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Twenty-Four-Hour Ambulatory Blood Pressure Monitoring

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Abstract

The diagnosis, management, and estimated mortality risk in patients with hypertension have been historically based on clinic or office blood pressure readings. Current evidence indicates that 24-hour ambulatory blood pressure monitoring should be an integral part of hypertension care. The 24-hour ambulatory monitors currently available on the market are small devices connected to the arm cuff with tubing that measure blood pressure every 15 to 30 minutes. After 24 hours, the patient returns, and the data are downloaded, including any information requested by the physician in a diary. The most useful information includes the 24-hour average blood pressure, the average daytime blood pressure, the average nighttime blood pressure, and the calculated percentage drop in blood pressure at night. The most widely used criteria for 24-hour measurements are from the American Heart Association 2017 guidelines and the European Society of Hypertension 2018 guidelines. Two important scenarios described in this document are white coat hypertension, in which patients have normal blood pressures at home but high blood pressures during office visits, and masked hypertension, in which patients are normotensive in the clinic but have high blood pressures outside of the office. The Centers for Medicare and Medicaid Services has made changes in its policy to allow reimbursement for a broader use of 24-hour ambulatory blood pressure monitoring within some specific guidelines. Primary care physicians should make more use of ambulatory blood pressure monitoring, especially in patients with difficult to manage hypertension.

Keywords

hypertension, blood pressure measurement, ambulatory blood pressure monitoring, nocturnal dipping, masked hypertension, white coat hypertension, blood pressure monitor

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Introduction

Changes in blood pressure (BP) occur frequently during aging and during normal physiologic responses to stress and exercise. An increase in BP becomes a clinical disorder when this change causes a threat to biologic functions and, during this time, is defined as a pathologic elevation in BP or systemic hypertension.[1] The World Health Organization has now listed hypertension as a health priority and the most important modifiable risk factor for death with specific global targets for mortality prevention by 2025. It accounts for more than 9.3 million deaths per year, surpassing tobacco with around 8 million deaths per year.[2-4]

Identifying and diagnosing high blood pressure in patients has become a standard quality measure, and blood pressure is one the most important vital signs to monitor during health care management. Consequently, clinicians must identify appropriate target measurements for blood pressure control based on state-of-the-art equipment, and this has now brought more attention to the precision of the blood pressure readings.

For over a hundred years, health care providers have used Korotkoff's technique for measuring blood pressure. However, a better understanding of cardiovascular physiology over the past 40 years has led to improved technology used for noninvasive blood pressure measurements to decrease human errors associated with measuring blood pressure.[5] With better understanding of the dynamic changes in blood pressure, health care providers now emphasize appropriate blood pressure techniques and have established medical diagnoses such as "white coat and

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Table 1. Recommendations for Out-of-Office Blood Pressure Monitoring.[a]

Class of recommendation	Level of evidence	Recommendation
I (strong)	C (expert opinion)	Proper methods are recommended for diagnosis and management of high blood pressure.
I (strong)	A (high quality)	Ambulatory blood pressure measurements are recommended to confirm the diagnosis of hypertension and for titration of blood pressure medications.

[a]Adapted from the 2017 American College of Cardiology guidelines for the prevention, detection, evaluation, and management of high blood pressure in adults.[7]

masked hypertension," which reflect blood pressure measurements that do not represent the true patient status.[6]

Recent hypertension guidelines from the American College of Cardiology maintain that accurate blood pressure measurement is an important standard of care needed for evaluation, confirmation of diagnosis, and titration of blood pressure medications. For appropriate out-of-office blood pressure measurement techniques, ambulatory blood pressure monitoring (ABPM) is regarded as the best method currently available[7] (Table 1).

Epidemiology of Hypertension

Primary Hypertension

Based on a cutoff of 140/90 mm Hg, 70% or more of American adults in their 60s and 70s have been diagnosed with hypertension.[8] In addition, the Framingham Heart Study demonstrates that men and women aged 55 years and older with normal BP will have a 90% lifetime risk of developing hypertension; therefore, the reality is that all individuals are at risk to develop hypertension at some point in their lives.[9]

Hypertension is a major contributor to vascular injury and atherosclerotic disease and is the main risk factor for cardiovascular events, including strokes. Worldwide, hypertension remains the single largest preventable risk factor for death, resulting in more than 9.4 million deaths/year (13% global total deaths) primarily in low- and middle-income individuals. Observational data have shown that mortality risk doubles with increases in systolic BP from 120 to 140 mm Hg and from 140 to 160 mm Hg in all age groups. These data have led to determination of blood pressure targets that will provide a reduction in mortality risk. With the increasing availability of information, awareness of high BP, its diagnosis, and management in the US population has reached 82% according to the National Health and Nutrition Examination Survey (NHANES 2008-2012).[8]

Secondary Hypertension

Epidemiological data from large cohorts have identified secondary hypertension in approximately 10% among all hypertensive patients.[3] Chronic kidney disease remains the major cause of the secondary form of hypertension (prevalence ~4%), followed by aldosterone-mediated hypertension (prevalence ~4%), renal artery disease (prevalence ~1%), and hyper- or hypothyroidism (prevalence ~1%).[10] Endocrine causes of abnormal BP have been identified in over 10 different endocrine disorders, providing targeted management and even curable treatment for hypertension in many patients.[11]

Ambulatory Blood Pressure System

Accurate out-of-office blood pressure monitoring is essential for blood pressure evaluation and medical management. ABPM has been available for clinical use for more than 20 years with more than 60 years of available data since it was first described.[12] It is currently accepted as the best ambulatory method to collect blood pressure readings, and its use has exponentially increased as part of the standard of care for hypertensive patients[7] (Figure 1).

The market for medical devices has increased partially from the surge in demand for personalized medicine and from the need to satisfy the consumer, specifically the public, not health providers. For this reason, many devices are currently available for out-of-office blood pressure monitoring. However, the accuracy at the time of blood pressure recording has become an issue. Therefore, the Food and Drug Administration (FDA) requires that medical devices that measure blood pressure pass at least the ISO 81060-2:2013 protocol for clinical validation, and this is based on the European Society of Hypertension International Protocol (ESH-IP) to ensure a blood pressure reading is within 5 mm Hg from a mercury device. Other common validation protocols include the Association for the Advancement of Medical Instrumentation (AAMI) and the British Hypertension Society (BHS) protocols.[13]

Currently, there are several different automated blood pressure monitors that are available for out-of-office blood pressure measurements. There are more studies validating ABPM devices than for any other technique (Table 2). Most of the available devices use the oscillometric technique, capable of recording 24 hours (or more) of blood pressure readings during normal daily activities and can be programmed to document readings every 10 to 30 minutes throughout the day and night. The current monitors available in the market are lightweight (weighing less than 1 kg

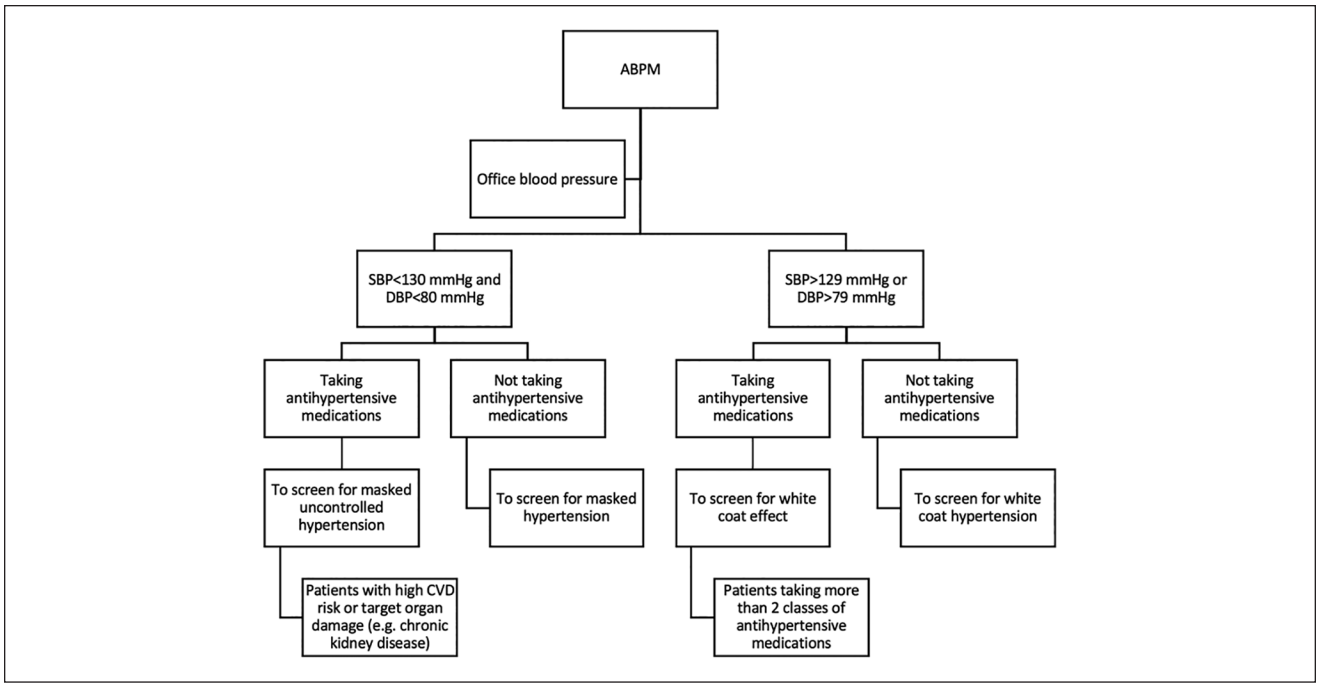

Figure 1. Recommendations for use by the 2017 American College of Cardiology guidelines for the prevention, detection, evaluation, and management of high blood pressure in adults.[7] ABPM, ambulatory blood pressure monitoring; SBP, systolic blood pressure; DBP, diastolic blood pressure. mm Hg, millimeters of mercury; CVD, cardiovascular disease.

or less than 2 pounds), measure approximately 7 × 2.5 × 9 cm (2.7 × 0.9 × 3.5 inches), have multiple cuff sizes available, and can be used in the right or left upper extremity (Figure 2). Finger devices using either compression of a digital artery or waveform analysis are available for outpatient monitoring of blood pressure, but these devices have poorly validated studies supporting their accuracy and are currently not widely recommended.

Ambulatory blood pressure monitoring can be used in many different clinical situations and provides a more accurate physiological description of systemic blood pressure throughout an entire 24-hour time period for patients either on or off antihypertensive drugs. Ambulatory blood pressure monitoring is recommended for the screening and evaluation of masked hypertension (for patients both on and off antihypertensive medications), white coat hypertension, suspected episodic hypertension (eg, pheochromocytoma), and hypotensive episodes while on medications; for the assessment of nocturnal decreases in BP; and for the follow-up of hypertensive therapies, including those in pregnant women with elevated office BP as well as individuals with orthostatic hypotension and supine hypertension.[7,24,25]

In clinical practice and for the primary care provider, since 2015, the United States Preventive Services Task Force has prompted individualizing blood pressure screening and management. This task force made major recommendations in regard to screening adults over the age of 18 years and using ABPM as a tool to confirm a suspicion or an initial diagnosis of hypertension in the clinic, which is consistent with the recommendations of the 2019 British guidelines for hypertension provided by the National Institute for Health and Care Excellence.[26,27]

The information obtained with ABPM is variable and can be adjusted based on medical necessity. The most compelling clinical data that can be documented with ABPM include daytime (awake) and nighttime (asleep) readings, 24-hour average BP, and nocturnal versus diurnal change in BP. When this information is combined with the office findings, the clinician will have 4 different patient scenarios; 2 of them will have similar findings with either normal or elevated blood pressure in the office and in the ambulatory setting. The other two are characterized by blood pressure readings that are different between the office and the ABPM, in which case the physician will be dealing with a "white coat effect" or "masked hypertension."

Ambulatory Blood Pressure Metrics

Systemic blood pressure selectively regulates blood flow and perfusion to each organ system based on metabolic demand, activity, time of day, and stress. Correspondingly, it is constantly changing depending on the physiologic status of the patient. Ambulatory blood pressure monitoring ABPM provides a more physiological measurement of the "real" BP and its changes throughout the day. The correlation coefficients between office BP readings and 24-hour

Table 2. Ten Most Recent Validation Studies for Ambulatory Blood Pressure Monitoring Devices.

No.	Year	Name	Technique
1	2019	Validation of the TM-2441 ambulatory blood pressure measurement device according to the ISO 81060-2: 2013 standard[14]	Oscillometric
2	2019	Validation of the Hingmed WBP-02A device for ambulatory blood pressure monitoring according to the European Society of Hypertension International Protocol Revision 2010[15]	Oscillometric
3	2017	Validation of the custo screen pediatric blood pressure monitor according to the European Society of Hypertension International Protocol revision 2010[16]	Oscillometric
4	2017	Validation of the TONOPORT VI ambulatory blood pressure monitor in adults according to the European Society of Hypertension International Protocol revision 2010[17]	Oscillometric
5	2015	Validation of the Somnotouch-NIBP noninvasive continuous blood pressure monitor according to the European Society of Hypertension International Protocol revision 2010[18]	Wrist pulse transit time
6	2014	Validation of the custo screen 400 ambulatory blood pressure-monitoring device according to the European Society of Hypertension International Protocol revision 2010[19]	Oscillometric
7	2010	Validation of the Tiba Medical Ambulo 2400 ambulatory blood pressure monitor to the ISO Standard and BHS protocol[20]	Oscillometric
8	2010	Validation of the mobil-O-Graph: 24 h-blood pressure measurement device[21]	Oscillometric
9	2010	Validation of the Microlife WatchBP O3 device for clinic, home, and ambulatory blood pressure measurement, according to the International Protocol[22]	Oscillometric
10	2007	Evaluation of the SCHILLER BR-102 plus noninvasive ambulatory blood pressure monitor according to the International Protocol introduced by the Working Group on Blood Pressure Monitoring of the European Society of Hypertension[23]	Auscultatory and oscillometric

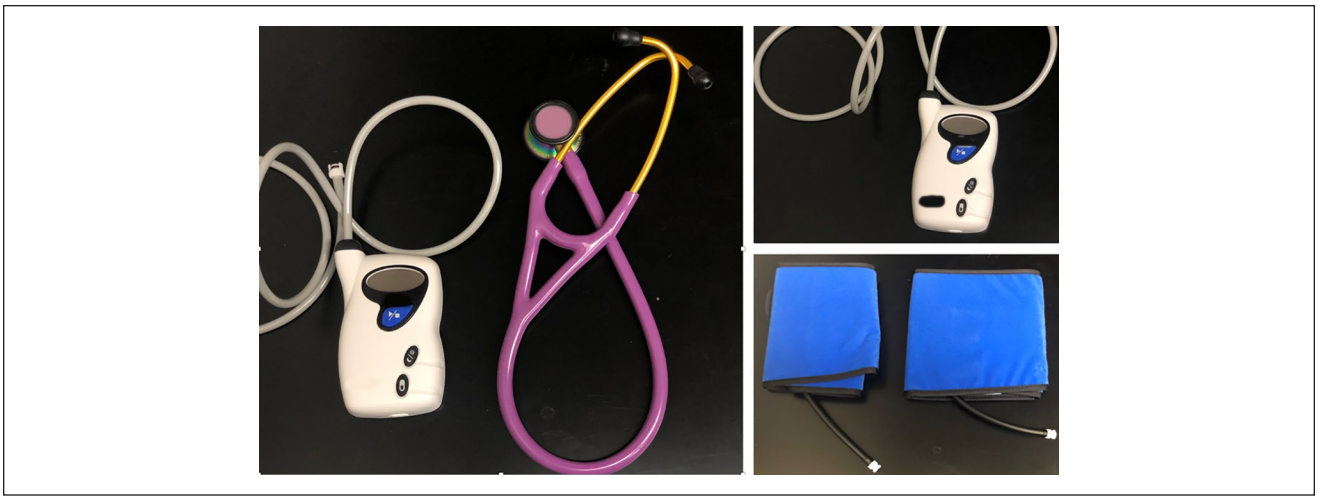

Figure 2. Ambulatory blood pressure monitor. Left picture: Typical monitor size compared with an average stethoscope. Right upper picture: Standard ambulatory blood pressure monitor. Right lower picture: Multiple cuff sizes available.

ABPM are 0.5 to 0.7 and 0.6 to 0.8 for systolic and diastolic blood pressure, respectively.[6,28,29]

The most commonly utilized data for clinical purposes is 24-hour average BP, daytime BP, nighttime BP, and nocturnal dipping patterns. The thresholds for normality depend on the measurement used and on the current definition of normal blood pressure. In most instances, a 24-hour mean BP of 125/75 mm Hg or less, a daytime BP of 130/80 mm Hg or less, or a nighttime BP of 110/65 mm Hg or less with a nocturnal dipping of 10% to 20% are considered normal values for ABPM (Table 3).[7]

Circadian Blood Pressure Rhythm

Blood pressure homeostasis involves dynamic changes in the cardiovascular system based on physiological need, which also involves neurohormonal changes occurring from internal day-night clocks.[31,32] Normal subjects have

Table 3. Twenty-Four-Hour Ambulatory Blood Pressure Monitoring (ABPM) Threshold Differences Between the North American and European Guidelines for diagnosis of hypertension.

	24-hour ABPM
2017 American College of Cardiology Guidelines[7]	≥125/75 mm Hg
2018 European Society of Cardiology Guidelines[30]	≥130/80 mm Hg

higher diurnal blood pressure, with a nocturnal decrease in both systolic and diastolic BP while sleeping (dipping) of 10% to 20% and a rapid increase in blood pressure in the morning related to waking up. Activity continues to be one of the main regulators of circadian blood pressure changes during the day, followed by sodium sensitivity and autonomic nervous system activity. Any disruption in circadian activity may predispose individuals to disequilibrium of the cardiovascular system, and these are the factors associated with abnormal daytime ABPM, nighttime ABPM, and nocturnal dipping in BP (Figure 3).[33]

Furthermore, the strongest correlation between cardiovascular risk and hypertension is related to the 24-hour BP average and nighttime BP. In fact, when tested against office BP measurements, epidemiological data consistently show ABPM to be a better tool to predict clinical outcomes, especially strokes.[7,34,35] In addition, the unique ability to evaluate BP at night while sleeping makes ABPM a superior instrument for BP management that adds prognostic information, since the absence of a physiological decrease in BP (nondipping) or an increase in BP while sleeping is associated with increased cardiovascular risk.[36,37]

Masked Hypertension

Masked hypertension occurs when a patient has out-of-office hypertension that is not apparent in clinic BP readings (ie, normal in-office blood pressure reading) but is evident with ABPM. The prevalence of masked hypertension is approximately 10% to 25% in normotensive patients and is associated with increased cardiovascular risk. Masked hypertension occurs more frequently in elderly men, smokers, patients with high alcohol intake, and patients with diabetes mellitus with or without chronic kidney disease. Poor medication adherence should be suspected in patients with masked hypertension, although there has not been a strong clinical correlation to suggest poor compliance as a major culprit.[38] It is recommended that these patients be treated with antihypertensive drugs to achieve normotension and decrease the risk for major cardiovascular events in the future.[7,39,40]

Nocturnal blood pressure abnormalities, such as failure to decrease blood pressure during sleep (nondipping) or nocturnal high blood pressure, provide important information in studies on the association of 24-hour mean blood pressure with cardiovascular morbidity. Furthermore, patients with isolated nocturnal hypertension appear to have an increased risk of cardiovascular morbidity than to normotensive patients, although more studies are probably needed to evaluate risk and associations.[37,41] In addition, the possibility of sleep apnea should be considered in these patients.

Masked hypertension remains a novel concept in the context of hypertension, with a clear cardiovascular risk association, and promising literature regarding underlying mechanisms, pathophysiology, and risk factors based on ongoing investigations should be available in the near future.

White Coat Hypertension

A diagnosis of white coat hypertension is based on an office blood pressure of 130/80 mmHg or higher in individuals with normal ABPM measurements. The prevalence of office hypertension has been estimated to be approximately 10% to 30% of patients. This condition has been described more frequently in women, and at this time, there is no evidence to suggest that it is associated with a higher cardiovascular risk than normal blood pressures. However, white coat hypertension does seem to be a risk factor for the development of sustained hypertension and possibly stroke. Although there is no evidence to support pharmacological treatment, a therapeutic focus on lifestyle modification is recommended. In addition, it is strongly recommended that these patients are followed periodically in the clinic with annual ABPM or home BP monitoring.[7,39,42]

White coat hypertension remains an evolving field, with unclear long-term outcomes, and more investigation is required. Current data are based on literature from essential hypertension studies, but ongoing studies should provide clearer guidelines for evaluation and management in clinical practice.

Limitations of ABPM

There is no doubt that the amount of clinical and epidemiological data available regarding ABPM continue to increase, but the actual scientific data comparing treatment outcomes between office BP readings and ABPM are not robust. The APTH (Ambulatory Blood Pressure and Treatment of Hypertension) trial in 1997, the THOP (Treatment of Hypertension Based on Home or Office Blood Pressure) trial in 2004, and the HOMERUS (Home versus Office MEasurements, Reduction of Unnecessary treatment Study) trial in 2007 failed to show any significant difference in surrogate endpoint outcomes, such as left ventricular mass changes, with a slight trend toward lower medication costs balanced by the higher costs of the ambulatory and home blood pressure equipment.[43-45]

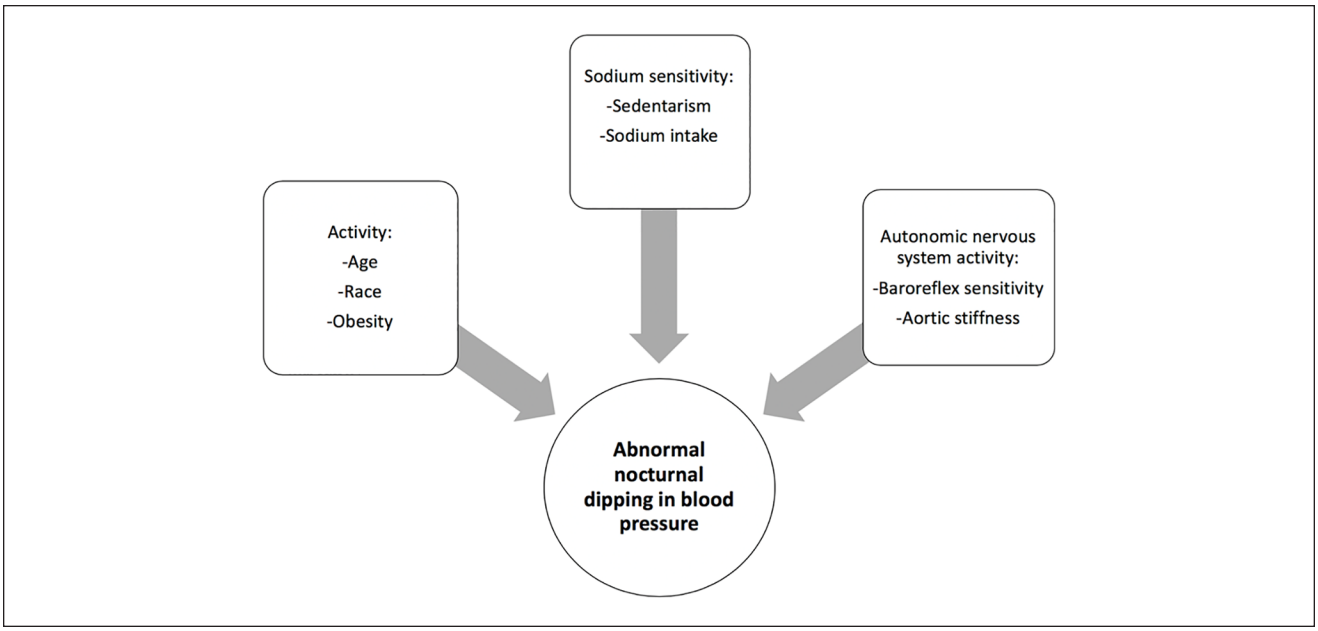

Figure 3. Major factors involved in abnormal circadian blood pressure variability.
Adapted from Agarwal.[33]

Moreover, the idea of developing an ideal trial for absolute evidence becomes a difficult task, as noted by the Agency for Healthcare Research and Quality (AHRQ), which has estimated that a sample size of 26 000 to 57 000 patients would be needed to achieve a 10% relative risk reduction in a 10-year trial comparing office versus ambulatory blood pressure monitoring.[46] Such a trial is unlikely to happen anytime soon.

Availability and Reimbursement

The Centers for Medicare and Medicaid Services (CMS) pays for ABPM under limited circumstances. Initially, in 2001, it would pay only for patients with suspected white coat hypertension, but after the revision of the policy in 2019, CMS expanded coverage for patients with suspected masked or white coat hypertension.

The prevalence of the use of ABPM as a clinical tool continues to be low, and the average reimbursement for the installation, review, interpretation, and report has been approximately US$50 to 60.[47] However, major global changes have occurred in the last year, and the availability of and preference for telemedicine-based care has made telemedicine an important platform for patient management. Therefore, the need for remote blood pressure assessment has made ABPM a more useful tool in clinical practice.

Conclusions

Hypertension is a pandemic disease with devastating consequences, and it is indisputably the most important preventable risk factor for death. Identifying patients with abnormal blood pressure and accurately diagnosing hypertension is extremely important for both health care providers and patients. Consequently, relying on precise BP readings is important; ambulatory BP monitoring is currently regarded as the gold standard technique for clinical decision making and is a better predictor of outcomes than office and home BP monitoring.

Physicians still depend primarily on office BP readings for medical decision making, and the availability of ABPM devices remains limited. The lack of standardization in techniques is due, in part, to the detachment of health care providers from the time-consuming task of checking vital signs, inadequate education concerning hypertension, a reluctance to change practice styles, and the restrictions related to the economic aspect of medicine. However, the clear evidence supporting ABPM and cardiovascular risk prognosis support a more personalized implementation of ABPM for the evaluation of borderline office readings, for initial hypertension diagnoses, and as standard of care for masked and white coat hypertension. Furthermore, an ABPM system should be available in every health care facility. With the global initiatives for hypertension evaluation and management and the ongoing changes in the CMS polices, the use ABPM systems will likely be in clinical practice guideline as the first choice for blood pressure care in the future.

Information about masked and white coat hypertension continues to improve with ongoing research, but treatment and sequelae from these diagnoses are still unclear and based primarily on observational evidence. Nocturnal blood pressure dynamics have been shown to be an interesting field of study with new clinical information, and the ability

to evaluate blood pressure at night with ABPM is extremely advantageous as it provides additive prognostic value to the average 24-hour readings. However, more clinical and experimental research is needed to better correlate nocturnal blood pressure with pathology and cardiovascular outcomes. Similarly, the use of 24-hour ABPM to tailor pharmacotherapy into a personalized schedule based on circadian variations in blood pressure could direct the prescription of antihypertensive medication in the future, but at this time, more investigation in this area is needed.

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