



## *Leuven consensus conference on ambulatory BP monitoring task force IV: self-monitoring of the blood pressure*

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### **ABSTRACT - TASK FORCE IV**

Self-monitoring of the blood pressure (BP) by patients at home or in other non-clinical settings has become increasingly common in recent years. This phenomenon has been fueled in part by the increased availability of automatic, sphygmomanometers which are now both affordable and easy to use by patients.

### **BENEFITS OF SELF-MONITORING OF THE BP**

Self-monitoring of the BP can be an important adjunct to hypertension management. The technique allows patients to become more participatory in their care. Self BP values are more likely to be representative of the average daily pressure than a clinic measurement and may be better related to hypertensive target organ involvement and cardiovascular morbidity than the clinic BP. Finally, the self-monitored BP has the potential to reduce the costs of hypertension-related care.

### **LIMITATIONS OF SELF-MONITORING OF THE BP**

There are a number of issues that prevent the more widespread use of self-monitoring of the blood pressure in clinical practice:

1) Devices marketed for patient use have technically advanced during the 1990s, but many

have not undergone a rigorous clinical validation trial for precision and reliability (e.g., AAMI or BHS guidelines). It is recommended that home BP devices used by patients be subjected to the same validation processes applied to ambulatory BP recorders.

2) While the mean self-monitored BP from a general population can be defined (approximately 135/85 mmHg), it is not yet possible to determine the normal self-monitored BP as these values must be linked to classical clinical cardiovascular endpoints or outcomes.

3) The relationships among self-monitored BP, clinic BP, and ambulatory BP are defined for some populations but require further study according to age, gender, ethnicity, and treatment status.

4) Several different schedules for self-monitoring of the BP by patients have been used in clinical research and/or practice. Studies are needed to determine the optimal schedule and number of recordings required when patients perform self-monitoring of the BP.

5) Self-monitoring of the BP is certainly feasible in clinical trials of antihypertensive therapies but has typically not been included in their design by either investigators or the pharmaceutical sponsors.

6) There are studies suggesting that self-monitoring of the BP may reduce the comprehensive costs associated with hypertension care

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on an annual basis. However, as most work on the economic impact of self-monitoring of the BP has been performed in U.S. managed care environments, it is not known if reduction in health care costs would be applicable to other types of practice environments on a worldwide basis.

## CONCLUSIONS

Self-monitoring of the BP is presently useful as an adjunct measurement for the management of hypertensive patients and may have benefits in clinical trials of antihypertensive therapy. Nevertheless, the available data for self-monitoring of the BP are inadequate for clinicians to make primary diagnostic or therapeutic decisions and should not override the blood pressure obtained in by clinical measurement or via ambulatory BP monitoring.

## INTRODUCTION

The potential usefulness of self-monitoring of the blood pressure (BP) by hypertensive patients was first reported nearly 60 years ago by Ayman and Goldshine<sup>(1)</sup>. In their seminal study, these investigators demonstrated that home pressures could persistently be as much as 30–40 mmHg lower than the physician's readings. This study demonstrated two key advantages of home BP over clinic (or office) BP – (a) much larger numbers of BP, and hence values more representative of the average daily pressure than clinical pressure could be obtained and (b) the likelihood of a white-coat or isolated office response was reduced<sup>(2)</sup>. Other advantages of self-monitoring of the BP include the ability to assess the response to antihypertensive medications, improvement in patient compliance, and reduction of the costs of ambulatory care of patients with hypertension<sup>(2-4)</sup> (Table I).

In this Task Force, we evaluated the state of self- (or home) monitoring of the BP for both clinical practice and research.

## I. TYPES OF SELF-MONITORS AND ADVANCES IN TECHNOLOGY

The types of monitors available for self-recording of BP include mercury column sphygmomanometers, aneroid manometers, and electronic semi-automatic or automatic devices. While patients occasionally wish to use portable mercury column sphygmomanometers, they are cumbersome and require a good deal of skill and dexterity on the part of the patient. Furthermore, in some countries mercury has been banned making this type of sphygmomanometer unavailable for patient use<sup>(5)</sup>. Aneroid (dial type) manometers have been widely used by patients but also require skill by the patient and training by the physician or nurse. Furthermore, aneroid manometers frequently become uncalibrated<sup>(6)</sup> making their precision questionable. It is possible to compare the aneroid device to a mercury column by using a y-connector.

The availability of electronic devices has increased markedly during the past several years and they are popular with patients. These devices have been developed to take the BP from the arm, wrist, or finger and use either manual or automatic inflation. Virtually all electronic self-monitors measure BP oscillometrically<sup>(2,3)</sup> rather than by auscultation. The accuracy of electronic BP recorders has been shown to vary substantially from device to device but recently many more recorders have been validated according to national or international validation guidelines<sup>(5,7)</sup>.

Monitors which measure the BP in the upper arm (brachial artery) appear to be the most reliable and clinically relevant devices based on both clinical practice and all of the major hypertension trials. Recently, automatic wrist monitors have also become quite popular due to their convenience for patients. Furthermore, they also may be helpful in patients with extremely obese upper arms. In fact, they may have gained as much as one-third of the world market share for automatic self-monitoring devices for measuring BP (Imai Y, personal

**Table I. Usefulness of self or home blood pressure monitoring.**

- Aids in distinguishing sustained hypertension from white-coat hypertension
- Assesses response to antihypertensive therapy
- Improves patient adherence to treatment
- Potentially reduces management costs

Modified from reference 10.

communication, 1999). However, there are some disadvantages for the use of wrist-cuff devices: first, the wrist must be held at the level of the heart when a reading is being taken, otherwise substantial error might occur due to the influence of hydrostatic pressure; secondly, error may occur due to flexion or hyperextension of the wrist during the BP measurement. In one study comparing a wrist monitor to mercury column sphygmomanometry<sup>(8)</sup> using the BHS guidelines, the wrist systolic pressure was nearly 3 mmHg lower than the arm cuff readings and the monitor received a 'C' grade for the protocol.

Finger monitors are also convenient from a patient perspective, however, they are prone to error due to physiologic differences between the digital artery and brachial artery (systolic wave is shorter and higher resulting in overestimation of the arterial pressure) as well as the impact of hydrostatic pressure associated with arm position<sup>(9)</sup>. Because of these problems with precision finger BP devices are not recommended for general clinical use<sup>(2,3,10,11)</sup>.

#### VALIDATION OF SELF-BP MONITORS

Monitors that have been independently tested according to guidelines of the American Association for the Advancement of Medical Instrumentation (AAMI)<sup>(12)</sup> or the British Hypertension Society<sup>(13)</sup> protocols by investigators unaffiliated with the manufacturer and have received a 'passing grade' would be preferred for patient use. At the present time, both of these protocols require that a minimum of 85 subjects are studied with device compared to a standard mercury column sphygmomanometer. For the AAMI protocol, the device cannot vary by more than  $5 \pm 8$  mmHg compared to the standard and for the BHS protocol, the device

must receive at least a B grading for both systolic and diastolic pressure<sup>(5,12-14)</sup>.

#### ADVANCES IN TECHNOLOGY WITH SELF-BP MONITORING DEVICES

The major advances in technology with self-BP monitoring devices have been oriented towards data acquisition and storage and in the electronic or trans-telephonic transfer of BP data to a computer or central server<sup>(2,15)</sup>. Some self-BP devices have a memory chip which allows for the storage of hundreds of readings which can be downloaded into a physician's computer, as in the Omron IC<sup>(16,17)</sup>. In studies using the Omron IC in clinical practice by Mengden and colleagues<sup>(16)</sup> and Myers<sup>(17)</sup>, it was shown that patients under-report the BP data. While mean values for the logbook recordings and BP device were similar for a period of 1 to 4 weeks, most patients under-reported BP values that they perceived to be too low or too high.

Trans-telephonic home or self BP monitors are new developments in the area of data transfer from a patient's home or worksite to a central server. The self-BP monitors have digital memory and a built-in modem to send BP values over the telephone within seconds to minutes after acquisition<sup>(18,19)</sup>. The central monitoring service can then graphically display the data and perform descriptive statistics on the values over a designated time period. The results may be sent to both the patient as well as the physician. In a study by Bondmass and colleagues<sup>(19)</sup>, trans-telephonic BP measurement was associated with improvement in BP control over a 3-month period in a group of African-American hypertensive patients who had been poorly controlled in the past (Figure 1). These data demonstrate that by

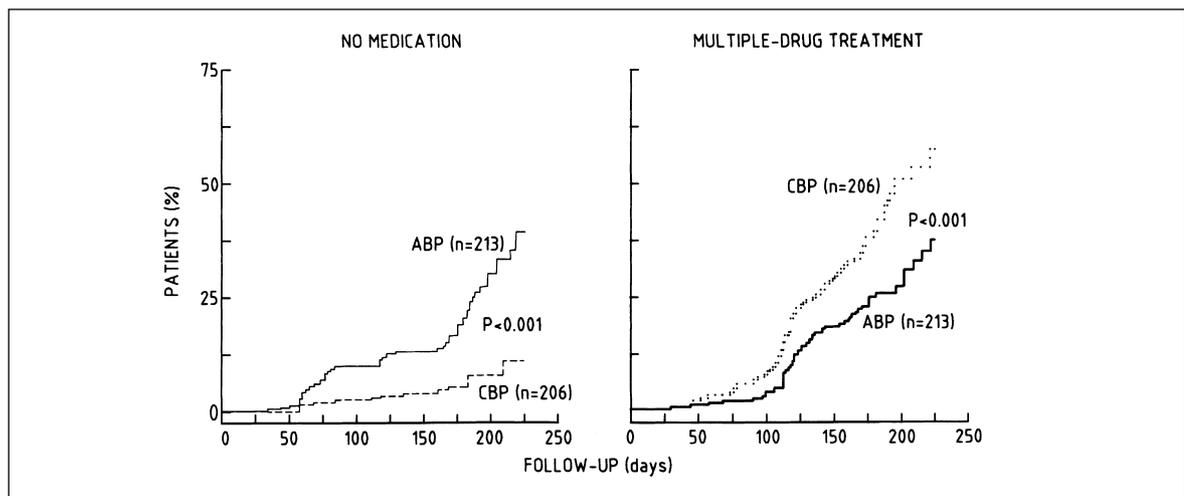


Figure 1. Effects of a self-recorded transtelephonic BP program on BP control in an African-American patient population (adapted from reference 19).

improving patient and physician communication regarding an individual's BP values, self-BP monitoring may provide a means to enhance hypertension control.

## II. REFERENCE VALUES FOR SELF-RECORDED BLOOD PRESSURE

While widespread, the clinical application of self-recorded BP measurements is still limited by the lack of generally accepted operational thresholds. Two meta-analyses<sup>(20,21)</sup> attempted to determine an operational threshold for self-recorded BP measurements. The first meta-analysis pooled the summary statistics of 17 published studies<sup>(22-37)</sup> in 5,422 subjects. Within each study an operational cut-off point between normotension and hypertension was derived from the 95<sup>th</sup> percentiles of the self-recorded BP distribution in subjects who were normotensive according to the current definition of the condition. The weighted mean of these thresholds, taken as a possible cut-off point between normotension and hypertension for self-recorded BP measurements, were 135 mmHg for the systolic pressure and 86 mmHg for the diastolic pressure.

The second meta-analysis pooled data from individual subjects in an international database of self-recorded BPs<sup>(21)</sup>. In total, this database included 4,668 untreated subjects from 13 research centers or groups. In the analyses, 2,401 subjects were normotensive, 494 were labeled as borderline hypertensive, and 1,773 had definite hypertension. Hypertension had been diagnosed from the mean of 1 to 6 (median, 3) conventional BP measurements obtained at one to three (median 1) visits. The reference values for the self-recorded BP measurements determined by the 95<sup>th</sup> percentile of the distribution in normotensive subjects were 137 mmHg systolic and 85 mmHg diastolic. There was considerable overlap between normotensives and hypertensives with regard to the distributions of their self-recorded BP (Figure 2). Of the subjects with systolic hypertension, 16% had self-recorded systolic BPs  $\leq$  137 mmHg. Similarly, 25% of those with diastolic hypertension had self-recorded diastolic BPs  $\leq$  85 mmHg. The probability that hypertensive subjects had self-recorded BP values below these thresholds was 34% (diastolic) to 62% (systolic) greater in women than in men, was two- to threefold greater if fewer than 3 clinic BP measurements had been averaged for establishing the diagnosis of hypertension, and increased by 50% (diastolic) to 126% (systolic) when the self-recorded BP had been measured for a period of

more than 3 days. In contrast, for each 10 mmHg increment in clinic systolic BP, the probability of self-recorded BPs  $<$  137/85 mmHg decreased by 35% for the self-recorded systolic BP and by 11% for the self-recorded diastolic BP. For each 5 mmHg increment in clinic diastolic BP, this probability decreased by 36% for self-recorded diastolic BP. In addition, the probability of a 'normal' self-recorded systolic BP decreased by 31% for each 10 year increment in age.

These findings from the 2 large databases on self-recorded BP suggest that  $<$  135/85 mmHg is probably a normal value.

## III. RELATIONSHIP OF SELF-MONITORED BLOOD PRESSURE TO CLINIC AND AMBULATORY BLOOD PRESSURE

Self-monitored BPs are typically lower than office BPs. This finding has been shown in both clinical trials aimed to assess the efficacy of antihypertensive agents<sup>(36,37,39,40)</sup> as well as in the general population<sup>(35)</sup>. Furthermore, some studies have shown that values determined by self-recorded BP measurements are close to those

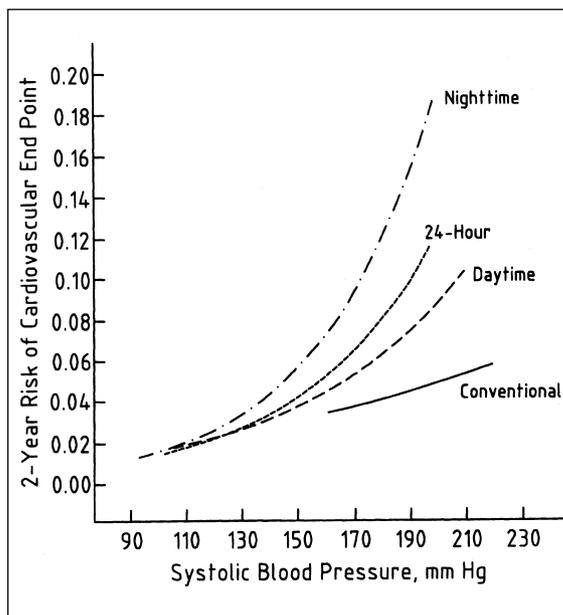


Figure 2. The distributions of conventional (left panel) and self-recorded (right panel) systolic (upper) and diastolic (lower) BPs in the subjects included in the international database on self-recorded BPs. Systolic and diastolic BPs are shown in normotensive subjects (open circles,  $n = 2,323$ ), systolic pressure in the subjects with isolated systolic hypertension (closed circles, upper panels,  $n = 2,067$ ) and diastolic pressure in the subjects with diastolic hypertension (closed circles, lower panels,  $n = 2,033$ ) (from reference 21).

obtained by the awake ambulatory BPs<sup>(35,39,40)</sup>. The difference between office BP and self-measured or ambulatory BPs is known as the white-coat effect<sup>(41)</sup>.

Data from a large sample of a general population ( $n = 1,438$ ) have shown a significant ( $p < 0.001$ ) relationship between clinic BPs and both home and 24-hour average ambulatory BP<sup>(35)</sup>. When considering just hypertensive patients, self-BP and ambulatory BPs are also significantly lower than corresponding clinic values<sup>(42)</sup>. Self-measured BPs are similar to ambulatory BPs recorded during daytime activities, but significantly higher than night-time BPs. Self-monitoring of BP like ambulatory monitoring of the BP, improves the reproducibility of measurements. The reduction in variability depends primarily on the number of readings<sup>(39,42)</sup>. In one study, the reproducibility of ambulatory BP recordings appeared to be better than that of office measurements and similar to that of home readings<sup>(22)</sup>.

The difference between home and office pressures or non-invasive ambulatory recorded pressures may be so wide that a given point it becomes impossible to derive with confidence one type of pressure from the other<sup>(40,43)</sup>. This is illustrated in figure 3. The same kind of observations

has been made comparing home and ambulatory pressures recorded intraarterially<sup>(44)</sup>. Here again, the agreement between the 2 sets of BP levels was too weak to allow any predictions in the individual patient. This findings make one wonder whether the white coat effect detected by self-monitoring of BP is related to the white coat effect assessed by ambulatory BP monitoring. Indeed, there is some agreement between the two methods, but this agreement is not close enough to correctly classify clinic reactors<sup>(43)</sup>.

#### IV. RELATIONSHIP OF SELF-MEASURED BLOOD PRESSURE TO HYPERTENSIVE TARGET ORGAN DISEASE AND PROGNOSIS

Most studies have shown that self-monitoring of the BP is a better determinant of target organ damage than the clinic (or casual) BP. However, the most important limitation of self-BP measurement is that there are limited data available about the prognostic value of this BP information.

Results of cross-sectional studies have shown that the degree of left ventricular hypertrophy determined by electrocardiograph<sup>(45)</sup> and echocardiography<sup>(46,47)</sup> is more strongly correlated to multiple self-measurements than it is to the clinic BP. In these studies, the self-BP was measured numerous times. In contrast, Mancia and colleagues recently reported that self-BP measurements were only slightly better than clinic BPs as correlates of treatment-induced regression of left ventricular mass indexed by body surface area<sup>(48)</sup>. However, in this study there were only 2 self-BP measurements made during the various phases of the trial. More recently, Rave et al.<sup>(49)</sup> reported that self-measured BP is a better predictor of the progression of diabetic nephropathy compared to the office pressure.

The original pilot data from the Ohasama study were reported in 1996<sup>(50)</sup>. In this study, casual BP was measured on 2 occasions while self-BP measurements were performed  $21 \pm 8$  times in the morning using an electronic device. Forty-six deaths due to cardiovascular diseases occurred during the  $5.1 \pm 2.2$  years of observation. The subjects were divided into quintiles based on both casual and self-measured BPs. A significant difference in the survival distribution among self-measured systolic and diastolic BP was observed with individuals in the highest quintile showing the poorest survival. This trend was not observed for the casual BP. In a followup study<sup>(51)</sup>, Tsuji and coworkers studied the relationship between self-measurements of BP and all cause mortality

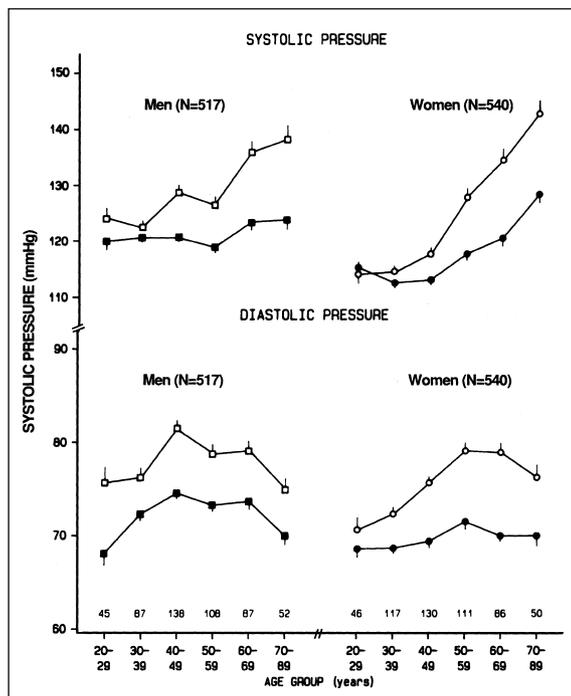


Figure 3. Comparison of home and office systolic blood pressures (SBP) according to the statistical method of Bland and Altman. Mean SBP was obtained by averaging the office and home SBP and the SBP difference was calculated by subtracting the home from the office SBP (from reference 40).

in the Ohasama cohort. This analysis showed a J-shaped relationship between self-measured diastolic BP and all-cause mortality, while a linear association was observed between the self-measured systolic BP and all-cause mortality. These results indicate that the predictive power of self-BP measurements for subsequent mortality was greater than that of the casual BP. In the same cohort, Sakuma et al.<sup>(52)</sup>, studied the predictive value of self-BP measurements in relation to stroke morbidity. The association between the baseline BP and the incidence of first-ever stroke was examined using a Cox proportional hazards regression model. The lowest risk of stroke morbidity occurred in the subjects with self-measured systolic BP of 117-123 mmHg and in those with self-measured diastolic BPs of 66-70 mmHg. The subjects in the quintile with the highest self systolic BP measurement (> 132 mmHg) and self diastolic BP measurements (> 80 mmHg) had significantly increased risk of stroke morbidity. This relation was not observed for the casual or clinic BP.

Most recently, Ohkubo and colleagues<sup>(53)</sup> compared the predictive power for cardiovascular and overall mortality between self-BP measurements and casual BP in the Ohasama population. They obtained self-BP and casual BP measurements for 1.789 subjects aged 40 years and over and followed up for a mean of 6.6 years. When the self-BP measurements and casual BP were simultaneously incorporated into the Cox models as continuous variables, only the average of multiple, self-measured systolic BP was significantly and strongly related to the cardiovascular mortality risk. The study also showed that even the average of the initial 2 self-BP measurements was a better predictor for future mortal events than the casual BP.

#### V. CLINICAL UTILITY OF SELF MEASUREMENT OF THE BLOOD PRESSURE

In clinical practice, self-measurement of the BP provides useful information in the management of hypertension (Table I). In addition to removal of the observer bias seen in a clinical environment, the patient can obtain multiple readings at various times of the day and evening. This is particularly useful when attempting to assess BP control at different times during a drug dosing interval.

Patient education is key for the success for self-monitoring of the BP when a non-electronic device is used in clinical practice<sup>(54,55)</sup>. Teaching the proper technique of BP measurements to

patients is time-consuming when a mercury column or aneroid manometer is used with a stethoscope. For example, in the home BP studies in Tecumseh<sup>(30)</sup>, teaching patients required an average of nearly 4 sessions (at 20 minutes per patient session) using a two-headed teaching stethoscope. It is, however, possible to achieve 100% concordance with a nurse's readings within 4 mmHg with careful instruction using an aneroid device<sup>(56)</sup>. Even with electronic devices, patient education is important to assure proper technique (such as arm level), how to record and document the recordings, and how to respond to high and low BP readings<sup>(54)</sup>.

There is no consensus in the literature to suggest how often BP should be measured by patients in practice. Many studies have used single or duplicate measurements twice daily. Brook<sup>(57)</sup> analyzed 12 studies that included home office, and awake ambulatory BPs to determine the agreement between home and office and home and ambulatory BP according to monitoring schedules. Large variations in the self-measured BP schedule had little effect on the accuracy of the final home BP average values. This finding suggested that just a few readings over a short period of time would be likely to predict the average home BP. However, this finding is most relevant for cross-sectional analyses while self-BP measurement is most useful to assess trends over time and on various therapeutic regimens<sup>(2,54,55)</sup>.

A number of demographic and environmental factors might influence the level of self-monitored BP<sup>(2)</sup>. For example, the home BP is lower in women than in men<sup>(20,21)</sup> and higher in older patients than in younger patients<sup>(27)</sup>. Environmental factors that may affect the level of the self-measured BP includes the season of the year<sup>(58)</sup> and the time of day<sup>(59)</sup>. As with clinic BP, self-measured BP tends to be higher in the winter than in the summer<sup>(58)</sup> and higher in the afternoon than in the morning<sup>(58)</sup>. Meals, alcohol, and caffeinated beverages may affect the self-measured BP for a short period of time. In the case of coffee, BP is increased within about 15 minutes of intake and may last for as long as 3 hours<sup>(59)</sup>. Thus, it is best if patients take the self-BP prior to meals and before drinking coffee, tea, or colas. Since smoking a cigarette raises the BP and pulse rate for about 15-20 minutes, it is best to avoid smoking before measuring the pressure at home. Finally, a period of heavy dynamic exercise may cause the BP to be lower than usual for a few hours<sup>(2)</sup>. These are all issues that must be part of any self-BP education program for patients prior to initiating the monitoring process<sup>(54)</sup>.

Self-monitoring of the BP may be a helpful adjunct to making the diagnosis of hypertension but it is not

a replacement for the doctor's office BP nor is it a substitute for ambulatory BP monitoring. For example, when self-BP measurements are confined to the home environment, they may not be representative of the higher BPs associated with a more stressful work environment<sup>(22,46)</sup>. White-coat hypertension has been diagnosed primarily by comparing ambulatory awake BPs with those pressures taken in a medical care environment. Studies that used clinic, home, and ambulatory pressures have shown that 20 to 33 per cent of home BP measurements do not correlate well with the ambulatory BP<sup>(60,61)</sup>. In a study by Padfield and colleagues<sup>(62)</sup>, self-monitored BPs were compared to clinic pressures over a repeated visits during a period of 4 weeks. The BP at the first clinic visit was substantially higher than the home BP but this difference tended to decrease as the month progressed. The conclusion was that the home BP predicted the results of repeated clinic visit BPs and would be of use in clinical decision making on drug therapy.

In addition to its importance in clinical practice, self-monitoring of the BP may be cost-effective. In a trial conducted by Soghikan and colleagues from Kaiser Permanente in San Francisco<sup>(63)</sup>, 430 patients with mild hypertension were randomized to either a usual care group or to use self-monitoring of the pressure for up to 1 year. During this one-

year period, the investigators showed that BP control was slightly, but significantly better in the self-BP group and the costs of care were reduced by 29%. The reduction in costs were associated with less frequent doctor visits while the volume of phone calls to the office increased in the self-BP patients (Figure 4).

**VI. THE ROLE OF SELF-MONITORED BLOOD PRESSURE IN CLINICAL RESEARCH TRIALS**

Self-BP measurements may improve the assessment of the effects of antihypertensive drugs on BP in clinical trials. With self-BP monitoring the placebo effect usually observed with clinic pressures is reduced substantially (and may not even exist)<sup>(64)</sup>. Self-monitoring of the BP also has fairly good short- and intermediate-term reproducibility compared to the clinic (or office) pressure. Enhanced precision (e.g, less digit bias and lack of the placebo effect) along with better reproducibility provide an advantage for the use of self-monitoring of the BP in addition to the clinic measurements since fewer patients would be needed to show an antihypertensive effect. The greater statistical power associated with the use of multiple self-BP measurements versus clinic BP values was demonstrated in a study by Menard et al.<sup>(65)</sup>. In a cross-over design trial, they showed

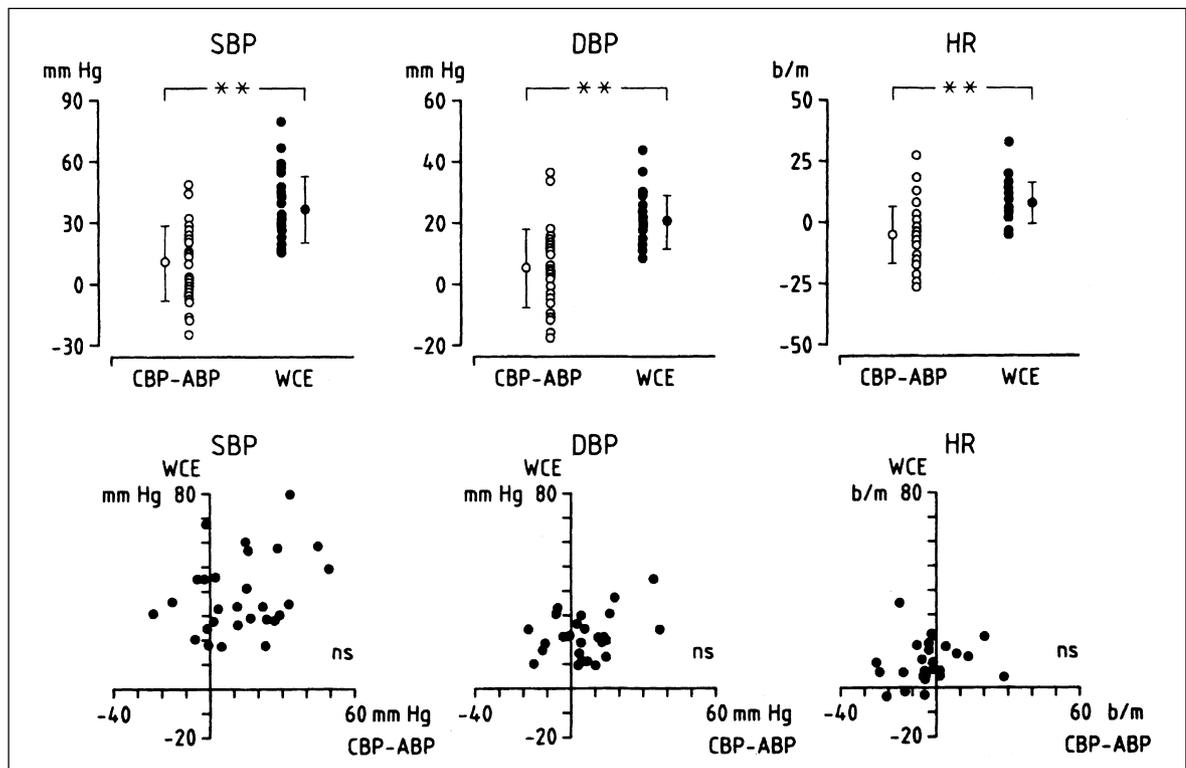


Figure 4. Frequency of office visits and telephone calls to the clinic (per patient) during a one year period where patients with hypertension were randomized to either a self-BP monitoring group or a usual care group in a physician staff model health maintenance organization (HMO) (adapted from reference 63).

that in order to detect a 5 mmHg treatment effect, 27 patients would be required using clinic pressures while 20 patients would be needed if self-BP measurements were made.

Studies using self-monitoring of the BP also suggest that the effect of treatment within 1 to 2 weeks is highly predictive of longer term drug effects<sup>(64-66)</sup>. Furthermore, self-monitoring of the BP may provide evidence of the drug's steady-state before a drug-induced BP reduction is evident with conventional clinic BP methods. The duration of an antihypertensive drug may be assessed in part through self-monitoring of the BP in trials where ambulatory measurement is not feasible. Self-BP monitoring facilitates assessment of the pharmacodynamics of a new antihypertensive agent since measurements can be made repeated before drug dosing (trough) and during the presumed peak effect of the drug.

Recently, a study was developed to test the hypothesis that antihypertensive treatment guided by self-measured BP may be more beneficial to the patient than treatment based on conventional BP measurement by the doctor<sup>(67)</sup>. The THOP trial is a 2-group randomized trial in which 1 group antihypertensive treatment is guided by the sitting diastolic BP measured by the doctor while in the other group by the sitting diastolic BP measured by the patient at home. In both treatment groups the same goal BP should be reached (diastolic BP = 80 to 89 mmHg) based on either clinic or home BP methods. The outcome measures will include 24 hour BP control, intensity of drug treatment, symptoms and adverse effects, and inhibition or regression of left ventricular hypertrophy<sup>(67)</sup>. The hypothesis of the study is that drug treatment guided by home BP will lead to a less antihypertensive drug regimen but with preservation of 24 hour BP control and inhibition of left ventricular enlargement.

## CONCLUSIONS

The use of self-monitoring of the BP has increased substantially in clinical practice and clinical research. Advances in technology will allow the patient to partner with their physician more and should help in controlling BP since the patient will undoubtedly become more vigilant in their own care. For a number of reasons, the self-monitored BP is more reproducible than the clinic BP and enhances its utility in clinical trials of antihypertensive therapies. Finally, preliminary target organ disease and prognostic data show that self-BP may be a better determinant of cardiovascular outcome than clinic BP in the hypertensive patient.

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