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Emiliya Khazan

Orlando Veteran Affairs Medical Center, emiliya.khazan2@va.gov

Augustus Hough

West Palm Beach Veteran Affairs Medical Center, augustus.hough@va.gov

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A Modern Method to Monitor Office Blood Pressure

Emiliya Khazan, PharmD, BCPS¹; Augustus (Rob) Hough, PharmD, BCPS (AQ-Cardiology)²

¹Orlando Veteran Affairs Medical Center; ²West Palm Beach Veteran Affairs Medical Center

Abstract

The diagnosis and management of hypertension relies on accurate and precise blood pressure (BP) measurements and monitoring techniques. Variability in traditional office based BP readings can contribute to misclassification and potential misdiagnosis of hypertension, leading to inappropriate treatment and possibly avoidable adverse drug events. Both home blood pressure monitoring (HBPM) and 24-hour ambulatory blood pressure monitoring (ABPM) can improve characterization of BP status over traditional office values and can predict cardiovascular morbidity and mortality risk; however, they are limited by availability and/or practical use in many situations. Available in-office blood pressure measuring methods include manual auscultation, automated oscillometric, and automated office blood pressure (AOBP) devices. A strong correlation exists between AOBP and awake ABPM measurements and has been linked to better prediction of end-organ damage and white coat response compared to standard office BP methods. While AOBP does not provide nocturnal BP readings, it can be utilized in several outpatient settings, and has the capability to decrease utilization of ABPM, white coat effect, and improve optimization of cardiovascular assessment, evaluation, and therapeutic assessment in clinical practice.

Hypertension affects over 80 million adults in the United States (US) and is a major risk factor for cardiovascular morbidity and mortality [1]. The condition's ubiquitous nature and broad impact potentially makes understanding the diagnosis and treatment of hypertension key elements of managing cardiovascular risk. Though much attention is paid to the treatment of hypertension, from 2009 to 2012, 45.9% of US patients with hypertension were uncontrolled [1]. Appreciating the aspects of proper assessment of blood pressure is crucial and creates the foundation for approaching hypertension management. Until recently, hypertension was defined as an appropriately measured office systolic blood pressure (SBP) of greater than or equal to 140 mmHg and/or diastolic blood pressure (DBP) greater than or equal to 90 mmHg, with the patient seated and resting for 5 minutes in a proper position, and preferentially, measured as an average of two readings taken 1 or 2 minutes apart [1-5]. While serving as the primary method, standard office blood pressure assessment with either manual or traditional automated BP cuffs is limited in accuracy and application in everyday practice, and faces many challenges. As such, an understanding of the potential limitations of current BP strategies, and the roles and rationale for novel assessment techniques are of value to clinicians [6].

Keywords: automated, ambulatory, blood pressure, monitoring, devices, manual, measurements, office, pharmacy

Office Blood Pressure Measurements

Inaccuracy and variability in single office-measured BPs can contribute to misclassification and/or potential misdiagnosis of hypertension [7]. The features contributing to inconsistencies in office measurements can be driven by several factors, such as variation from proper BP measurement technique (outlined in Table 1), measurement of a single BP reading, and digit preference (rounding BP reading to 0 or 5 mmHg), all of which may cause deviations in BP readings and reduce accuracy [8]. As an example of the potentially significant impact of the timing of BP measurement, an evaluation showed that rechecking BP in the clinic a second time exhibited an average reduction of 11/5.2 mmHg in BP compared to the initial assessment [9].

This follow-up BP assessment consequentially lead to a reclassification of BP status (SBP greater than 140 mmHg or DBP greater than 90 mmHg, reclassified as SBP less than 140 mmHg or DBP less than 90 mmHg) in 49% of patients. Note, both readings were obtained during the same office appointment, and the average time between the first and second measurements was not specified.

Observer differences may exist and impact BP assessment. A systematic review and meta-analysis of 15 studies found that physicians record BPs, on average, 7/3.8 mmHg higher than nurses [10]. The presence of observer variability can create what is known as the "white coat effect" or "white coat hypertension," both of which have been defined in previous literature [7, 11, 12]. This white coat response affects nearly 25% of patients with hypertension and may lead to misclassification of BP status, inappropriate initiation, and/or intensification of anti-hypertensive treatment, adverse drug events, and increases in healthcare costs.

Corresponding author: Emiliya Khazan, PharmD, BCPS
Clinical Pharmacy Specialist – Cardiology
Orlando Veteran Affairs Medical Center
13800 Veterans Way, Orlando, FL 32827
Email: Emiliya.Khazan2@va.gov

Alternative Methods of Blood Pressure Assessment

Because of the limitations of traditional office blood pressure assessment, interest has grown in the use of alternative strategies to measure BP, most notably focusing on home blood pressure monitoring (HBPM) and 24-hour ambulatory blood pressure monitoring (ABPM). HBPM, with an automated oscillometric device, is recommended for use by several hypertension guidelines, as it provides a relatively inexpensive and convenient method for monitoring BP over long periods of time [13-16]. While HBPM increases the number of evaluable BPs and is minimally intrusive for the patient, it can require a significant amount of time to accrue these values. Also, its accuracy is predicated on the patient's ability to use proper BP technique and values may be subject to reporting bias (e.g. reporting lower BP readings especially in patients with a negative medication experience) [16]. HBPM only provides an assessment of awake BPs, which may limit understanding of the patient's entire BP phenotype.

As a method to fully understand awake and asleep BP values and mitigate the effects of the "white coat" phenomena, ABPM has been considered the gold standard for diagnosing hypertension and providing a clinically meaningful assessment of BP and impact on cardiovascular risk. ABPM has also been endorsed by many major practice organizations [13, 14, 16-19]. The 2011 United Kingdom guidelines on adult hypertension diagnosis and management recommend that ABPM be offered for patients with office BP greater than 140/90 mmHg [20]. Unfortunately, ABPM monitoring can be burdensome for patients and availability is limited across health care systems [16]. A final strategy, automated office blood pressure (AOBP) monitoring, provides an alternative option worthy of consideration by clinicians as it can mitigate or reduce the impact from the white coat effect and is strongly associated with predicting BP related end-organ damage [21, 22].

Automated Office Blood Pressure Monitoring

AOBP is a unique fully automated device which uses an electronic sphygmomanometer to record multiple BP readings in 1-2 minute intervals over 5-10 minutes, and averages the values while the patient rests alone in a quiet area, without observation by healthcare staff [23]. There are currently three AOBP devices (BpTRU, Omron HEM-907, and Microlife WatchBP Office) which have been independently validated for use, with slightly differing characteristics (Table 3). This monitoring strategy was initially employed only in hypertension research, but has now been fully validated for use in a variety of settings.

Importantly, AOBP monitoring does not appear to be affected by location [22, 23] and has been studied in a variety of different practice settings, ranging from community-based pharmacies [24], primary care practice exam rooms [25], 24-hour ABPM units [8], and waiting rooms [26]. The ability to obtain valid AOBP readings in waiting rooms exemplifies that

additional space or a private room is unnecessary to realize benefits from this device.

More than 10,000 AOBP monitors are currently in use, of which, approximately 25% are located in primary care physician practices in Canada [24]. The accuracy of AOBP utility in a real-world setting was demonstrated in The Conventional versus Automated Measurement of Blood Pressure in the Office (CAMBO) trial, which compared manual office blood pressure (MOBP) and AOBP versus awake ABPM in primary care practice settings. Pre-enrollment mean BP of 150/81 mmHg was reduced to 136/78 mmHg with AOBP and 141/80 mmHg with MOBP compared to the awake ABPM reading of 133/74 mmHg [27]. In comparison with MOBP in this evaluation and others, a significantly stronger BP correlation exists between mean AOBP and awake ABPM measurements [8, 25, 27].

The aforementioned correlation between AOBP and awake ABPM measurements extends to predicting end-organ damage, which may occur from sustained uncontrolled hypertension [28, 29]. Left ventricular mass index (LVMI) is an example of a surrogate for predicting intermediate-organ damage in hypertensive patients. When the correlations between LVMI and AOBP, MOBP, and awake ABPM devices were examined, AOBP readings were more closely associated with LVMI ($r=0.37$) than MOBP ($r=0.12$). The mean AOBP was similar to the mean awake systolic ABPM correlation to LVMI ($[r=0.34; P=0.001]$ and $[r=0.37; P<0.001]$, respectively) [28]. AOBP, unlike MOBP, also had a significant correlation with carotid artery wall thickness, another predictor of end-organ damage [29].

The definition of hypertension with AOBP (greater than or equal to SBP of 135 mmHg and/or greater than or equal to DBP of 85 mmHg) is quite similar to the defined blood pressure thresholds set for HBPM and mean awake ABPM [13]. AOBP (BpTRU device) was used to assess BP thresholds in determining cardiovascular risk (non-fatal and fatal events) in 3,627 community-dwelling individuals aged greater than or equal to 65 years for 4.9 years as part of The Cardiovascular Health Awareness Program (CHAP) trial [30]. Cardiovascular risk was significantly elevated at SBP 135-144 mmHg (HR, 1.66; 95% CI, 1.09-2.54 ($P=0.02$)) and DBP 80-89 mmHg (HR, 1.72; 95% CI, 1.21-2.45 ($P=0.003$)). The results confirmed that SBP of less than 135 mmHg and DBP of less than 85 mmHg is a reasonable hypertension target to achieve with this device to potentially reduce the risk of cardiovascular events.

Similarly to ABPM, AOBP nearly eliminates white coat response in patients [12]. A study examined routine MOBP versus AOBP (BpTRU device) in relation to mean awake ABPM in family physician offices; this study demonstrated a higher correlation between SBP/DBP mean awake ABPM and AOBP ($r=0.62/0.72; P<0.001$) compared to MOBP ($r=0.32/0.48$), both of which were measured by family physicians, with regards to white coat

response [8]. The outcomes were positive in both treated and untreated patients [8]. Given this information, AOBP has the potential to be an alternative to 24-hour ABPM for diagnosing white coat response and/or mitigating white coat effect during screening. However, AOBP does not provide data on nocturnal values, and thus poses a limitation for patients that may have nocturnal hypertension.

Implementation in Clinical Practice and Potential Limitations

AOBP monitoring has been recognized as an option for monitoring blood pressure in the Canadian Hypertension Education Program Guidelines [22]. Utilizing standardized and validated electronic oscillometric devices is recommended over auscultation (Grade C), but the preferred method of performing in-office BP measurements is by AOBP (Grade D). Additionally, the 2013 European Society of Hypertension and European Society of Cardiology states AOBP is a potential method to improve BP reproducibility and reconcile variations between office and out-of-office methods, such as awake ABPM and HBPM monitoring [13]. The U.S. Preventive Services Task Force also states that AOBP can produce similar results as awake ABPM, but does not make specific recommendations on in-office BP methods [17]. See Table 2 for in-office methods preferred by various guidelines.

In order to successfully integrate AOBP into practice, the device must be fully automated and configured to record multiple readings. Even when AOBP was replaced with an *automated* HBPM and activated by the patient, unattended in the clinic setting, mean BP values were 5 mmHg higher than that of AOBP measurements [31]. However, white coat response still occurs with the initial AOBP reading; yet, BP appears to drop by 15 mmHg within 2 minutes of the observer leaving the patient alone [32]. Thus, in addition to the full automation of AOBP, the patient must not be directly observed by healthcare staff.

While there is a valuable role for AOBP in clinical practice, certain limitations exist as well. A critical shortcoming of AOBP is the inability to provide nocturnal blood pressure readings, which is the most significant predictor of cardiovascular morbidity and mortality [33]. Thus, 24-hour ABPM continues to be the best device available to evaluate BP control, especially where nocturnal hypertension may be suspected. Additionally, as with most oscillometric automatic blood pressure devices, AOBP may be less accurate in the presence of arrhythmias such as atrial fibrillation [24].

AOBP has been incorporated in research for several years perhaps most notably in the Systolic Blood Pressure Intervention Trial (SPRINT) study, although the technique was not formally validated [34]. In this study of patients with or at risk for cardiovascular disease but without diabetes or cerebrovascular disease, pharmacologic lowering of SBP to less than 120 mmHg versus a traditional target of less than 140 mmHg on AOBP measures led to a significant reduction in risk

of a composite endpoint of cardiovascular events and death as well as overall mortality. Adoption of AOBP technology in clinical practice may facilitate the translation of the SPRINT findings to routine hypertension management.

Pharmacists and Blood Pressure Technology

Expansion of AOBP technology into community pharmacies, which are generally easily accessible to patients, may offer several advantages. As previously mentioned, the CHAP trial demonstrates a successful example of incorporation of AOBP screenings (along with other interventions) in community-based pharmacies leading to improved blood pressure related risk assessment amongst older adults in Ontario, Canada [30]. AOBP devices are fairly small and easy to use; thus, increased availability in community pharmacies may provide an opportunity for patients with suspected white coat syndrome to validate their blood pressure status and potentially prevent initiation or addition of anti-hypertensive therapy and, conversely, those with values above the cut offs defined in the CHAP trial may benefit from interventions targeted at lowering blood pressure.

Pharmacists' involvement in the screening and management of hypertension has been demonstrated to improve clinical and economic outcomes in multiple ambulatory settings [35-38]. Pharmacists are often involved in directly measuring patients' blood pressures using standard, calibrated devices prior to making pharmacotherapeutic recommendations or interventions [39]. As cardiovascular team-based care continues to expand and integrate clinical pharmacy services [40, 41], pharmacists could directly encounter increasingly changing dynamics in blood pressure monitoring, including the possible utilization of AOBP technology in routine medical care. Innovations in blood pressure monitoring techniques and integration of new strategies and technology are pivotal aspects of hypertension assessment in an evolving clinical practice.

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Table 1: Technique for manual office blood pressure measurement [6]

Important Instructions for Proper Manual Clinical Blood Pressure Measurement
<ul style="list-style-type: none"> • Patient is comfortably seated, legs uncrossed, with back supported, for at least 5 minutes • Upper arm is free of constrictive clothing and supported at heart level • Blood pressure cuff is appropriately sized with at least 80% of the bladder encircling the arm circumference • Cuff should be deflated at 2 to 3 mm/s (first and last audible sounds taken as systolic and diastolic pressure read to the nearest 2 mmHg) • Neither the patient nor the observer should be in conversation during the blood pressure measuring procedure • At least 2 measurements should be made

Table 2: Preferred In-office BP Methods per selected guidelines

Guideline	Preferred In-office BP Method
The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure [42]	Auscultation method
Clinical Practice Guidelines for the Management of Hypertension in the Community: A Statement by the American Society of Hypertension and the International Society of Hypertension [2]	Automated electronic device
2013 European Society of Hypertension and the European Society of Cardiology Guidelines for the management of arterial hypertension [13]	Auscultation or oscillometric semiautomatic sphygmomanometers Consider automated recording of multiple BP readings
National Institute for Health and Care Excellence: Hypertension in adults: diagnosis and management [43]	Automated device or manual auscultation (if pulse irregularity is present, then use direct auscultation)
Hypertension Canada’s 2016 Canadian Hypertension Education Program Guidelines for the Blood Pressure Measurement, Diagnosis, Assessment of Risk, Prevention, and Treatment of Hypertension [22]	Automated Office Blood Pressure measurements (Grade D)
Screening for High Blood Pressure in Adults: U.S. Preventive Services Task Force Recommendation Statement [17]	No particular office blood pressure measurement protocol recommended Manual (auscultation) or automated office BP may be used

Table 3: Validated Automatic Blood Pressure Devices

Device (adult)	BpTRU [44]	Omron 907 [45]	Microlife WatchBP Office [46]
Mode	Automated oscillometric	Automated oscillometric	Automated oscillometric
Instruction	Up to six consecutive BP readings are taken. The first reading is discarded and the next five are averaged. The average is displayed as the final result.	Two to three consecutive BP readings are taken. The readings are averaged and displayed as the final result.	Three inter-arm BP measurements are taken and averaged for the initial screening. Three single arm measurements are taken and averaged for follow-up screenings.
Cost	~ \$960	~ \$600	~ \$650
			