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Conventional versus automated measurement of blood pressure in the office (CAMBO) trial

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Background: Effective strategies to identify office-induced hypertension in routine clinical practice are required to improve diagnosis and management of hypertension.

Objective: To compare the quality and accuracy of automated office blood pressure (AOBP) measurement using the BpTRU device with manual office blood pressure (MOBP) in routine clinical practice using awake ambulatory blood pressure (AABP) as the gold standard.

Methods: Primary care practices in Eastern Canada were allocated by cluster randomization to use of AOBP (36 practices, 52 physicians) or to MOBP (31 practices, 36 physicians) in patients with systolic hypertension. The last routine MOBP reading pre-enrolment was compared to the blood pressure (BP) at the first visit after enrolment and after 2 years of follow-up. The primary outcome measure was the mean difference between the AABP and MOBP versus AOBP.

Results: The mean (95% confidence interval) decrease in systolic BP from pre- to post-enrolment was greater ($P < 0.001$) at the first visit in the 252 AOBP patients [–14.3 (–16.6, –12.0)] compared to the 209 MOBP patients [–8.0 (–2.2, –5.8)]. At Year 2, AOBP decreased by –16.3 (–18.6, –14.1) compared to a decrease in MOBP of –12.4 (–14.7, –10.1) ($P = 0.02$). The mean difference between systolic AABP and MOBP at the first post-enrolment office visit [–7.3 (–9.7, –4.9)] was greater ($P < 0.001$) than the difference for AOBP [–1.8 (–4.0, 0.4)]. At Year 2, these differences were –5.2 (–7.5, –3.0) for MOBP and –2.8 (–4.9, –0.7) for AOBP ($P = 0.13$).

Conclusions: AOBP virtually eliminated office-induced hypertension. The decrease in MOBP was attributed to participation in a research study and not to any specific intervention.

Keywords. Blood pressure measurement, hypertension diagnosis.

Introduction

Manual blood pressure (BP) measurement can be very accurate if performed properly using a device such as the mercury sphygmomanometer. Under research conditions, manual BP readings are comparable to the mean awake ambulatory blood pressure (AABP), a gold standard for predicting future cardiovascular events on the basis of an individual's BP status.[1] There is general agreement that manual BP recorded in routine clinical practice often lacks the accuracy and reliability of readings taken under research conditions. The main concern about routine manual office blood pressure (MOBP) is that a lack of adherence to recommended techniques for BP measurement uniformly leads to higher readings, resulting in misclassification of patients as being hypertensive as a consequence of a white coat effect. These readings are not just systematically higher but they also tend to correlate poorly with AABP readings.[2–4]

Recently, there has been a shift in the paradigm of BP measurement in primary care. Studies using automated office blood pressure (AOBP) have reported BP values similar to the AABP and home BP.[3–9] The white coat effect that may lead to over diagnosis of hypertension is substantially reduced when AOBP replaces MOBP in routine clinical practice. AOBP requires three basic tenets: 'multiple consecutive readings' taken using a 'fully automated' device with the patient 'resting alone' in a quiet room.

The Conventional versus Automated Measurement of Blood pressure in the Office (CAMBO) Trial was

undertaken to evaluate the quality and accuracy of AOBP measurement in routine primary care practice over a 2-year period. CAMBO was designed as a cluster randomized trial in which physician practices were randomized to managing patients with systolic hypertension using either AOBP or conventional MOBP readings. The initial results of the baseline data from the CAMBO trial showed that AOBP eliminated office-induced hypertension (white coat effect) associated with MOBP with AOBP exhibiting a closer relationship to the AABP.[10] The present article examines the persistence of the benefits of AOBP and assesses changes in the quality of MOBP measurement after patients were followed with either AOBP or MOBP in routine primary care practice over a 2-year period.

Trial registration: Clinical Trials NCT00214053.

Methods

Study design

Community-based family physicians in five Canadian cities who were using MOBP in their clinical practice were invited to participate in the CAMBO study. Physician practices (sites) consisted of either one family physician or a group of two or three physicians sharing the same office space. In order to reduce potential measurement contamination, a cluster randomization design was used in which blocks of four to six sites were randomized to either MOBP with continuing use of manual sphygmomanometry (control group) or management of patients with AOBP (intervention group) using the BpTRU device (BpTRU Medical Devices Inc., Coquitlam, BC, Canada).

Patients were seen by their primary care physicians for routine visits. The frequency of visits was at the discretion of each physician. A target AOBP of <135/85 mmHg and MOBP <140/90 mmHg was set for patients in the two groups based upon the relative equivalence of each with a normal AABP of <135/85 mmHg. No other instructions such as the type of drug therapy or dose to be prescribed were given to the physicians. The 24-hour ABPM was performed at baseline and repeated at the end of the 2-year follow-up period. Only patients who had office BP and 24-hour ABPM data recorded at baseline and at 2 years were included in the final analysis.

Patient recruitment

Patients with predominantly systolic hypertension were enrolled because the main advantage of AOBP over MOBP is the elimination of the white coat response that is manifested as a disproportionate increase in systolic BP. The last routine MOBP recorded on the visit immediately prior to entry into the study was abstracted. Untreated patients were required to have a systolic BP ⩾160 mmHg and diastolic BP <95 mmHg on their most recent pre-study visit as recorded in their medical chart. Patients already receiving antihypertensive therapy were eligible if their systolic BP was ⩾140 mmHg and diastolic BP <90 mmHg. An intensity score for antihypertensive therapy incorporating both the number of drugs and dosages using arbitrary units was developed in order to assess treatment at baseline and during subsequent visits. Excess alcohol consumption was defined as 14 or more standard alcoholic beverages for men and 9 or more beverages for women per week.

BP measurement

The BpTRU is a fully automated sphygmomanometer that records BP by the oscillometric method. It is designed to take an initial 'test' reading to verify that the cuff is properly positioned in order to obtain valid readings. The observer then leaves the patient alone with five more readings being taken automatically. A rest period is not required before the first reading. In CAMBO, the BpTRU was set to take readings at 2-minute intervals (from the start of one reading to the start of the next one).

Twenty-four-hour ABPM was recorded using a Spacelabs Model 90207 (Spacelabs Healthcare Ltd, Issaquah, WA) ABPM unit. Patients were instructed to engage in routine daily activities during ABPM. The device was set to record BP at 15-minute intervals between 0600 and 2200 and at 30-minute intervals during the night. Mean awake ambulatory BP was then calculated according to the actual awake period as recorded in each patient's diary where time asleep was noted. The ABPM results were not given to the patients or their physicians during the study period.

Patient management and follow-up

For the AOBP group, physicians and their staff were instructed on how to measure BP using the fully automated BpTRU device with the patient resting alone in the examining room. For practices randomized to MOBP, readings were taken manually the same as before enrolment, with a mercury or aneroid sphygmomanometer. Otherwise, no special instructions were given on proper BP measurement technique to either group. The CAMBO trial personnel were not involved in any way with the care of the patients.

Data analysis

Descriptive statistics were computed for variables of interest. Continuous variables are reported as mean ± SD and differences between mean values are shown with confidence intervals. Accuracy and reliability of BP readings were compared at baseline and at the completion of the two year follow-up period. Differences between BP readings were evaluated using analysis of variance for repeated measures models. These models took into account the correlated nature of the data and

the potential data dependency associated with the cluster design.

Differences in correlations between comparisons of BP readings were assessed using independent Pearson correlation coefficients for between-group comparisons and correlated coefficients for within-group comparisons. Differences between groups in the proportion of patients exhibiting digit preference (rounding off BP readings to the nearest zero value) were evaluated using chi-square tests. Applying the method of Donner *et al.*,[11] the study was powered for the primary outcome measure to detect a difference of 5 mmHg between groups (differences in awake ambulatory systolic BP minus MOBP versus difference in awake ambulatory systolic BP minus AOBP) with 90% power at alpha = 0.05, a hypothesized intracluster correlation of 0.07 and a 20% attrition rate. The resulting estimated sample size was 276 subjects per group. All analyses were carried out using SAS version 9.1 (SAS Institute, Cary, NC).

Results

The process for recruiting patients from primary care practices in four regions in Central and Eastern Canada (Belleville, Brantford, Montreal and St. John's/Corner Brook) is shown in Figure 1. Cluster randomization allocated 36 practices/sites (52 physicians) to the AOBP intervention group and 31 practices/sites (36 physicians) to the MOBP control group, with 252 patients in the AOBP group and 209 in the MOBP group satisfactorily completing the 2-year follow up (Figure 1).

There were no significant differences in the characteristics of the patients who successfully completed the 2 years of follow-up in the AOBP versus MOBP groups

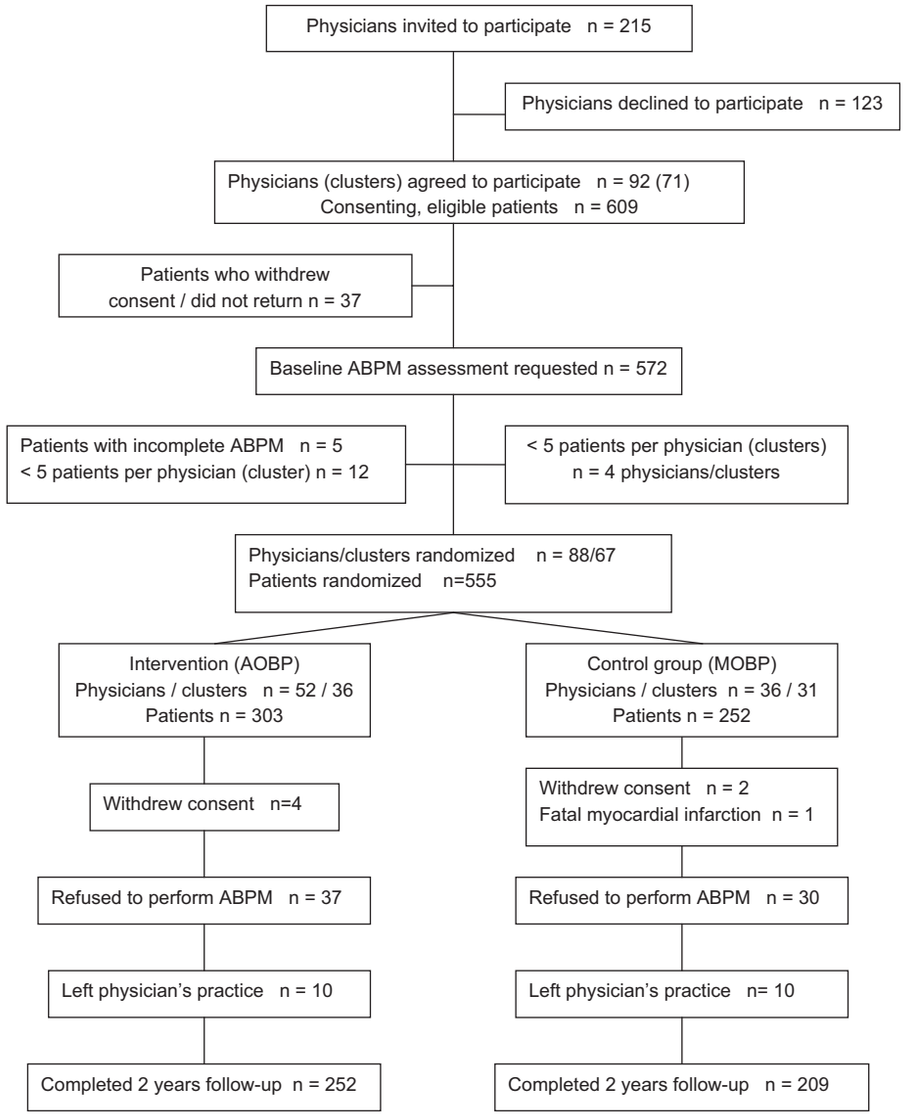

FIGURE 1 *Consort diagram with details of patient recruitment and exclusions from study*

(Table 1). Routine MOBP readings taken during the visit immediately before enrolment into the study and the mean awake ambulatory BP at baseline were similar for the two groups (Table 2).

Patients in both the AOBP and MOBP groups exhibited a decrease in recorded BP between the pre- and post-enrolment office visits (Table 2). The mean AOBP was decreased by –14.3/–4.0 mmHg, which was a significantly ($P < 0.001/P = 0.007$) greater decrease compared to the MOBP group (–8.0/–1.5mmHg). At 2 years, AOBP had decreased further to –16.3/–4.8 mmHg from the BP pre-enrolment with the decrease in systolic AOBP being significantly ($P = 0.02$) greater than the decrease in MOBP at 2 years (–12.4/–3.6 mmHg). The increase in the intensity of antihypertensive drug therapy from baseline to Year 2 was similar for AOBP (0.41 units) and MOBP (0.66 units) patients.

With respect to the primary outcome measure at the first visit post-enrolment, the difference in systolic BP between AOBP and AABP (–1.8 mmHg) was significantly ($P = 0.001$) less than the difference between MOBP and AABP (–7.3 mmHg). At Year 2, the difference in awake ambulatory systolic AABP minus MOBP was –5.2 mmHg compared to –2.8 mmHg for the difference between the systolic AABP and AOBP. A comparison of these differences from the AABP ($P = 0.13$) was no longer statistically significant.

Prior to enrolment, routine manual office diastolic BP correlated significantly with the baseline diastolic AABP for both groups, whereas the correlation for systolic BP was relatively weak (Table 3). For both AOBP and MOBP groups, there was a significant increase in the correlation coefficients between office BP and AABP pre- versus post-enrolment for systolic BP readings. Only the correlation for diastolic AOBP versus AABP increased significantly after enrolment. The correlation for diastolic AOBP was significantly stronger compared to MOBP at the first post-enrolment office visit and similar results were seen at Year 2 (Table 3).

In the MOBP group, digit preference with the percent of BP readings ending in a zero value was similar at the pre-enrolment visit (48.8%/53.6%), first office visit after enrolment (44.0%/47.4%) and at year two (49.8%/48.3%). In contrast, digit preference in the AOBP group was significantly reduced at the first post-enrolment (13.9%/13.9%) and Year 2 visits (21.8%/21.4%) compared to the last routine MOBP reading pre-enrolment (57.9%/56.3%). A trend to rounding off readings to zero values re-appeared at the Year 2 visit with twice

TABLE 1 *Characteristics of patients completing the 2-year follow-up period randomized to either the intervention group (AOBP) or to the usual care control group (continued MOBP) for management of hypertension*

	AOBP	Conventional MOBP	*P* value
Number of patients	252	209	
Number of males (%)	89 (35.3)	84 (40.2)	0.327
Mean age (range)	64.4 (45–85)	64.8 (45–89)	0.717
Duration of hypertension in years (SD)	9.2 (8.8)	9.6 (10.3)	0.665
Number of patients not receiving antihypertensive therapy (%)	7 (2.8)	9 (4.3)	0.524
Intensity of antihypertensive drug therapy in units (SD)	3.8 (2.2)	3.5 (2.1)	0.208
Cigarette smokers (%)	30 (12)	30 (14)	0.361
Excess alcohol use (%)	29 (11.5)	20 (9.6)	0.603

P values are for differences between groups.

TABLE 2 *Shows the mean (SD) BP taken in the physicians' office before and after enrolment into the study and at 2 years, the mean awake ambulatory BP at baseline and at 2 years, and within-group differences between BP values for the patients randomized to the intervention (AOBP) and control (conventional MOBP) groups*

	BP (mmHg)	
	AOBP group ($n = 252$)	Conventional MOBP group ($n = 209$)
Last routine MOBP (SD)	149.5(10.7)/81.4(8.5)	149.7(10.5)/82.1(8.1)
Office BP (SD) after enrolment	135.2(17.5)/77.4(10.6)	141.7(14.9)/80.6(9.9)
Difference from last routine office BP.	-14.3^{+}(–16.6, –12.0)/-4.0^{+}(–5.3, –2.7)	-8.0^{+}(–10.2, –5.8)/$-1.5^{@}$(–2.8, –0.1)
Office BP (SD) at 2 years	133.1(16.8)/76.5 (10.3)	137.3(14.9) / 78.5(8.8)
Difference from last routine pre-enrolment office BP	-16.3^{+}(–18.6, –14.1/-4.8^{+}(–6.1, –3.6)	-12.4^{+}(–14.7, –10.1)/-3.6^{+}(–4.8, –2.4)
Mean (SD) awake ambulatory BP at baseline	133.4(12.6)/74.4(9.6)	134.4(13.3)/75.9(9.9)
Difference from last routine office BP	-16.1^{+}(–18.0, –14.2)/-6.9^{+}(–8.2, –5.7)	-15.3^{+}(–17.6, 12.9)/-6.1^{+}(–7.5, –4.7)
Difference from post-enrolment office BP	–1.8(–4.0, 0.4)/-2.9^{+}(–4.1, –1.7)	-7.3^{+}(–9.7, –4.9)/-4.7^{+}(–6.2, –3.1)
Mean (SD) awake ambulatory BP at 2 years	130.3(12.4)/71.9(9.8)	132.1(13.0)/73.7(9.3)
Difference from baseline awake ambulatory BP	-3.1^{+}(–4.5, –1.7)/-2.5^{+}(–3.4, –1.7)	–2.4*(–3.9, –0.8)/-2.3^{+}(–3.2, –1.3)
Difference from office BP at 2 years	–2.8*(–4.9, –0.7)/-4.6^{+}(–5.8, 3.4)	-5.2^{+}(–7.5, –3.0)/-4.8^{+}(–6.2, –3.3)

Estimated mean differences (95% confidence intervals) between BP readings are shown indented for within-group comparisons: $^{+}P \leqslant 0.001$; $^{*}P < 0.01$; $^{@}P = 0.03$.

TABLE 3 *Coefficients of correlation (r) between office systolic/diastolic BP readings and mean awake ambulatory BP are shown*

	AOBP group (n = 252)	MOBP group (n = 209)
Routine office BP before enrolment versus baseline awake ambulatory BP	r = 0.13/r = 0.39	r = 0.03/r = 0.38
Office BP after enrolment versus baseline awake ambulatory BP	r = 0.35/r = 0.56	r = 0.22/r = 0.32
Difference (95% CI) in r before versus after enrolment	0.22(0.09, 0.35)*/0.17(0.07, 0.27)*$^{+}$	0.24(0.08, 0.39)*/ r = 0.06(–0.08, 0.19)
Office BP at 2 years versus awake ambulatory BP	r = 0.36/0.55	r = 0.28/r = 0.32
Difference (95% CI) in r from pre-enrolment to Year 2 office visit	0.23(0.10, 0.36)**$^{++}$/0.16(0.05, 0.26)*$^{+}$	0.31(0.15,0.45)**/0.05(–0.09, 0.19)

CI, confidence interval. Estimated mean differences (95% CI) in within-group coefficients of correlation before versus after enrolment and at 2 years are shown for AOBP and MOBP groups (*$P < 0.005$; **$P < 0.001$ for within-group comparisons and $^{+}P < 0.005$, $^{++}P < 0.001$ for between-group comparisons).

the expected percent of AOBP readings ending in zero being reported.

Discussion

The results of the CAMBO trial are consistent with previous reports[3–9] on the use of AOBP in the diagnosis of hypertension (Table 4). The introduction of AOBP into routine primary care practice led to a 14/4 mmHg decrease in office BP on the first visit after enrolment compared to the last routine manual BP recorded prior to the patient being recruited for the study. The fall in AOBP persisted at 2 years. Systolic AOBP readings were only 1.8–2.8 mmHg higher than the mean AABP at baseline and at 2 years, respectively. The coefficient of correlation between AOBP and AABP was significantly stronger when compared to the coefficient of correlation between routine manual BP pre-enrolment and baseline AABP. Digit preference (rounding off BP readings to the nearest zero) was not seen with AOBP at the first post-enrolment office visit. However, at 2 years, there was a partial return to digit preference with the AOBP measurements in that 22% of systolic/diastolic readings ended in zero compared to the expected 10%.

In previous studies,[3–9] the introduction of AOBP resulted in a reduction in systolic BP of between 10 and 20 mmHg when compared to routine MOBP. In community-based primary care populations similar to the present study,[3,8] decreases of 9–13 mmHg have been reported on the first AOBP visit which is similar to the 14 mmHg decrease in AOBP noted in the CAMBO trial patients.

It should be noted that the BpTRU was set to take readings every 2 minutes in the CAMBO trial that required patients to be alone for a total of 10 minutes. A subsequent study[6] has shown that readings taken every 1 minute are similar to those obtained at 2-minute intervals. The 1-minute setting is now recommended for AOBP in order to minimize the time required to assess BP status.[12] Interrupting patients during the 10-minute period of AOBP measurement in the CAMBO trial would likely have increased BP and could explain the slightly higher AOBP readings when compared to the AABP.

TABLE 4 *Studies comparing AOBP with AABP*

Articles	# Subjects	Population	AOBP	AABP
Beckett and Godwin[3]	481	Family practice	140/80	142/80
Myers *et al.*[4]	309	ABPM	132/75	134/77
Myers *et al.*[5]	62	Hypertension clinic	140/77	141/77
Myers *et al.*[6]	200	ABPM	133/72	132/76
	200	ABPM	132/76	134/77
Myers[7]	254	ABPM	133/80	135/81
Godwin *et al.*[8]	654	Family practice	139/80	141/80
Myers *et al.*[9]	139	ABPM	141/82	142/81

The unique feature of the CAMBO trial was having the study conducted in community-based primary care practices with the inclusion of an MOBP control group. The main reason for taking this approach was to demonstrate the benefits of AOBP over MOBP in such a way as to maximize the external validity of the study and thus generalizability of the results to routine clinical practice. However, the data on MOBP obtained in routine primary care practice over a 2-year period also provided an opportunity to examine the impact participation in a research study might have on BP measurement.

MOBP in the control group was significantly lower on the first visit after enrolment compared to the BP obtained during the last routine office visit, which suggests that participation in a research study led to a change in the way BP was being recorded. This trend to lower BP values continued for 2 years with final BP readings being even lower and the difference between MOBP and AOBP being quite small. Systolic MOBP readings also correlated more strongly with AABP at 2 years than before enrolment, whereas digit preference with MOBP was still present. These findings in the control group of the CAMBO trial show that it is possible to substantially

reduce the white coat response usually seen with MOBP and improve the quality of MOBP in routine clinical practice when readings are taken in the context of a research study. Similar observations have been made in clinical research settings where carefully performed manual BP measurements have been similar to the AABP.[13] Thus, the problems generally associated with MOBP in routine clinical practice are not inherent in the measurement technique itself but are invariably due to poor BP measurement technique in the 'real world' outside of the context of a research study.

The current gold standard for BP measurement is 24-hour ABPM based on studies showing ABPM to be a significantly better predictor of future cardiovascular events when compared to manual BP readings. Similar evidence exists for home BP but ABPM also provides readings taken during sleep with nocturnal BP being the best predictor of clinical outcome. Since 2005, the guidelines of the Canadian Hypertension Education Program have recommended using ABPM, if available, to diagnose hypertension, with home BP recommended as an alternative if ABPM is not available.[14] Starting in 2010, these guidelines also added AOBP as an alternative to MOBP for the diagnosis of hypertension, recognizing that AOBP provides more accurate office readings in routine clinical practice and virtually eliminates white coat hypertension.[15] The near complete elimination of office-induced hypertension suggests that significantly fewer patients would require further assessment with 24-hour ABPM if AOBP were to be widely adopted into the clinical practice.

Consideration for more widespread use of AOBP is timely given the recent guidelines[16] for using ABPM to diagnose hypertension as proposed by the National Institute of Health and Clinical Excellence. Although ABPM may be the ideal method for diagnosing hypertension, it is not always available and is also impractical for following patients during repeated office visits. AOBP in combination with home BP represents an alternative to managing hypertensive patients, especially the 20–25% who exhibit a white coat effect and will otherwise require multiple ABPM for diagnosis and monitoring of their response to antihypertensive therapy.

The CAMBO trial has demonstrated that AOBP virtually eliminates the white coat response experienced by many patients when manual BP readings are recorded in routine clinical practice. The benefits of AOBP can be seen immediately, with AOBP readings on the first office visit being substantially reduced. The CAMBO trial extends previous observations to routine primary care practice in the community showing mean AOBP to be only slightly higher than the mean AABP. These results also mitigate any concerns that AOBP may be too low when compared to the AABP. Thus, AOBP appears to improve the precision of BP measurement while substantially reducing the white coat response.

A second conclusion from the CAMBO trial is that the accuracy and quality of MOBP readings can be substantially improved with little or no intervention aside from participation in a research study. This finding was not unexpected given the well-known impact of the 'Hawthorne Effect' leading to changes in human behaviour when an individual's performance is being assessed, such as during a clinical trial.[17] High-quality MOBP readings are clearly possible, even in routine primary care, but such readings very much depend upon multiple human factors, whereas AOBP simply requires that the patient be left alone in a quiet room for 5 minutes in order to obtain an accurate office BP reading that is similar to the AABP. Thus, AOBP is complementary to both ABPM and home BP and should maintain the role of office BP measurement in the management of hypertensive patients at a time when MOBP is under increased scrutiny and the mercury sphygmomanometer is in the process of disappearing because of environmental concerns.

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Declaration

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