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Controversies in Hypertension Implementing Automated Office Blood Pressure Measurement: PRO

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Introduction

Why is it we talk and write so much about BP measurement? Why another debate about yet another BP measurement methodology? Of all the important risk factors for cardiovascular disease (CVD), it is only BP measurement that attracts so much discussion and debate.[1] The methodological approaches for measuring other CVD risk factors such as glucose, HgbA1C, LDL-cholesterol, non-HDL cholesterol, body weight, height, BMI, waist circumference, and smoking status are well-defined and widely agreed upon. What distinguishes BP from these more easily measured CVD risk factors?

First, and perhaps most difficult to address from a measurement perspective, is the moment-to moment-biologic variability in BP. While most other CVD risk factors are characterized by some level of biologic variability, BP is unique in its volatility. Physical activity (even mild), emotional stress, and many other factors can result in sudden changes to one's BP. Like other risk factors, BP changes over time (with age), especially in industrialized societies.[2]

Secondly, all the convenient and clinically practical methods for measuring BP are indirect measurements. The reference standard for BP measurement is intra-arterial measurement, a precise, but impractical method for most clinical settings.[3–5] Indirect measurement methods, on the other hand, generally depend on the use of a pressurized cuff to impede blood flow in an artery, usually the brachial artery.

Precise determination of BP is essential. Clinicians rely on precise BP levels to predict and manage cardiovascular disease risk, to accurately diagnose hypertension, to determine appropriate initial therapy for BP management in those with hypertension or elevated BP, and to assess patients' progress toward goal BP.[1] In recent years, the use of performance measures to evaluate quality in patient care has driven a new focus on assessment of all common CVD risk factors. BP control is a frequently used performance measure for these evaluations, further necessitating accurate methods for measuring and monitoring BP.

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Conflicts of Interest

None

Currently, office BP measurements are the most frequently used measure of control, with the last recorded office BP often cited as the performance measure.[6]

AOBP is Unique

The controversy regarding office BP measurement has recently escalated, with the introduction of an automated oscillometric instrument that, in the office setting, can be programmed to measure BP at intervals, usually after a five-minute rest period (some instruments) and then at one-minute intervals, for a total of three measurements following the rest period. The device also allows measurement to occur without an observer in the room with the patient. This BP measurement method is usually referenced as automated office blood pressure (AOBP) measurement.[7–9] The purpose of this paper is to review the reasons that this BP measurement device and approach should be the preferred approach for measuring “office BP” in clinical practice and in clinical research.

Automated Office Blood Pressure (AOBP) measurement is gaining popularity as an approach to office blood pressure (BP) measurement. As evidence has evolved that among available BP measurement methodologies, ambulatory BP measurement (ABPM) best predicts future cardiovascular disease (CVD) measurement methods have been compared to this standard. The use of AOBP has increased as evidence of the close correlation between AOBP measurements and daytime ABPM results have been reported. For the foreseeable future, both in-office and out-of-office BP measurement will be needed. This paper does not address whether office BP measurement of any kind should be abandoned in favor of only measuring BP out of the office. AOBP is simply a modification on the use of oscillometric instruments to determine an accurate BP measurement in the office setting. The method allows an indirect measurement of BP without the use of a mercury containing instrument and allows close agreement to appropriately measured BP with a mercury manometer. This leads to improvement in both the diagnosis of hypertension and a more reliable assessment of goal BP.

For the first 100 years of clinical measurement of blood pressure, a mercury sphygmomanometer using auscultation was the gold standard for indirect measurement of blood pressure. Beginning in the late 1990s, however, various regulatory groups around the world began calling for the elimination of mercury from any medical device for safety reasons.[3,4] Gradually, most medical facilities discontinued the use of the mercury manometer. With loss of access to the mercury manometer, other instruments came into more common use in both research and clinical settings. Today, the most widely used BP measurement devices are aneroid auscultatory instruments and automated oscillometric instruments.[3]

In their early use, mercury manometers were evaluated for accuracy by comparing their readings to intra-arterial measurements of pressure. One important advantage of the mercury manometers over other devices is the ease and certainty of calibration. Because the mercury manometer is dependent on gravity for determining pressure all that is necessary for calibration is to assure an accurate zero reading when the cuff is not pressurized. As other

instruments were developed, the simplicity of the mercury manometer led to its use as the standard against which these new devices were calibrated and evaluated for accuracy. [3]

It is important to note that none of the devices used for indirect measurement of BP are completely accurate, even the mercury manometer. After evaluating the methodology with a mercury manometer in his physiology lab, Dr. Arthur Guyton noted in his first edition of *The Textbook of Medical Physiology*, "The auscultatory method for determining systolic and diastolic pressures is not entirely accurate, but it usually gives values within 10 percent of those determined by direct measurements from the arteries."[10] More recent studies in humans, comparing direct intra-arterial pressures to indirect pressures using a mercury manometer, show slightly lower systolic BP (SBP) values and slightly higher diastolic BP (DBP) values for the mercury manometer.[5]

Before addressing the pros and cons of the use of AOBP, it is important to note that the critical question is not whether this device/approach should be used to the exclusion of other BP measurement methods, especially out-of-office measurements. In other words, the question is not AOBP *or* other methods. Rather, the question is whether AOBP should be included among the methods used to measure BP and whether or not it should be the preferred method for the measurement of office BP.

AOBP Implementation

AOBP has gained added attention in recent years because of its use in two large, well known clinical trials – the Action to Control Cardiovascular Risk in Diabetes Trial (ACCORD) and the Systolic Blood Pressure Intervention Trial (SPRINT) – and because of recommendations in recent national or regional guidelines.[11] The Canadian guidelines recommend AOBP measurement as the "preferred" method for office BP measurement; the European Society of Cardiology and European Society of Hypertension Guidelines encourage its use "when feasible;" and the 2017 ACC/AHA Blood Pressure Management Guidelines note, "There is a growing evidence base supporting the use of automated office BP measurements."[12–15] The decision to use AOBP in ACCORD and SPRINT was likely driven by the evidence that it was the "best" method for measuring office resting BP among the instruments and methods available to the study planners.

Advocates for the use of AOBP note the positive attributes of the technology/approach. Among the commonly used office BP measurement methods, AOBP gives the lowest BP readings.[9,11,16] The results from AOBP are more consistent with home BP measurement and daytime ABPM than with other office measurement devices and methods. Clinicians evaluated by performance measures have favored AOBP, because it improves the ability to more accurately evaluate BP in individuals and favorably impacts hypertension control rates in a practice.[16,17]

Critics of the use of AOBP point to several issues. AOBP was not used in most of the studies on which blood pressure risk for CVD has been determined and on which treatment recommendations are based.[18,19] However, a number of studies evaluating the association of AOBP and CVD outcomes have recently been published.[20–22] Critics also point to a concern

that AOBP will underestimate usual BP and therefore will underestimate CVD risk, leading to under treatment of blood pressure. Another frequently noted concern is that the AOBP approach to measuring office BP is inefficient in that it keeps an examination space occupied for a long period and requires excessive personnel time.[23] The relatively high cost of the measuring device itself is also noted to be problematic. In the view of many, these concerns are generally unfounded.

Critics express concern that in order to have an accurate diagnosis of hypertension, current measurements need to use the same methodology as the studies upon which the guidelines are based. While it is true that AOBP methodology was not the basis for these larger longitudinal epidemiological studies, what has been constant and consistent in BP trials over five to seven decades, regardless of the device used, has been the use of BP measurement guidelines from respected organizations including the American Heart Association (AHA) and the European Society of Hypertension (ESH).[24,25] Importantly, key methodologies have been utilized in most studies, including a three to five minute rest before BP measurement, multiple readings at each visit, and standardized training of observers (those measuring the BP). What has not been consistent is the BP measuring device.

AOBP in Research Settings

Over the last several decades, designers of clinical trials typically have selected the “standard of care” instrument at the time of the initiation of the study. Generally, this has been defined as the instruments and methods that resulted in the lowest office BP readings after a three to five minute rest. For many years, the preferred device was a mercury manometer. Sometimes, variations of a mercury manometer were used, including the random zero mercury manometer. This instrument eliminated the risk of digit preference. Most observational studies used the mercury manometer as well. AOBP was selected for ACCORD and SPRINT on the same basis for which devices were selected in earlier studies. Of the available instruments for measurement of office BP, AOBP consistently produced the lowest BP measurement results.

Some of the concern by critics was raised by results of studies examining the accuracy of AOBP devices compared to standard office BP measurement (oscillometric and auscultatory) in ordinary clinical settings. Some of these studies showed differences of 14–16 mm Hg for SBP. On the basis of these studies, some began to voice concern that the AOBP approach provided artificially low readings – not true readings.[10,16]

In evaluating the potential differences between standard office BP measurements and AOBP measurements, many have pointed to the absence of a health care provider in the room while BP was measured. AOBP was the first instrument to offer that option. Because it is an option, many assumed that the BP results in the intensively-treated group in SPRINT were related to this issue of non-attendance by an observer. Again, the concern was that the absence of a provider resulted in outcomes that were not comparable to previous studies. However, the SPRINT protocol for BP measurement did not specifically require the BP measurements be taken in the absence of an observer. A post-hoc analysis of BP measurement methods in SPRINT showed that at about half of the sites, BP measurement

was unattended and was attended in the others. The analysis demonstrated no difference in the group mean BP for the attended versus unattended measurements for both the intensive arm and the less intensive arms of the study.[26] A subsequent study, unrelated to SPRINT, confirmed no difference in attended versus non-attended measurements using AOBP in their evaluation of four primary care offices.[27]

Importantly, studies comparing other methods (oscillometric and auscultatory) in research settings where measurement guidelines were carefully followed (including a five-minute rest period before measuring BP), discrepancies between standard office BP measurement and AOBP were very small (1–2 mm Hg).[28] These differences are comparable to those noted in studies comparing many BP measurement instruments, including comparison of direct intra-arterial measurements and mercury manometers. Importantly, in the National Health and Nutrition Examination Survey (NHANES), 2009–2010, an AOBP device (Omron HEM-907XL) was compared to the mercury manometer auscultatory method used in the standard NHANES examinations for years. In this study, mean between-device differences were −1.6 mm Hg for SBP and −0.6 mm Hg for DBP. This study represents the most reassuring data on the comparability of AOBP measurements, when standard measurement protocols are followed.[29]

This leaves the important question of why the studies comparing the methods in office practice settings show such different results.[30] If it is not the attended versus unattended issue, what is the likely difference? Observing BP measurement in my own institution over a number of years in a variety of clinic settings, the five-minute rest called for by the guidelines is rarely utilized. This is true in most ambulatory settings around the world.[31] The “forced” five-minute rest enforced by some AOBP instruments, when used properly, likely accounts for much of the difference between AOBP and “standard” office BP measurement using other devices.

Critics of AOBP also express concern that it is more time consuming than usual office BP measurements. This is absolutely correct – because usual office BP measurements are done so poorly. In the typical patient visit in most clinics, the patient is called from the waiting room to an examination room. The patient is asked to sit (often on the examination table with the back and feet not supported). With no rest period, a BP cuff (often without consideration of arm size and appropriate cuff size) is applied to the brachial area over a shirt or blouse. A thermometer is inserted into the mouth. If an automatic oscillometric monitor is used, the observer often takes the medication history during the BP measurement, requiring the patient to answer questions as the cuff is deflating.[31]

Granted, this approach is less time consuming than using AOBP to measure BP. However, if the standard guidelines from the AHA or ESH for BP measurement are followed, the time used for BP measurement is essentially identical, regardless of the device used. It is only when office BP is measured inappropriately and inaccurately that it saves time.

AOBP Value

A related concern is that the AOBP procedure results in a patient spending more time in the exam room, disrupting the flow in the office. Extending each visit by 8 minutes for AOBP could foreseeably make for a longer clinic day for the clinician or result in fewer patients being seen. Some practices have dealt with this issue successfully by utilizing a designated area for measuring vital signs with an AOBP device. This could be a dedicated area of the hallway, a designated examination room, or a quiet area of the waiting room. These strategies have been utilized successfully with similar results to utilizing the patient's examination room.[10]

In a South Carolina BP management program in primary care practices, standard oscillometric or auscultatory methods are used initially.[32] AOBP is then used in any patient who has a recorded BP above goal. Also, a three-minute rest period is utilized in their protocol, saving some time. BP measurement results are similar to those after a five-minute rest. There are likely other time-saving approaches that can be tested in this still relatively new approach to BP measurement.

A final concern expressed by critics is that AOBP devices are prohibitively expensive. While it is true that the cost of an AOBP instrument is two to three times the cost of other manometers commonly used in clinical offices, this method has the potential to save money in the long term by lowering health care costs. We live in a world of healthcare cost inflation. We see the cost of testing rise every year – lab tests, imaging tests. What differentiates BP measurement, is that it is one of the few areas of medical testing where the cost of equipment is often the responsibility of the clinician.

When HgbA1C was introduced, the cost of evaluating the status of a diabetic patient increased significantly. But because in this case, the cost was borne by insurers, patients, and health systems, clinicians did not object to the higher cost associated with a better way to diagnose and monitor an important CVD risk factor. The same can be said for the use of expensive imaging modalities such as CT, MRI, and PET scans.

Evaluated by total cost of care, the overall cost of managing BP will decrease with better measurement of BP. By providing a more accurate and reliable approach for BP measurement, AOBP measurement has the potential to reduce the number of patients misdiagnosed with hypertension, limiting the prescription of unnecessary or superfluous medications, saving money for both the clinic and the patient. Despite the slightly higher initial expense, AOBP devices are an invaluable investment, with the potential to lower health costs and improve patient outcomes.

Ideally, the role of AOBP in management of patients will be the use of this device as the standard in office BP measurement. However, the use of this device does not eliminate the need for out-of-office BP measurement devices and methodologies. HBPM and ABPM will remain useful tools, especially in recognizing and evaluating white coat hypertension, masked hypertension, and nocturnal hypertension.[33]

It is clear that none of the currently available non-invasive devices for measuring BP are perfect. Further research leading to more accurate and less cumbersome devices is needed.[1] Devices convenient to patients with the ability to monitor and report moment-to-moment BP measurement would be ideal.

Conclusion

In this series of "Controversies in Hypertension," the authors on both the pro and con sides of an issue often agree more than disagree on key elements. I suspect that is the case here. Both Dr. Staessen and I are on record as supporting both in-office and out-of-office contemporary BP measurement methods. In this paper, I have voiced strong support for the use of AOBP. I also acknowledge the importance of out-of-office BP measurement. In fact, as a co-author of the 2017 ACC/AHA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults, I supported this key recommendation: "Out-of-office BP measurements are recommended to confirm the diagnosis of hypertension and for titration of BP-lowering medication, in conjunction with telehealth counseling or clinical interventions."[15] And Dr. Staessen, as co-author of a recent review on office BP measurement noted: "Based upon the current evidence, AOBP has definite advantages over attended manual BP measurement in clinical practice… AOBP is now the preferred method for office BP measurement in Canada. The Canadian experience suggests that replacement of attended office BP for hypertension screening is indeed feasible in places such as the United States and Europe."[34]

Given the capacity to measure BP with a forced period of rest and without an observer in the room as well as its close correlation with out of office BP measurement and the "gold standard" mercury manometer, it seems clear that AOBP is an important advance in more accurate determination of BP in the office setting and should be implemented broadly for the benefit of improved patient management.

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