatment of hypertension.

An advantageous feature of HBPM is that the measurement conditions can be standardized. ABP is monitored during unrestricted routine daily activities. Thus, the reproducibility of HBP is superior to that of ABP (see w-2 in Supplementary Information). The JSH guidelines[1–3] recommend that HBP should be measured daily over a long period, that is, life-long measurements. This recommendation is different from the European and the US guidelines. The standard of the Japanese guidelines is that HBPM is not only a tool for diagnosis and therapeutic decisions but is also a tool for lifestyle modification and the self-management of hypertension. In Japan, almost all people with hypertension have their own HBPM devices, whereas in some developed countries, HBPM devices are lent to patients by a primary care center for only a short period to diagnose and manage hypertension.[22]

2. CBP, ABP AND HBP FROM A CLINICAL STANDPOINT

Although the general characteristics of HBP appear to be superior to CBP and ABP, ABPM is recommended more often in several guidelines (Table 2).[8,11] Most guidelines emphasize that the evidence on the prognostic significance of HBP is insufficient when compared with ABP and that ABP should be the gold standard for clinical practice and research of hypertension. This concept is downgrading the value of HBP.

Accumulation of evidence

Much evidence has accumulated that shows that HBP is able to predict hypertensive target-organ damage (TOD) and a prognosis of cardiovascular disease more effectively than CBP.

The Tecumseh study investigators first reported that hypertensive TOD in subjects with borderline hypertension could only be predicted by HBP.[23]

The comparative predictive power of HBP, ABP and CBP for cardiovascular mortality was first reported by the Ohasama study in 1996.[24] In 1998, they reported that HBPM had higher predictive power for cardiovascular morbidity and mortality than CBPM.[25] The Ohasama study investigators reported the prognostic value of HBP from various points of view (see w-5 in Supplementary Information).

In 1999, Okumiya *et al.*[26] reported a U-shaped association between the average level of SHBP and mortality in old men.

The Self-Measurement of Blood Pressure at Home in the Elderly: Assessment and Follow-up (SHEAF) study followed 4939 treated hypertensive patients for 3.2 years and observed that HBP has a better prognostic accuracy than CBP.[27,28]

Table 2 Differential clinical standpoints for the three BP measurement methods

	CBP	*ABP*	*HBP*
Accumulation of evidence	Adequate	Adequate	Adequate
Reflection of target organ damege	Weak	Adequate	Adequate
Reflection of prognosis	Weak	Adequate	Adequate
Use in non-hypertensive population	Possible	Not adapted	Adapted
Tool for lifestyle modification	Not adapted	Not adapted	Adapted
Interference in daily activity	Significant	Significant	Negligible
Anxiety over measurement	Possible	Possible	Possible
Alerting reaction	Significant	Initially	Initially
Observer bias	Possible	Absent	Absent
Selection/reporting bias	Absence	Absent	Possible
Regression to the mean	Significant	Weak	Absent or weak
Compliance/adherence	No effect	Uncertain	Ameliorates
Awareness of hypertension	Uncertain	Uncertain	Improves
Patient's active participation for medication	Uncertain	Uncertain	Improves
Patient's motivation to control BP	Uncertain	Uncertain	Improves
Doctor–Patient cooperation and communication	Uncertain	Uncertain	Improves
Doctor's motivation to provide active treatment	Uncertain	Improves	Improves
Tool for self-management	Not adapted	Not adapted	Adapted
Risk for self-modification of treatment	None	None	Possible

Abbreviations: ABP, ambulatory blood pressure; CBP,clinic blood pressure; HBP, home blood pressure.

In 2005, the Pressioni Arteriose Monitorate e Loro Associazion (PAMELA) study investigators reported the comparative prognostic value of HBP, ABP and CBP. They reported that the overall ability to predict death was comparable among HBP (with an average of two measurements in one day), ABP and CBP.[29]

In the same year, Flemish investigators reported that the prognostic significance of HBP measured by medical staffs was higher than that of CBP and was at least equal to that of daytime ABP in older hypertensive patients in a primary care cohort.[30]

The Japan Hypertension Evaluation with Angiotensin II Antagonist Losartan Therapy (J-HEALTH) study followed 4596 subjects and observed that the risk of masked hypertension determined by HBPM was similar to that of poorly controlled hypertension.[31]

In 2010, the Fin-Home study investigators reported that HBP predicted the risk of cardiovascular events more effectively than CBP during the 6.8 years of follow-up of 2081 randomly selected subjects in Finland.[32]

The Didima outcome study investigators reported that HBP measured twice in the morning for 3 days predicted cardiovascular events as well as CBP did during the 8.2 years of follow-up of a general population in Greece.[33]

The evidence of the prognostic significance of HBP has been accumulating. It has been criticized that none of the studies with HBPM were conducted in untreated subjects at the time of quantifying HBP.[34] To address this point, the Ohasama study demonstrated the prognostic value of HBP in untreated subjects. HBP-based classifications showed a linear increase in stroke risk among untreated individuals, and this trend was more apparent in untreated subjects than in treated subjects.[35]

Evidence regarding the prognostic value of HBPM suggests that this method is a reliable diagnostic test and an alternative to ABPM to be used for decision making in hypertensive management.[36]

Use in hypertensive and non-hypertensive subjects

A specific feature of HBPM compared with ABPM and CBPM is that HBPM is available not only for hypertensive subjects but also for non-hypertensive subjects. This finding is supported by the situation in Japan where >35 million HBPM devices have already been distributed; this distribution rate equals approximately one device per household.[4,5] It is assumed that monitoring of HBP in the non-hypertensive population as well as in the hypertensive subjects increases the awareness of BP and hypertension in the general population.[7,32,37–40] This result may have a substantial effect on motivating subjects to make lifestyle modifications.[7,17,41,42]

It has been reported that HBPM mediates the patients' active participation in hypertension medication treatment[21,43–46] due to the activated motivation of patients for BP control[46,47] and that it improves compliance with antihypertensive medication.[18,19,22,37,43,48–51]

It has been confirmed that HBPM motivates doctors to begin treatment, overcomes doctors' inertia regarding the management of hypertension and facilitates doctor–patient cooperation.[21,22,45,52,53] These beneficial effects of BP measurement are observed with HBPM but not with CBPM and ABPM.

Shortcomings of HBPM

HBPM interferes with daily activities, but the extent of this interference is minimal compared with ABPM and CBPM. In Japan, HBPM is practiced customarily, and subjects do not feel that HBPM is troublesome.[5]

It is possible that some patients feel anxiety about HBPM, and others might become overly focused and take too many measurements. Appropriate interactions between patients and physicians, including patient education, may help overcome these types of problems.[54]

The alerting as well as the novelty effect remain for HBPM.[55] These effects are most significant in CBPM and are apparent in ABPM during the initial few hours of use.[56] In HBPM, the novelty effect is small or practically absent.[57] The novelty effect, if present, is observed only during the initial few days, and thereafter, HBP is stabilized.[57] Therefore, the regression to the mean effect is minimal or absent in HBP compared with CBP or ABP,[57] suggesting that HBPM has no or minimal placebo effect.[43,57,58]

Selection/reporting bias

The most serious problem associated with HBPM may be the selection and reporting bias of HBPM data.[59,60] Patients frequently select inaccurately low or sometimes high values. Low readings may be reported to prove to the physician that medication or uptitration is not needed, whereas high readings may result in uptitration.[60] To exclude the selection/reporting biases, the JSH guidelines[1–3] recommended that HBP should be measured 1–3 times in the morning and evening and that all HBP readings should be documented. The Japanese guidelines emphasize that measuring once in the morning and evening for a long period is preferable to facilitate ruling out a selection/reporting bias.[1–3] The use of devices with an integrated circuit memory solves this problem.

Self-management

HBPM is essentially a favorable tool for self-management, but this also brings a risk of self-modification of treatment. The JSH guidelines[1–3] emphasize that patients should be instructed not to self-modify the treatment regimen on the basis of HBP. Recently, several studies recognize that with the combination of HBPM and telemedicine, self-titration of the antihypertensive regimen is feasible.[61–63]

3. TECHNICAL ISSUES OF CBPM, ABPM AND HBPM

Systemic and observer bias of BP measurements

BP measurements based on conventional sphygmomanometer and auscultatory methods in the clinical setting have been confirmed to be inappropriate as a tool for decision making in clinical practice due to their inaccuracy (Table 3). Every guideline claims to comply with the suggested procedures for CBPM. Such procedures are prescribed to reduce the random variations in BP and to increase the reliability and reproducibility of BP measurements. BP is rarely measured in accordance with such guidelines in a screening or clinical setting, and worries about the accuracy of measurements are often disregarded or ignored.[1,8,64] The challenges of low compliance with the procedure of CBPM remains, at least in Japan.[64]

Accuracy of devices

HBP and ABP are measured by automatic devices based predominantly on the cuff-oscillometric principle. Issues with the accuracy of the automatic devices remain. Several devices sold globally are not validated on the basis of a global standard. At least in Japan, the accuracy of the automatic devices is certified by a regulatory authority, indicating that the accuracy of the devices is adapted to the criteria of the Association for the Advancement of Medical Instrumentation[65] or of the European Society of Hypertension, International protocol.[66] It seems that the problem of the accuracy of the device lies with the authorities who regulate the systems.

Table 3 Technical issues for the three BP measurement methods

	CBP	*ABP*	*HBP*
Automatic/manual	Automatic/manual	Automatic	Automatic
Inaccuracy of device	Possible	Possible	Possible
Observer bias	Present	Absent	Absent
Training of staff	Essential	Essential	Necessary
Instructions for users	Not necessary	Essential	Necessary
Telemedicine	Not adapted	Not adapted	Adapted
Memory function	Not available	Available	Available
Download to computer	Not available	Available	Available
Averaging	Labor-intensive	Easy	Easy

Abbreviations: ABP, ambulatory blood pressure; CBP, clinic blood pressure; HBP, home blood pressure.

Integrated circuit memory and related functions

A considerable number of recent devices for HBPM incorporate an integrated circuit memory, which allows data to be downloaded to a microcomputer. The averaging of a large number of BP measurements is easily available, and the application of telemedicine is possible. These functions of HBPM are not provided by ABPM and CBPM.

Instructions for patients

Past guidelines emphasized that ABPM and HBPM should be performed under medical supervision. In Japan as well as in other developed countries, the introduction of HBPM among hypertensive patients started spontaneously without instruction by health professionals.[5] Most patients or subjects had little difficulty using the HBPM devices.[67] Now it is emphasized that elaborate training is no longer necessary for the automatic electrical devices.[68–72] At least for Japanese subjects, the written instructions attached to the device are sufficient to allow accurate measurements of HBP. This finding was shown in the Ohasama study,[14,25] HOMED-BP study,[71] Japan—Home versus Office measurement evaluation (J-HOME) study[41] and Babies and their Patients' Longitudinal Observation in Suzuki Memorial Hospital on Intrauterine period (BOSHI) study[72] in which HBPM was used for the determination of BP in a large number of subjects. Instruction for ABPM is essential. Substantial training of staff for ABPM is indispensable, whereas training of staff for HBPM is unnecessary.

4. BENEFITS OF HBPM FOR THE DIAGNOSIS OF HYPERTENSION

Unlike CBPM, ABPM and HBPM provide BP information in relationship to time (Table 4). Although ABPM provides 50–100 BP measurements obtained every 15–30 min on a particular day, each BP value is unreliable.[73]

BP in the morning and morning hypertension

ABP in the morning just after awaking are unstable because, in this time period, it is difficult to keep the arm still, and it is known that BP measurements in this time period are frequently inaccurate.[74,75] Morning BP on the basis of HBP is measured under fixed conditions at fixed hours of the day. Morning HBP averaged for a long period is reliable and reproducible.

The prognostic significance of morning HBP was reported in the Ohasama study[76] and the Jichi Morning Surge (JMS)-1 study,[77] demonstrating that morning hypertension, which indicates

Table 4 Diagnosis of hypertension from the three BP measurement methods

	CBP	*ABP*	*HBP*
Long-term average of BP	Available	Not available	Available
Daily average of BP	Not available	Available	Partly available
Worksite BP/hypertension	Not available	Available	Possibly available
Morning BP/hypertension	Not available	Available	Available
Morning surge	Not available	Available	Possibly available[a]
Evening BP/hypertension	Not available	Available	Available
Nocturnal BP/hypertension	Not available	Available	Possibly available[a]
Nocturnal dipping status	Not available	Available	Possibly available[a]
White-coat effect (hypertension)	Not available	Available	Available
Masked hypertension	Not available	Available	Available
Short-term BP variability	Not available	Available	Possibly available
Circadian BP variability	Not available	Available	Possibly available[a]
Long-term variability	Available	Not available	Available
Day-to-day BP variability	Not available	Not available	Available
Morning–evening difference	Not available	Available	Available
Heart rate	Available (labile)	Available (labile)	Available

Abbreviations: ABP, ambulatory blood pressure; CBP, clinic blood pressure; HBP, home blood pressure.
[a]HBP monitoring devices that can monitor blood pressure during sleep at night are available.

hypertension specifically observed in the morning, might be a better predictor of stroke than evening hypertension, particularly among individuals using antihypertensive medication.[76]

Morning hypertension is mediated by a morning surge or is observed following the non-dipper/riser or nocturnal hypertension. The latter was first reported in the Ohasama study in which subjects underwent 24-h ABPM and HBPM.[75]

The predictive value of morning BP for TOD has been confirmed (see w-6 in Supplementary Information). Morning–evening differences in HBP are one of the indices of high morning BP or morning hypertension. The Ohasama study first reported that the greater the morning–evening difference was, the higher the cardiovascular mortality.[78] The predictive value of the morning–evening difference for TOD was confirmed (see w-6 in Supplementary Information).

BP in the evening

Evening BP on the basis of HBPM is affected by daytime physical and mental activities and the lifestyle of subjects such as time of the evening meal, alcohol consumption and bathing (see w-7 in Supplementary Information). Taking antihypertensive drugs in the evening also affects evening HBP (see w-7 in Supplementary Information). The JSH guidelines[1–3] recommend that HBP in the morning should be measured within 1 h after waking up, after urination, before drug ingestion and before breakfast. These guidelines also recommend that evening HBP be measured once immediately before going to bed. Evening HBP is lower than morning HBP in Japanese subjects (see w-8 in Supplementary Information). It has been reported that evening HBP is higher than morning HBP in a Caucasian population (see w-8 in Supplementary Information). This difference may be mediated by the difference of lifestyles.

BP at night during sleep and the morning surge

The poor reproducibility of nocturnal BP measurements and nocturnal dipping status on the basis of ABPM have widely been recognized because nocturnal BP levels are affected by the quality and quantity of nocturnal sleep (see w-9 in Supplementary Information). The morning surge noted by the difference between morning BP and nocturnal BP measurements on the basis of the ABPM[79] is not reproducible.

The assessment of nocturnal BP is of major clinical relevance because of its demonstrated prognostic value.[80] The Ohasama study investigators developed an HBPM device that can monitor nocturnal BP during sleep.[81,82] Such devices are now used in epidemiological surveys,[83] large-scale intervention trials[16] and clinical pharmacology studies[84] in Japan. More recently, HBPM devices that have an ability to work as ABPM have also been marketed.[85,86] Nocturnal BP can be assessed repeatedly by HBPM. Nocturnal BPs are normally measured by a HBPM device a limited number of times during sleep, and subjects can recall whether they woke up during the measurements. ABPM measures BP every 30–60 min during the night, and normally, subjects cannot remember if they woke up during the BP measurements (see w-9 in Supplementary Information). Now, with HBPM, we can determine the relationship between the nocturnal BP levels and quality of sleep.[81,82] Measurements of nocturnal HBP during sleep as well as morning and evening HBP over a long period might provide reliable information on the nocturnal dipping status.

Masked hypertension

Morning hypertension, evening hypertension, worksite hypertension and nighttime hypertension are not diagnosed unless out-of-office BPs are measured. These hypertensive conditions are defined as masked hypertension.[87] In 1996, the Ohasama study first noticed the presence of masked hypertension on the basis of HBPM in the general population.[88] It has been confirmed that masked hypertension determined by HBPM is associated with a poor prognosis of cardiovascular disease (see w-10 in Supplementary Information). Masked hypertension on the basis of HBPM predicted the TOD, future development of sustained hypertension, future development of impaired glucose metabolism or metabolic syndrome and other cardiovascular risks (see w-10 in Supplementary Information). When masked hypertensive patients are treated, HBPM can determine masked resistant hypertension.[71,89–91]

White-coat hypertension

HBPM seems to be the most plausible method to diagnose white-coat hypertension or to define the white-coat effect (see w-11 in Supplementary Information), as HBPM can provide timely and relevant clinical data and direct feedback without the presence of a health-care provider. It seems that the definition of the normotensive level of HBP prescribes the risk of white-coat hypertension (see w-11 in Supplementary Information). Another issue to define white-coat hypertension or the white-coat effect is the method of out-of-office BP monitoring. Because the reproducibility of ABPM is low, the reproducibility of white-coat hypertension or effect on the basis of ABPM is low[92,93] (see w-11 in Supplementary Information).

Even if white-coat hypertension is harmless for a certain period, its long-term effects are unknown. The Ohasama study investigators first reported that white-coat hypertension determined on the basis of HBPM is a transitional condition to true hypertension.[94] Recently, the PAMELA study investigators confirmed that subjects with white-coat hypertension are at increased risk of developing true hypertension.[95] It has been reported that white-coat hypertension defined by HBPM is accompanied by metabolic disorders, a higher risk of cardiovascular mortality and worse prognosis than true normotension (see w-11 in Supplementary

Information). Long-term follow-up of subjects with white-coat hypertension is indispensable. HBPM is the best means to maintain awareness of the long-term risk of white-coat hypertension.

Blood pressure variability

Morning hypertension, evening hypertension, nocturnal hypertension, nocturnal dipping and the morning surge are types of BP variability phenotypes. Since the report in 2010 on the prognostic significance of the visit-to-visit variability of CBP,[96] the interest in BP variability has increased. To obtain an index of the visit-to-visit variability of CBP, we must wait longer than one year.

The robust prognostic evidence on the short-term BP variability obtained by ABPM was first reported by the Ohasama study.[97] These investigators were also interested in the clinical significance of the day-to-day variability of HBPM.[98] They reported that day-to-day variability of HBP was predictive of stroke in the Ohasama population. The Fin-Home study investigators demonstrated that greater variability in morning HBP is an independent predictor of cardiovascular events.[99] The predictive value of day-to-day variability of HBP for hypertensive TOD has been confirmed.[100,101] Johansson *et al.*[99] emphasized that HBPM can provide data on the short-term variability of BP using the first and second measurements of HBP on one occasion, and this short-term BP variability can predict the total and non-fatal cardiovascular events and total mortality.

HBPM is an excellent way to detect long-term variations in BP, including seasonal variations. We first reported that minimal seasonal changes in BP were captured by HBPM in subjects with borderline hypertension.[102] Seasonal variation of BP defined by HBPM was reported extensively under several pathophysiological conditions (see w-12 in Supplementary Information).

5. DIFFERENTIAL FEASIBILITY OF CBPM, ABPM AND HBPM FOR THE TREATMENT OF HYPERTENSION

It has been revealed that HBPM yields minimal alerting effects and novelty effects (Table 5).[43,57,58] These characteristics of HBPM reflect good reproducibility of BP levels (see w-2 in Supplementary Information), no regression to the mean and a minimal placebo effect.[43,57,58] HBPM can distinguish small but significant serial changes in BP.[12,13] Such features of HBPM are superior to ABPM for determining the antihypertensive efficacy of drugs and apparently surpasses the data available from CBPM.

Benefit of HBPM for the treatment of hypertension

ABPM has the advantage of being able to determine the time-dependent effects of antihypertensive drugs.[103] A weak point of ABPM for the determination of the antihypertensive effect of drugs is the low reproducibility of BP levels and the unreliability of each BP value (see w-13 in Supplementary Information). It is not practical to perform multiple ABPM sessions in the same patients to evaluate the response to treatment.

Repeated measurements under standardized conditions at fixed times for an extended length of time result in HBPM being the most appropriate method for evaluating the efficacy of antihypertensive drugs.[104]

Regular use of HBPM can enhance the evaluation of how effectively BP is being controlled in patients who are taking medication.[105] BP control in people with hypertension on the basis of HBPM improved BP control (see w-14 in Supplementary Information) and increased the proportion of patients achieving target BP goals (see w-14 in Supplementary Information).

Duration of action of antihypertensive drugs

The duration of the action of the antihypertensive drug effects can be determined by HBPM. This was indicated by the trough/peak ratios on the basis of ABPM. Because the reproducibility of ABP is poor, the reproducibility of the trough/peak ratio is also poor and unreliable.[106] The duration of action of antihypertensive drugs can be determined by the morning effect versus the evening effect ratio on the basis of HBPM. In this case, multiple morning effects and evening effects are available with HBPM. The morning/evening ratio is stable and reliable.[107–111]

Trend of antihypertensive effects

HBPM is the most practical way to detect and monitor BP in the day-by-day management of patients with hypertension and is appropriate for tracking changes in BP induced by treatment.[107] Recently, trends of the antihypertensive effects of drugs have been shown by fitting data to the exponential decay function curve using daily HBPM values.[112] This analysis provides the maximum hypotensive effect and the time to attain the maximum hypotensive effect.[113]

Compliance/adherence

HBPM can detect the short-term effects of withdrawing antihypertensive drugs (non-compliance).[114] It has widely been recognized

Table 5 Differential feasibility of the three BP measurement methods for treatment of hypertension

	CBP	*ABP*	*HBP*
Determination of antihypertensive effect	Unreliable	Adapted but unreliable	Reliable
Achievement of target BP	Uncertain	Uncertain	Improved
Amelioration of BP control	No	No	Possible
Duration of action of antihypertensive effect	Not adapted	Adapted (T/P ratio)	Adapted (M/E ratio)
Trend of antihypertensive effect (long-term) (exponential decay function)	Not suitable	Not adapted	Adapted
Time-dependent antihypertensive effect (short-term) (antihypertensive drug coverage)	Not available	Adapted but low reproducibility	Adapted
Effect of drugs on BP variability	Not reliable	Adapted	Adapted
Placebo effect	Significant	Moderate	None or minimal
Compliance/adherence	No effect	No effect	Ameliorated
Hypotensive effect of BP measurement *per se*	No	No	Possible
Number of patients needed to detect antihypertensive effect	Many	Uncertain	Small number
Operational threshold			
Diagnositic criteria	Established	Established	Established
Target BP level	Established	Not established	Not established

Abbreviations: ABP, ambulatory blood pressure; CBP, clinic blood pressure; HBP, home blood pressure; M/E ratio, morning effect/evening effect ratio T/P ratio, trough/peak ratio.

that HBPM improves compliance/adherence to antihypertensive medications (see w-15 in Supplementary Information).

Characteristically, it has been reported that HBPM *per se* has a certain antihypertensive effect.[115,116] The use of HBPM in drug trials has been shown to reduce the number of patients needed to detect antihypertensive effects.[57,117]

Operation threshold of HBP

In national and global guidelines,[2,3,7–10] a HBP of 135/85 mm Hg was adopted as a criterion for hypertension on the basis of the Ohasama Study[25,118] and international database,[119,120] whereas the World Health Organization/International Society of Hypertension guidelines in 1999[121] stated that a HBP of 125/80 mm Hg was equivalent to a CBP of 140/90 mm Hg according to research studies, including the Ohasama study[14] and PAMELA study.[122] The 2007 European Society of Hypertension/European Society of Cardiology guidelines proposed a HBP of 130–135/85 mm Hg as a criterion for hypertension, revealing a margin of flexibility in SBP.[123] A value of $\geqslant$125/80 mm Hg and $<$135/85 mm Hg of HBP cannot be regarded as normotension and should be recognized as a high normal range or above.

The target HBP for antihypertensive treatment has not been established. In an American Heart Association, American Society of Hypertension and Preventive Cardiovascular Nurse Association joint statement, the target of hypertensive treatment for hypertensive patients in general is an HBP of 135/85 mm Hg, and the target for high-risk patients is 130/80 mm Hg.[8] According to a meta-analysis of studies on HBP, the optimal HBP was reported to be $<$120/80 mm Hg.[124] The JSH guidelines[1,3] determined the expected target HBP level for antihypertensive treatment for young and middle aged persons to be 125/80 mm Hg and for elderly persons to be 135/85 mm Hg. The former is equivalent to the upper normal range of HBP, and the latter is equivalent to the hypertension criterion of HBP. There is no evidence to support these target HBP levels. The HOMED-BP study explored the extent to which long-term antihypertensive treatment guided by HBPM affected cardiovascular outcomes in patients randomized to usual versus tight control and to the initiation of treatment with three different classes of antihypertensive drugs (see Section 1). Although there was no difference among the groups in a 2×3 study design, the risk of the primary endpoint independently increased by 41% and 47% for a 1 s.d. increase in baseline and follow-up systolic HBP, respectively, in all patients combined.[16] The 5-year risk was $<$1% if the on-treatment systolic HBP was $\leqslant$131.6 mm Hg.[16] The HOMED-BP study proved the feasibility of adjusting antihypertensive drug treatment based on HBP and suggested that a systolic HBP level of 130 mm Hg should be an achievable and safe target.

6. APPLICATION OF THE THREE BP MEASUREMENTS FOR CLINICAL STUDY

ABPM enables measurement of BP over 24 h during normal living activities, which leads to random and rhythmic variations of BP. ABPM is suitable to detect short-term (for example, every 15–30 min) variability of BP. Theoretically, ABPM is most suitable for evaluation of circadian BP variation. The low reproducibility of the ABP level, nocturnal BP level and dipping patterns or circadian BP variations have widely been recognized (see w-13 in Supplementary Information). These characteristics of ABPM are not suitable for general clinical studies or clinical pharmacological studies. Although ABPM maintains its role as a research tool, its use might be restricted. HBPM can surpass and replace many useful components of ABPM.

HBPM provides objective measurements and strict phenotypes of BP compared with ABPM and CBPM.[125] This strict phenotype of BP unmasks the relationship between genes and hypertension. The PAMELA study investigators emphasized that the method of BP measurement has a significant impact on genetic associations with BP.[126] In a 12-year follow-up of the Ohasama study, it was clarified that the accumulation of common polymorphisms predicted the risk of future development of hypertension defined by HBPM only in 403 subjects[127] and reported the relationship between parental longevity and HBP in their children.[128] The heritability of BP levels has never been clarified by CBP in such a small number of subjects.

7. ECONOMIC VIEWPOINTS OF THE THREE BP MEASUREMENT METHODS

The introduction of ABPM into the diagnosis and treatment of hypertension has been shown to have a strong effect on the medical economy.[129,130] If HBPM provides information comparable with that provided by ABPM, HBPM would also be expected to have a significant effect on the medical economy (see w-16 in Supplementary Information). In Japan, where HBPM devices are purchased and used by most hypertensive patients, the introduction of HBP into the care of hypertension has resulted in a decrease in annual medical expenditures of approximately 1 trillion yen.[131,132] This decrease has been mediated primarily by screening for white-coat hypertension and masked hypertension. A meta-analysis reported that regular HBPM use correlated with twice the reduction in the dose of antihypertensive drug used compared with patients whose BP was monitored in the clinic (see w-16 in Supplementary Information). As a result of large-scale intervention studies, the introduction of HBPM has been reported to lead to a reduction in medical expenditures via a decrease in the amount of drugs used (see w-16 in Supplementary Information). The introduction of HBPM in the management of hypertension allows the health-care professional to obtain daily BP levels from patients without frequent visits to the clinic, with the potential of curtailing the escalating cost of health care (see w-16 in Supplementary Information).

The costs for the device and analysis associated with ABPM are high when compared with HBPM. If all the subjects with newly diagnosed and treated hypertension underwent ABPM, an untenable rise in costs would be anticipated.[92] HBPM is less expensive in terms of the cost of the device and the analysis of information (see w-16 in Supplementary Information). Many HBPM devices have been purchased by people in Japan, and no economic burden for medical institutions and the nation has been determined.

The NICE clinical guideline 127 emphasizes that if CBP is $\geqslant$140/90 mm Hg, ABPM, not HBPM, should be offered for all patients to confirm the diagnosis of hypertension.[11] This recommendation was made based on the grounds that ABPM is the most cost-effective strategy to diagnose hypertension.[133] This analysis was performed based on an assumption that ABPM is the gold standard, indicating that the sensitivity and specificity of ABPM for diagnosis of hypertension are 100%. If we compensate for the findings shown in the present review, HBPM should be considered the gold standard for the diagnosis of hypertension. Thus, the cost-effectiveness of HBPM should be greater than that of ABPM.

It is important to consider that ABPM is covered by health insurance in the United States, European countries and Japan,[1,8] but HBPM is not.

Limitation of the review

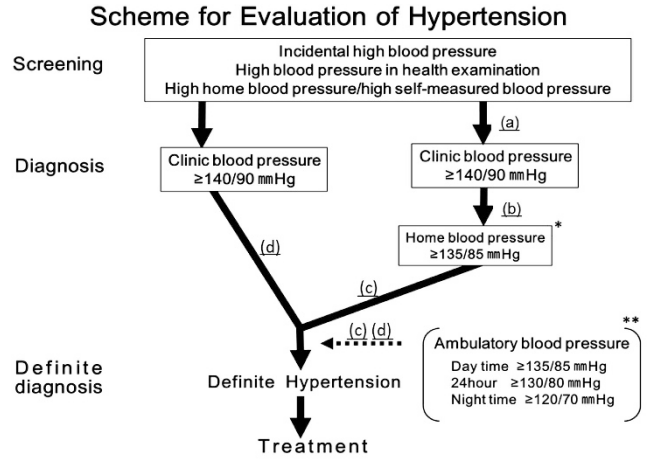
In the present review, we emphasized the superiority of HBPM over ABPM. The most serious limitation of this conclusion is the lack of a

direct comparative study of ABPM and HBPM for the prediction of cardiovascular outcome.

It has been hypothesized that ABPM and HBPM have different roles and may supplement each other. HBPM and ABPM may independently and cumulatively predict cardiovascular and all-cause mortality.[93] The Ohasama study investigators reported recently that the clinical significance of HBPM and ABPM for predicting TOD differ for different target organs.[134]

At present, a strict target BP level for ABP and HBP have not been established. Extensive application of HBPM and ABPM in the intervention trials for hypertension is expected in the future.

We must highlight the clinical significance of the home heart rate, monitoring schedule of HBPM and the result of clinical studies based on HBPM. However, space does not permit us to include these considerations in this report.



* When the diagnosis of hypertension is not consistent between clinic and home blood pressure , the diagnosis based on home blood pressure has priority over that based on clinic blood pressure.
Self- measured blood pressure indicates measurements of blood pressure by the devices in the public places, worksite, pharmacy, etc.

** Indication of ambulatory blood pressure monitoring.

1. In the case when home blood pressure is around 135/85mmHg or clinic blood pressure is around 140/90mmHg.
2. In the case with white-coat hypertension where HBP is equal to or higher than 125/80mmHg and less than 135/85mmHg.
3. In the case where home blood pressure is very variable.
   a. In the case where white coat hypertension is not defined by the variable home blood pressure.
   b. In the case where masked hypertension is not defined by the variable home blood pressure.
   c. In the case who is suspected of work site hypertension but who can not obtain self-measurement of blood pressure in the work site.
   d. In the case when resistant hypertension is not defined on the basis of home blood pressure.
   e. In the case who is suspected of having nocturnal hypertension, non-dipper, and riser but who can not measure nocturnal blood pressure by the home monitoring device
4. In the case when short-term blood pressure variability is objective.
   a. In the case when incidental and transient hypertension or hypotension is suspected.
   b. In the case where home blood pressure and/or clinic blood pressure is very variable.

Figure 1 Scheme for the evaluation of hypertension. In Japan, home blood pressure (HBP) is measured spontaneously without instruction by a health professional. Many subjects are aware of their high blood pressure before a diagnosis of hypertension at clinic (screening phase; route a). At clinic, almost all subjects suspected of having hypertension are recommended to measure HBP (route b). When the diagnosis of hypertension is not consistent between clinic blood pressure (CBP) and HBP, the diagnosis based on HBP has priority over that based on CBP. Ambulatory blood pressure monitoring (ABPM) may be used, if available, when home blood pressure monitoring (HBPM) cannot provide a definite diagnosis of hypertension (route c). If patients do not have a HBPM device, diagnosis by ABPM, if available, would have priority for the diagnosis of hypertension (route d); however, this situation is relatively rare because ABPM devices are not distributed widely in the primary care center. In such a case, the purchase of HBPM devices by patients should be strongly suggested or HBPM devices should be lent to patients by a primary care center for a certain period to diagnosis and manage hypertension.

Perspective

According to the present general survey of HBPM, ABPM and CBPM, the superiority of HBPM over ABPM and CBPM is apparent from almost all practical and clinical research perspectives. Although the use of ABPM has a certain contribution for the diagnosis and treatment of hypertension, the widespread diffusion of this approach to daily practice is limited by the low acceptability, low tolerability, high cost, low reproducibility and low reliability.

The general agreement is that HBPM should be used in all subjects with BP considerations.[135] Because HBPM is applicable to the non-hypertensive population as well, the use of HBPM in the initial screening of subjects with possible hypertension or with normotension is promising. HBPM provides information simultaneously on white-coat hypertension, the white-coat effect, masked hypertension and masked resistant hypertension while the treatment of hypertension proceeds. These advantages of HBPM are assured by high reproducibility, reliability, practicality and low costs. These characteristics of HBPM indicate that this method is the model for the diagnosis of hypertension and for short-term and long-term monitoring of the response to antihypertensive treatment in daily practice.

The European Society of Hypertension guidelines suggest the evaluation of resistant hypertension for the potential indication of HBPM in all patients receiving antihypertensive medication, to improve compliance and adherence and to improve the hypertension control rate.[7] The phrases 'all potentially hypertensive subjects' or even more widely 'all population for screening' of hypertension should be added as a potential indication of HBPM. A recent Japanese health examination for the general population has introduced HBPM for the screening of hypertension. The flow-chart for diagnosis of hypertension on the basis of several BP measurement methods is proposed (Figure 1).

HBPM should not be assigned a supporting role but rather should be the leading actor for the management of hypertension.

CONFLICT OF INTEREST

YI received lecturing fees and research support from Astellas, AstraZeneca, Daiichi Sankyo, Dainippon-Sumitomo, Merck Sharpe and Dohme, Novartis, Pfizer, Takeda and Tanabe-Mistubishi. TO received lecturing fees from Astellas, AstraZeneca, Daiichi Sankyo, Dainippon-Sumitomo, Kyowa Hakko Kirin, Merck Sharpe and Dohme, Novartis, Pfizer, Takeda and Tanabe-Mitsubishi. Omron Healthcare gave research support to YI.

ACKNOWLEDGEMENTS

This study was supported, in part, by Grants for Scientific Research (18390192, 18590587, 19590929, 19790423, 20590629, 21390201, 21591016, 22590767, 22790556 and 23249036) from the Ministry of Education, Culture, Sports, Science and Technology, Japan; Grants-in-Aid (H18-Junkankitou[Seishuu]-Ippan-012, H20-Junkakitou[Seishuu]-Ippan-009, 013 and H23-Junkakitou[Seishuu]-Ippan-005) from the Ministry of Health, Labor and Welfare, Health and Labor Sciences Research Grants, Japan; Grant-in-Aid for Japan Society for the Promotion of Science fellows (18.54042, 19.7152, 20.7198, 20.7477 and 20.54043); Health Science Research grants and Medical Technology Evaluation Research grants from the Ministry of Health, Labor, and Welfare, Japan; Japan Atherosclerosis Prevention Fund; and Biomedical Innovation grants.

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Supplementary Information accompanies the paper on Hypertension Research website (http://www.nature.com/hr)