REVIEW

Implementing Automated Office Blood Pressure Measurement

Controversies in Hypertension - Con Side of the Argument

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*Excitabat enim fluctus in simpulo**

—Marcus Tullius Cicero in De legibus, 3, 16, 36

Hypertension is by far the predominant modifiable cardiovascular risk factor, overriding all others.[1] Over the past 25 years, automated devices entered clinical practice, first for ambulatory and home blood pressure monitoring, and more recently also for routine office blood pressure measurement. One manufacturer of a validated[2] oscillometric device (BpTRU Vital Signs Monitor, BpTRU Medical Devices, Coquitlam, British Columbia, Canada), highly motivated clinical investigators[3–8] and national guideline writers,[9,10] all from Canada, established automated office blood pressure (A_{OBP}) measurement as an alternative to manual office blood pressure readings (M_{OBP}), or as an adjunct to home or ambulatory blood pressure monitoring. The main objective was to improve the accuracy of what was termed clinical-grade M_{OBP} readings.[5] The A_{OBP} measurement protocol, around which the BpTRU was designed, consisted of 3 steps: (1) taking a single measurement in the presence of an observer to ensure the correct position of the cuff over the brachial artery at the heart level and the proper execution of the subsequent A_{OBP} readings; (2) leaving the patient alone and next, after the patient has rested for 5 minutes, taking 6 unattended measurements at 1- or 2-minute intervals; (3) and finally providing a read-out of the average of the 6 programmed readings, leaving out the first. Production of the BpTRU ceased in 2017, but properly validated alternative devices, specifically intended for A_{OBP} measurement by professionals, had meanwhile entered the market.[5]

Lighting the Fuse

The SPRINT (Systolic Blood Pressure Intervention Trial) was the fuse that ignited the debate on A_{OBP} measurement.[11–16] SPRINT enrolled 9361 high-risk patients with a systolic blood pressure of 130 mm Hg or higher but without diabetes mellitus or previous stroke.[17] They were randomized to intensive or standard antihypertensive drug treatment with as systolic targets 120 versus 140 mm Hg, respectively. The trial stopped early after 3.3 years (median), owing to a lower incidence of the primary cardiovascular end point in the intensive treatment group (hazard ratio [HR] versus standard treatment, 0.75; 95% CI, 0.64–0.89; $P<0.001$).[17] For the selection of patients and treatment adjustments, SPRINT investigators used the OMRON 907XL, which was programmed to take 3 blood pressure readings at 1-minute intervals after 5 minutes of rest.[18,19] Of note, blood pressure was measured in the same way in the ACCORD trial (Action to Control Cardiovascular Risk in Diabetes).[20] However, only after publication of SPRINT,[17] the controversy on the clinical usefulness of A_{OBP} arose, probably because in the 4733 type-2 patients with diabetes mellitus enrolled in ACCORD tighter control of systolic blood pressure (120 versus 140 mm Hg) did not reduce the rate of the primary cardiovascular end point (HR, 0.88; CI, 0.73–1.06; $P=0.20$).[20]

The opinions expressed in this article are not necessarily those of the editors or of the American Heart Association.

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*Excitabat enim fluctus in simpulo: It (automated office blood pressure measurement) caused a tempest in a teapot.

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The debate after publication of the SPRINT trial essentially centered on 2 points.[11–16] First, how does the systolic M_{OBP} used in all previous trials to recruit and adjust antihypertensive drug treatment compare with the A_{OBP} target levels in SPRINT? Second, how did the conditions of A_{OBP} measurement, unattended versus attended, affect the SPRINT results? To address these concerns, we will focus on: (1) the difference between auscultatory and oscillometric blood pressure measurement; (2) the real-world clinical application of A_{OBP}; (3) the comparison of A_{OBP} levels with those obtained by M_{OBP} readings or by home and ambulatory blood pressure monitoring; and (4) the prognostic accuracy of the A_{OBP} versus M_{OBP}. The main literature sources referenced in our debate article are summarized in the Table.

Auscultatory Versus Oscillometric Blood Pressure Measurement

As the heart cycles through contraction and relaxation, the pressure exerted on the walls of arteries into which the left ventricle ejects attains a maximum, systolic blood pressure, and next, after closure of the aortic valve, gradually falls to a minimum, diastolic blood pressure, which is similar throughout the arterial tree. The auscultatory approach to measure blood pressure, established by Korotkoff[21,22] in 1905, accounts for these basic physiological principles. The pivotal population studies that initially established hypertension as the overriding modifiable cardiovascular risk factor all relied on the M_{OBP}.[23–25] Similarly, most intervention trials in hypertension, which established the benefits of antihypertensive

Table. Summary of Main Literature Sources

Research Question Study Identification	Study Design	Study Participants	Main Finding	Comment
Unattended vs attended A_{OBP}				
Hong et al[41]	R-, CS	n=600; 50 y; F, 50%; HT, 55.8% (…)	Unattended<attended A_{OBP}	White-coat hypertensive patients included
Andreadis et al[44]	R-, CS	n=146; 56 y; F, 46.6%; HT 100% (47%)	Unattended=attended A_{OBP}	Sequence of A_{OBP} measurements not randomized
Johnson et al[45]	RCT	n=9361; 67.9 y; F, 36.0%; HT (SBP ≥130 mm Hg), 100% (90.6%)	Unattended=attended A_{OBP}	Unattended/attended A_{OBP} measured in different participants.
Kollias et al[47]	MA	n=1004; 60.8 y; F, 45%	Unattended=attended A_{OBP}	10 studies reviewed, which all used the same device/protocol for comparing unattended with attended A_{OBP}
Salvetti et al[50]	R-, CS	n=564; 61 y; F, 41%; HT, 78% (63%)	Unattended=attended A_{OBP}	Association of target organ damage with unattended/attended A_{OBP} was similar
Bauer et al[48]	R-, CS	n=158; 68.0 y; F, 44.3%; HT 100% (93.0%)	Unattended=attended A_{OBP}	No coverage of the whole blood pressure and age range
Five minutes rest vs no rest before A_{OBP}				
Colella et al[39]	RCT	n=100; 68.4 y; F, 30%; HT (SBP ≥130 mm Hg), ≈100% (≈100%); mean systolic A_{OBP}, 122.2 mm Hg	Antecedent rest is not needed for A_{OBP} at lower treatment targets	Convenience sample of patients enrolled in cardiac rehabilitation program; no ambulatory blood pressure monitoring
A_{OBP} vs M_{OBP}				
Myers et al[4]	RCT	n=555; 65 y; F, 65.2%; HT, 100% (95.5%)	$A_{OBP}<M_{OBP}$	Cluster randomization resulting in imbalance between A_{OBP} (n=303) and M_{OBP} (n=252); no attempt to improve quality of M_{OBP}; 14% terminal zero digit preference, using A_{OBP}
A_{OBP} vs ABP_W				
Beckett[3]	R-, CS	n=481; 64.9 y; F, 56.3%; HT, 100% (100%)	$A_{OBP}=ABP_W$	No coverage of the whole blood pressure and age range
Myers et al[4]	RCT	n=555; 65 y; F, 65.2%; HT, 100% (95.5%)	$(ABP_W–A_{OBP})<(ABP_W–M_{OBP})$: −2.3/−3.3 vs −6.5/−4.3 mm Hg	No attempt to improve M_{OBP} biases results in favor of A_{OBP}
A_{OBP} vs HBP				
Bauer[48]	R-, CS	n=158; 68.0 y; F, 44.3%; HT 100% (93.0%)	Systolic unattended/attended A_{OBP}>HBP	No coverage of the whole blood pressure and age range
Kollias[58]	R-, CS	n=790; 64.5 y; F, 49%; HT 100% (100%)	A_{OBP} misclassified ≈40% treated HT patients according to HT status based on HBP	No information on untreated patients

ABP_W indicates ambulatory blood pressure during wakefulness; A_{OBP}, automated office blood pressure; CS, cross-sectional; F, proportion of women; HBP, home blood pressure; HT, proportion of hypertensive patients (treated); MA, meta-analysis; M_{OBP}, manual office blood pressure; N, number of participants (mean age); R-, not randomized; RCT, randomized clinical trial; and SBP, systolic blood pressure. A ellipsis indicates data not reported.

drug treatment[26,27] or compared the properties of antihypertensive agents,[28,29] have used M_{OBP} for selecting patients and for adjustment of antihypertensive treatment.

The oscillometric method of blood pressure measurements involves high pass filtering of the small pressure oscillations with each heartbeat in the cuff surrounding the upper arm and computing the envelope of these oscillations.[30,31] The point of maximal oscillations corresponds closely to mean arterial pressure, but systolic and diastolic pressure are computed by complex proprietary algorithms, sometimes with hidden particularities.[32] Oscillometric monitors, including devices for A_{OBP} in a professional setting, therefore require validation against the gold standard, that is, auscultatory measurement of systolic and diastolic blood pressure according to standardized validation protocols.[33] To pass validation, the fault tolerance is a deviation from the auscultatory readings of up to 5 mm Hg for both systolic and diastolic blood pressure.[33]

In addition to the indirect measurement of systolic and diastolic blood pressure, oscillometric devices can be inaccurate in patients with atrial fibrillation or with a hyperdynamic circulation. Atrial fibrillation affects 1 in 25 adults 60 years or older and nearly one in 10 adults 80 years or older.[34] In pregnant women, children and young adults, phase-4 diastolic blood pressure should be measured, if the Korotkoff[21,22] sounds remain audible at zero cuff pressure.[35] In view of the ban on mercury, professionals can use *hybrid* devices as an alternative to standard sphygmomanometers. Blood pressure is then taken by the auscultatory Korotkoff[21,22] approach, but the cuff pressure is displayed as a simulated mercury column, using an array of light emitting diodes, or as a digital display.[36,37]

The Application of A_{OBP} Measurement

Apart from the Canadian guidelines,[9,10] our literature review did not reveal strong endorsement of A_{OBP} measurement or a generally accepted consensus on how A_{OBP} should be practically organized. The ideas underlying A_{OBP} were to remove observer error—not necessarily device error—and by leaving the patient alone and resting during A_{OBP} to minimize the white-coat effect. However, over the years, the approach to A_{OBP} underwent modifications to make it more practicable in daily clinical care in terms of the required time and the office space allowing unattended A_{OBP}.

Resting Period and Interval Between Readings

In 2006, Meyers reported that nearly 75% of the decrease in A_{OBP} occurs within 2 minutes of the patient being left alone.[38] In a randomized cross-over study involving a convenience sample of 100 patients, the systolic/diastolic A_{OBP} level (average of 3 unattended readings at 1-minute intervals) was 4.0/1.0 mm Hg lower, if preceded by a 5-minute resting period versus no rest (120.2/66.9 versus 124.2/67.9 mm Hg; $P \leq 0.01$).[39] A study published in 2008 demonstrated that the averages of 5 unattended A_{OBP} readings were similar, irrespective of whether readings were obtained at 1- or 2-minute intervals.[40]

Unattended Versus Attended A_{OBP} Measurement

In a Chinese study of 600 outpatients, 8 consecutive blood pressure readings were obtained at 2-minute intervals after the patients had rested for 10 minutes.[41] The first 2 and the last 2 readings were taken in the presence of a physician. Hypertension was a M_{OBP} of 140 mm Hg systolic or 90 mm Hg or higher or use of antihypertensive drugs. Among 335 (55.8%) hypertensive patients, compared with the first 2 and the last 2 attended readings, unattended A_{OBP} (mean, 132/76 mm Hg) was respectively 7.6/6.2 and 2.0/3.0 mm Hg lower ($P<0.05$ for all). Among 265 (44.2%) normotensive participants, the corresponding differences with unattended A_{OBP} were 4.3/4.7 and 0.8/2.5 mm Hg. What this Chinese study,[41] from which hyperreactive white-coat hypertensive patients were not excluded, showed foremost is that with repeated measurement, the attended A_{OBP} substantially decreased ($P<0.05$ for all). Already in 1983, one of us reported as part of his doctoral dissertation that systolic/diastolic blood pressure decreased by 5.7/3.8 mm Hg ($P<0.001$) over 10 observer-made auscultatory readings,[42] 5 at each of 2 home visits, an observation subsequently replicated by other researchers applying the same protocol.[43]

In a cross-sectional study of 146 patients with office hypertension, the difference between attended and unattended systolic/diastolic A_{OBP} (3 measurements at 1-minute intervals after a 5-minute rest) was only 0.6/0.2 mm Hg (CI, −0.3 to 1.6/−0.5 to 0.8 mm Hg).[44] A limitation of this study was that the sequence of the A_{OBP} measurements was alternating and not randomized.[44] However, the findings of this small study[44] were in agreement with a SPRINT report[45] published to answer the criticism that in SPRINT A_{OBP} was not measured truly unattended.[46] At 38 sites (4082 participants), A_{OBP} had been measured after leaving the participant alone for the entire time (always alone), 25 sites (n=2247) had personnel in the room the entire time (never alone), 19 sites (n=1746) left the participant alone only during the rest period (alone for rest), and 6 sites (n=570) left the participant alone only during the A_{OBP} readings (alone for blood pressure measurement).[45] Similar systolic and diastolic blood pressure levels within randomized groups were noted during follow-up at the majority of visits in the 4 measurement categories, even though the SPRINT participants were different across the 4 groups (Figure 1). In the always alone and never alone categories, the intensive group had a similarly reduced risk for the primary outcome compared with the standard group (HR, 0.62 [CI, 0.51–0.76] versus 0.64 [CI, 0.46–0.91] respectively; pairwise interaction *P* value, 0.88).[45] Risk was not significantly reduced in the intensive group in the alone-for-rest and the alone-for-A_{OBP} measurement categories, because of the smaller sample size.[45] Thus, similar blood pressure levels and risk reductions were observed in the intensive group in SPRINT participants, irrespective of whether A_{OBP} was unattended or attended.[45]

Whether or not unattended as opposed to attended A_{OBP} has clinical relevance remains a matter of intense debate.[47–50] The best evidence comes from a meta-analysis of summary statistics from 10 studies (mean age, 60.8 years; 45% women), which all used the same device and measurement protocol for measuring the unattended and attended A_{OBP}.[47] Unattended A_{OBP} (pooled systolic/diastolic blood pressure, 133.9/80.6 mm Hg) did not differ from attended A_{OBP} (135.3/81 mm Hg). The pooled differences amounted to −1.3 mm Hg (CI, −4.3 to 1.7 mm Hg) systolic and −0.4 mm Hg (CI, −1.2 to 0.3 mm Hg) diastolic. This conclusion is supported by an Italian study of 564 subjects, in whom correlations of unattended and attended A_{OBP} with left ventricular mass index ($r=0.194$ versus $r=0.205$)

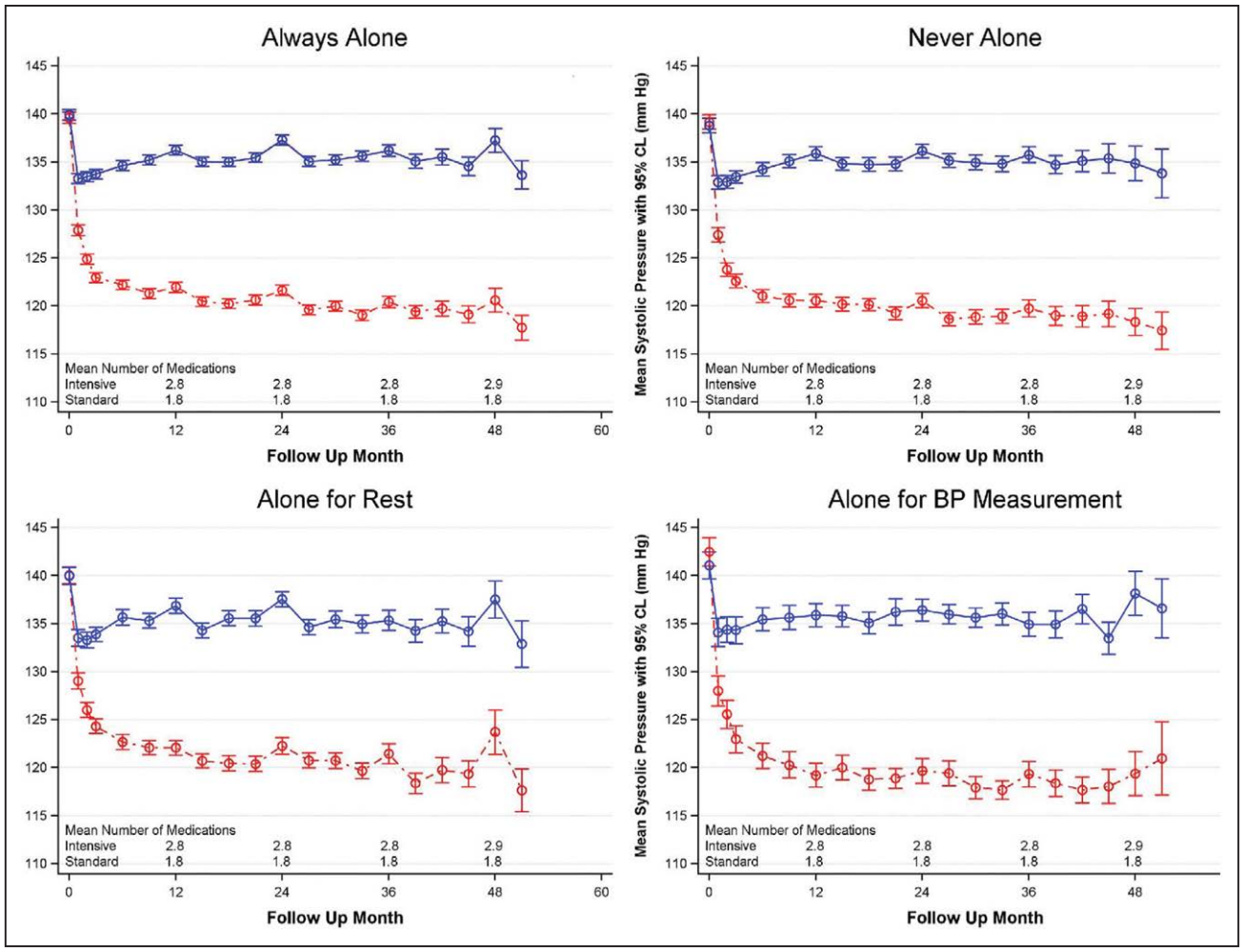

Figure 1. Systolic blood pressure by technique of automated office blood pressure recording. Plotted values are means ±95% CI in patients randomized to tight and usual blood pressure control in the Systolic Blood Pressure Intervention Trial. BP indicates blood pressure. Reprinted from Johnson et al[45] with permission. Copyright ©2018, Wolters Kluwer.

and carotid intima-media thickness (r=0.194 versus r=0.206) were similar.[50]

Automated Office Compared With Other Blood Pressure Measurements

Most studies comparing unattended A_{OBP} with the ambulatory blood pressure enrolled patients with hypertension [3,4] and, therefore, provide little information of the performance of A_{OBP} to screen for hypertension at the point of entry in health care, where a measurement technique minimizing the white-coat effect would be of greatest value.

Studies in Canadian Primary Practices

The Centre for Studies in Primary Care, Queen's University, Kingston, Ontario, Canada enrolled 481 treated patients with hypertension from 51 family practices.[3] The M_{OBP} was extracted from patient charts covering 3 visits at intervals ranging from weeks to months. The unattended A_{OBP} was recorded at a subsequent visit.[3] The systolic/diastolic M_{OBP} taken at the 3 preceding visits and the M_{OBP} test reading before unattended A_{OBP} were similar (150.8/82.9 versus 150.0/83.3 mm Hg), whereas the average of the 5 unattended A_{OBP} readings taken at 1- or 2-minute intervals after patients had rested for at least 5 minutes (140.0/79.8 mm Hg) were 10.0/6.5 mm Hg lower than the M_{OBP} test reading before unattended A_{OBP} measurement[3] but within 1.5/0.1 mm Hg similar to the daytime (6 AM–10 PM) ambulatory blood pressure (141.5/79.7 mm Hg). Daytime included the transition periods in the morning and evening, during which in most individuals blood pressure increases from and reverts to the lower nighttime blood pressure. Including these transition periods underestimates the true daytime blood pressure level based on short-fixed clock time intervals (10 AM–8 PM), which is within 1 mm Hg of the awake blood pressure.[51] Another limitation of this study[3] was that it enrolled only treated and older hypertensive patients (56.3% women; mean age, 64.9 years) and did, therefore, not cover the whole blood pressure spectrum or age range. Moreover, close to one-third of the patients probably had controlled or uncontrolled white-coat hypertension.[52]

The CAMBO (Conventional versus Automated Measurement of Blood Pressure in the Office) Trial (URL: http://www.clinicaltrials.gov. Unique identifier: NCT00325832) cluster randomized general practices to management of patients with systolic hypertension, using either unattended A_{OBP} or continuing M_{OBP} measurement with either mercury or aneroid sphygmomanometers.[4] Randomization was not completely balanced, resulting in 36 practices (299

patients analyzed) being allocated to the unattended A_{OBP} group (intervention) and 31 practices (249 patients) to the M_{OBP} group (control).[4] M_{OBP} readings were also obtained from the last routine visit of the patients to their primary care physicians. CAMBO included a majority of women (65.2%).[4] Mean age was 65.0 years. Antihypertensive drug treatment was unchanged throughout the trial. Compared with the intervention group, the control group had similar blood pressure levels at the last routine M_{OBP} readings before the trial (149.5/81.4 versus 149.9/81.8 mm Hg; difference [CI], 0.4 [−0.6 to 1.4]/0.4 [−0.8 to 1.6] mm Hg; $P \geq 0.43$) and during awake blood pressure monitoring (133.2/74.4 versus 135.0/75.9 mm Hg; difference [CI], 1.8 [−0.4 to 4.0]/1.5 [−0.2 to 3.2] mm Hg; $P \geq 0.08$).[4] The only between-group difference was in the in-trial office blood pressure as obtained by unattended A_{OBP} versus M_{OBP} (135.6/77.7 versus 141.4/80.2 mm Hg; difference [CI], 5.8 [3.1–8.5]/2.5 [0.8–4.2] mm Hg; $P \leq 0.0045$). Compared with the ambulatory blood pressure during wakefulness, the systolic/diastolic unattended A_{OBP} was 2.3/3.3 mm Hg higher (CI, 0.3–4.3/2.2–4.4 mm Hg) in the intervention group and the in-trial M_{OBP} 6.5/4.3 mm Hg higher (CI, 4.3–8.6/2.9–5.8 mm Hg) in the control group.[4] Remarkably, unattended A_{OBP} was still associated with a 14% terminal zero digit preference,[4] highlighting that contrarily to what is often claimed, this technique of blood pressure measurement does not completely eliminate observer error. The prevalence of terminal zero's was close to 50% among the in-trial M_{OBP} readings. This illustrates how little effort was spent in educating physicians how to measure M_{OBP}, thereby biasing the results in favor of A_{OBP}.[4]

Population Studies

The white-coat effect associated with M_{OBP} in CAMBO[4] was substantially smaller than in other studies of patients,[53,54] populations[55] or healthy workers,[56] casting doubt on the generalizability of the findings. Another issue hampering the interpretation of the Canadian studies[3,4] is the over-representation of older patients. The relevance of this is illustrated by a combined analysis of data from the International Database on Ambulatory Blood Pressure in Relation to Cardiovascular Outcome (n=11 262) and the Genetic and Phenotypic Determinants of Blood Pressure and Other Cardiovascular Risk Factors Study (n=2044).[55] All participants were untreated. Their age ranged from 18 years to over 70 years. Among individuals aged 18 to 30 years (n=1543), 30 to 40 years (n=2063), and 40 to 50 years (n=2141), daytime blood pressure was significantly higher than the corresponding M_{OBP} (6.0, 5.2, and 4.7 mm Hg for systolic pressure and 2.5, 2.7, and 1.7 mm Hg for diastolic pressure (Figure 2; $P<0.0001$). In individuals aged 60 to 70 years (n=1408) and over 70 years (n=719), M_{OBP} was significantly higher than the daytime blood pressure (5.0 and 13.0 mm Hg for systolic pressure and 2.0 and 4.2 mm Hg for diastolic pressure; $P<0.0001$). The prevalence of white-coat hypertension exponentially increased from 2.2% to 19.5% from those aged 18 to 30 years to participants aged 70 years or older, with little difference between women and men.[55] This international study suggested that to the extent that A_{OBP} was designed to minimize the white-coat effect and to reflect the daytime ambulatory blood pressure, its clinical utility might be limited to older patients with hypertension.[55]

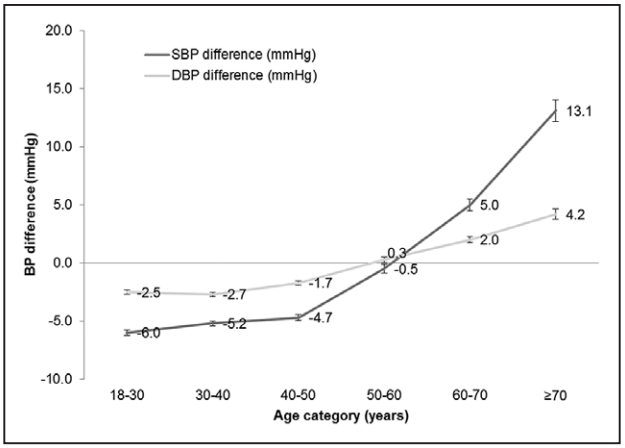

Figure 2. Systolic (SBP) and diastolic (DBP) blood pressure differences obtained by subtracting manual office from daytime ambulatory blood pressure levels in 9950 untreated people recruited in various population studies. Values are means±SE. Reprinted from Conen et al[55] with permission. Copyright ©2014, Wolters Kluwer.

We did a similar analysis of the baseline data of 6571 untreated participants enrolled in The International Database of Home Blood Pressure in Relation to Cardiovascular Outcome.[57] Age ranged from 18 to over 80 years. The home blood pressure was consistently lower ($P<0.001$) than M_{OBP}, which was the average of 2 conventional office readings (Figure 3). The difference between the 2 modalities of blood pressure measurement was again strongly dependent on age, increasing from 2.4/3.0 mm Hg in the youngest age group to 7.5/4.3 mm Hg and 7.5/3.0 mm Hg in the 40 to 50 year and 50 to 60 year age bands, and decreasing to 4.7/3.1 mm Hg in the very elderly. These findings are consistent with a study of 158 patients recruited at 4 German general practices.[48] Both unattended and attended systolic and diastolic A_{OBP} were significantly higher compared with the home blood pressure measured over 7 days.[48] A study of 790 patients on stable antihypertensive drug treatment recruited by 135 Greek general

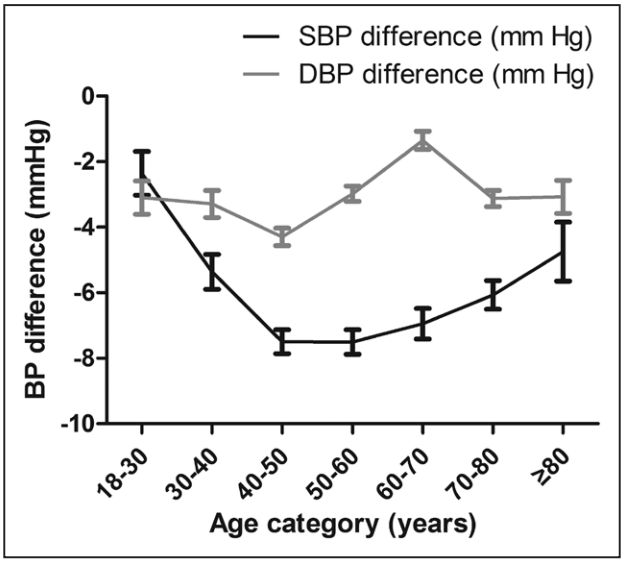

Figure 3. Systolic (SBP) and diastolic (DBP) blood pressure differences obtained by subtracting manual office from home blood pressure levels in 6571 untreated people recruited in various population studies. Values are means±SE.

practitioners demonstrated that attended A_{OBP} after 5 minutes of rest misclassified ≈40% of patients according to their blood pressure status based on home blood pressure monitoring.[58]

Meta-Analysis

Canadian investigators compiled data from 31 articles comprising 9279 participants (49.0% women).[59] In studies with systolic unattended A_{OBP} of 130 mm Hg or higher, routine clinical and research-grade systolic blood pressure readings were substantially higher than unattended A_{OBP} with a pooled mean differences of 14.5 mm Hg (CI, 11.8–17.2 mm Hg; data extracted from 9 studies) and 7.0 mm Hg (CI, 4.9–9.1 mm Hg; 9 studies), respectively. Systolic awake ambulatory blood pressure and unattended A_{OBP} readings were similar, with a pooled mean difference of 0.3 mm Hg (CI, −1.1 to 1.7 mm Hg; 19 studies).[59] Interpretation of these results is difficult, because of the large heterogeneity between reviewed studies, which the authors addressed by using a random-effect model to compute pooled estimates. Furthermore, most reviewed studies did not randomize the order of the blood pressure measurements. These meta-analytic results should not be extrapolated to systolic unattended A_{OBP} levels below 130 mm Hg. They did not address the issue of masked hypertension. Finally, in several studies, unattended A_{OBP} was highly standardized, whereas no attempt was made to educate doctors and nurses obtaining the routine clinic blood pressure readings.

Prognostic Accuracy

A major issue related to the clinical application of A_{OBP} is the lack of evidence convincingly relating adverse health outcomes to A_{OBP} in prospective studies and the unavailability of outcome-driven diagnostic thresholds. Preliminary cross-sectional studies of healthy men (n=176)[60] or patients with office hypertension (n=90)[61] suggested that target organ damage, as for instance captured by carotid intima-media thickness[60] or left ventricular mass,[61] might be closer associated with unattended A_{OBP} than with the M_{OBP} measured by auscultation[60] or oscillometrically.[61] However, these small studies did not account for clustering of the blood pressure measurements within individuals[60,61] or derived significance by entering 2 modalities of blood pressure measurement along with covariables in a single regression model.[60] A nonsignificant *P* value for M_{OBP} does not indicate less accuracy in the association with target organ damage.

Canadian investigators published 2 studies, respectively focusing on diagnostic thresholds of the attended A_{OBP}[6] and on the association of cardiovascular risk with A_{OBP}.[7] The first study enrolled 3627 community-dwelling residents, aged 65 years and older.[6] All were untreated for hypertension (58.8% women; mean age, 74.2 years). A_{OBP} readings were obtained in a community pharmacy by trained volunteers with the participants seated in a quiet room, not speaking and left undisturbed, and with the observer remaining nearby.[6] The primary outcome was a composite of acute-care hospital admissions with as discharge diagnosis myocardial infarction, congestive heart failure, stroke, or death caused by cardiovascular disease. Over an average follow-up of 4.9 years, 271 primary end points occurred.[6] Systolic and diastolic A_{OBP} were stratified in 10 mm Hg bands ranging from below 110 mm Hg to over 160 mm Hg systolic and from less than 60 mm Hg to over 90 mm Hg diastolic. The lowest rate of the primary end point occurred in the 110 to 119 mm Hg systolic and the 60 to 69 mm Hg diastolic A_{OBP} bands, in which the rates were 5.75% (number of events/number at risk, 36/626) and 6.09% (56/920), respectively. In multivariable-adjusted analyses, the risk of a primary end point in the other strata was compared with the reference bands. There was a significant increase in the risk at a systolic A_{OBP} of 135 to 144 mm Hg (HR, 1.66; CI, 1.09–2.54; P=0.02) and at a diastolic A_{OBP} of 80 to 89 mm Hg (HR, 1.72; CI, 1.21–2.45; P=0.003). The advanced age of the participants, the self-reporting of the baseline risk factors and the distinctive local setting were factors limiting the generalizability of this otherwise well-conducted Canadian study.[6] Nevertheless, the 135/85 mm Hg A_{OBP} threshold proposed by Myers et al[35] is in keeping with most guidelines, but substantially higher than the thresholds for normotension (<120/<80 mm Hg) and elevated blood pressure (120–129/<80 mm Hg) published in the 2017 guideline of the American Heart Association.[62]

The second Canadian study addressed the association between the incidence of cardiovascular events and baseline attended A_{OBP} in a real-world setting,[7] as described before.[6] The investigators enrolled 6183 community-dwelling residents of Ontario with a minimum age of 66 years, who were receiving antihypertensive drug treatment (58% women; mean age, 76.2 years). Participants had their A_{OBP} measured at pharmacies with the majority of sessions held between 9 AM and 12 AM. Participants rested quietly, undisturbed, before and during the A_{OBP} readings. The research staff remained near the patients, but did not speak or otherwise interacted with them. A_{OBP} was the average of 5 readings taken at 1-minute intervals.[7] The statistical analysis was done as in the 2015 Canadian report,[6] with the 110 to 119 mm Hg systolic and the 60 to 69 mm Hg diastolic A_{OBP} bands as reference groups. In these treated patients, the risk of a composite cardiovascular end point was only higher at a systolic A_{OBP} of 120 to 129 mm Hg (HR, 1.30; CI, 1.01–1.66) and at a systolic A_{OBP} higher than 160 mm Hg (HR, 1.85; CI, 1.45–2.41). The risk of a composite cardiovascular end point did not increase with diastolic A_{OBP}. Although the study participants included 24.1% of patients with diabetes mellitus and 2.5% of patients with a history of cerebrovascular disease, the Canadian investigators[6,7] suggested that the results of their observational study supported the 120 mm Hg target proposed by SPRINT in older patients without diabetes mellitus or a history of stroke.[17] In both Canadian studies,[6,7] the association of the composite cardiovascular end point with systolic A_{OBP} was curvilinear with a significant HR of 1.38 (CI, 1.04–1.81)[7] in treated participants with a systolic attended A_{OBP} of less than 110 mm Hg compared with the reference group (110–119 mm Hg).[7] Although this observation was not emphasized, it is relevant in the light of various editorial comments,[11,14,16] warning that a 120 mm Hg A_{OBP} threshold is likely to expose older frail people to overtreatment and to cause rather than to prevent cardiovascular or renal[17] complications. At the end of the line, the SPRINT outcome data provided, in the context of a randomized clinical trial, provided the strongest evidence that A_{OBP} readings do not have different prognostic significance, irrespective of whether they were unattended or attended.[17,45]

Conclusions

Cardiovascular disease remains the leading cause of mortality and is worldwide directly responsible for ≈18 million deaths, representing over 30% of all-cause mortality globally.[63] The Lancet Commission on Hypertension identified ten essential and achievable goals that should substantially contribute to the management of blood pressure globally.[64] One priority measure was better quality of blood pressure measurements through endorsed protocols and by using certified and validated blood pressure monitors.[64] Modern guidelines recommend out-of-the-office blood pressure measurement, either by ambulatory monitoring or by the self-measurement at home, as the method of choice.[65–67] A_{OBP} does not exclude white-coat hypertension and does not identify masked hypertensive patients, which in the presence of an optimal/normal office blood pressure (<120/<80 mm Hg) have a 2- to 3-fold higher risk of major cardiovascular complications.[68,69]

A_{OBP} is a modality of blood pressure measurement, which was primarily designed to overcome the limitations of what has been termed clinical-grade[5] M_{OBP}. While A_{OBP} may be incorporated in the diagnostic and therapeutic workup of patients, it needs to be combined with out-of-the-office blood pressure measurement and in this way does not differ from M_{OBP}. The prognostic value of A_{OBP} remains largely unsettled, available studies being limited to older patients on antihypertensive drug treatment, among whom a large proportion had white-coat hypertension.[3–8] Furthermore, this review highlighted that key features of A_{OBP} measurement, including the duration of the resting period before A_{OBP},[40,41] the interval between readings and their number,[41,44] and the absence of an observer[45] should be formalized in a universally endorsed protocol. Until this is done in properly designed clinical studies, the whole discussion around the hypothetical, but largely unproven, benefits of A_{OBP} measurement is nothing more than a storm in a teapot (excitabat enim fluctus in simpulo). Moreover, future research should also include a cost-benefit analysis, comparing the application of A_{OBP} with the benefits of educating physicians to improve their skills in M_{OBP} and managing hypertension. Such health-economic analysis should include real costs as well as the more intangible patient values in a 5-P approach (predictive, preventive, personalized, participatory, and psycho-social context).[70]

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Response to Implementing Automated Office Blood Pressure Measurement: Controversies in Hypertension - Con Side of the Argument

Daniel W. Jones

A key difference of opinion in this debate on the use of automated office blood pressure (AOBP) measurement is the difference in precision compared with manual OBP measurement. When protocols are carefully followed, indeed, there is little difference in the precision of the 2 methods. This was demonstrated by the National Health and Nutrition Examination Survey investigators in a carefully controlled study (1.6 mm Hg difference in systolic BP).[1] Unfortunately, in routine clinical practice, BP measurement protocols are not carefully followed[2] (14 mm Hg systolic BP difference).[3] The primary advantage of AOBP over manual OBP is better adherence to 2 key protocol recommendations: the rest period and multiple measurements. Clinical trials on which BP management recommendations are based have used many different BP measurement methodologies over the years…always seeking to use methods that offer the lowest BP at rest.[4] AOBP is simply a tool to assist providers in protocol adherence and obtaining more precise measurement. Many interested in BP measurement (including this author) resisted the abandonment of manual OBP for years.[5] However, with the loss of the mercury manometer to most clinical practices, this narrowed the instrument options for manual OBP to inferior aneroid manometers. Oscillometric instruments became the norm. AOBP is not a dramatic change in the approach to measuring BP. It is a simple modification of existing technologies to assist busy practitioners and their staffs in ideal measurement methodologies. As noted by Professor Zhang, modern guidelines advocate for more use of out of OBP measurement. However, none calls for the abandonment of office BP. "Out-of-office BP measurements are recommended *to confirm the diagnosis of hypertension*..." (2017 US Guidelines),[6] and "Wider use of out-of-office BP measurement with ABPM and/or HBPM, especially HBPM, as an option *to confirm the diagnosis of hypertension*…" (2018 European Guidelines).[7] Central to each of these statements is the notion that out-of-office BP measurement confirms the diagnosis based on OBP measurement, still an essential tool in BP management decisions and one which is enhanced by the use of AOBP. This innovation should not be feared or resisted. It should be embraced.

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