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Does This Adult Patient Have Hypertension? The Rational Clinical Examination Systematic Review

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IMPORTANCE Office blood pressure (BP) measurements are not the most accurate method to diagnose hypertension. Home BP monitoring (HBPM) and 24-hour ambulatory BP monitoring (ABPM) are out-of-office alternatives, and ABPM is considered the reference standard for BP assessment.

OBJECTIVE To systematically review the accuracy of oscillometric office and home BP measurement methods for correctly classifying adults as having hypertension, defined using ABPM.

DATA SOURCES PubMed, Cochrane Library, Embase, ClinicalTrials.gov, and DARE databases and the American Heart Association website (from inception to April 2021) were searched, along with reference lists from retrieved articles.

DATA EXTRACTION AND SYNTHESIS Two authors independently abstracted raw data and assessed methodological quality. A third author resolved disputes as needed.

MAIN OUTCOMES AND MEASURES Random effects summary sensitivity, specificity, and likelihood ratios (LRs) were calculated for BP measurement methods for the diagnosis of hypertension. ABPM (24-hour mean BP ≥130/80 mm Hg or mean BP while awake ≥135/85 mm Hg) was considered the reference standard.

RESULTS A total of 12 cross-sectional studies (n = 6877) that compared conventional oscillometric office BP measurements to mean BP during 24-hour ABPM and 6 studies (n = 2049) that compared mean BP on HBPM to mean BP during 24-hour ABPM were included (range, 117-2209 participants per analysis); 2 of these studies (n = 3040) used consecutive samples. The overall prevalence of hypertension identified by 24-hour ABPM was 49% (95% CI, 39%-60%) in the pooled studies that evaluated office measures and 54% (95% CI, 39%-69%) in studies that evaluated HBPM. All included studies assessed sensitivity and specificity at the office BP threshold of 140/90 mm Hg and the home BP threshold of 135/85 mm Hg. Conventional office oscillometric measurement (1-5 measurements in a single visit with BP ≥140/90 mm Hg) had a sensitivity of 51% (95% CI, 36%-67%), specificity of 88% (95% CI, 80%-96%), positive LR of 4.2 (95% CI, 2.5-6.0), and negative LR of 0.56 (95% CI, 0.42-0.69). Mean BP with HBPM (with BP \geq 135/85 mm Hg) had a sensitivity of 75% (95% CI, 65%-86%), specificity of 76% (95% CI, 65%-86%), positive LR of 3.1 (95% CI, 2.2-4.0), and negative LR of 0.33 (95% CI, 0.20-0.47). Two studies (1 with a consecutive sample) that compared unattended automated mean office BP (with BP ≥135/85 mm Hg) with 24-hour ABPM had sensitivity ranging from 48% to 51% and specificity ranging from 80% to 91%. One study that compared attended automated mean office BP (with BP ≥140/90 mm Hg) with 24-hour ABPM had a sensitivity of 87.6% (95% CI, 83%-92%) and specificity of 24.1% (95% CI, 16%-32%).

CONCLUSIONS AND RELEVANCE Office measurements of BP may not be accurate enough to rule in or rule out hypertension; HBPM may be helpful to confirm a diagnosis. When there is uncertainty around threshold values or when office and HBPM are not in agreement, 24-hour ABPM should be considered to establish the diagnosis.

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Supplemental content

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Clinical Scenarios

In the following cases, the clinician wants to determine whether the patient has hypertension.

Case 1

A 51-year-old healthy woman presented to her physician's office for a routine wellness visit. She felt well, exercised by walking 1 to 2 miles 3 days per week, and was taking no medications. Her body mass index was 23.6 and her office blood pressure (BP), averaging 2 measures, was 155/83 mm Hg when measured by the medical assistant using the office-based oscillometric device with an appropriately sized cuff and proper positioning. Findings of her cardiovascular examination were otherwise normal. She recorded her home BP using proper technique and cuff size at about the same time daily for 5 consecutive days after the physician visit, and mean BP was 129/77 mm Hg.

Case 2

A 34-year-old physician presented to his physician's office for a pretravel consultation. He reported not exercising regularly, drinking 1 to 2 glasses of wine per night, and taking a statin for familial hypercholesterolemia. His body mass index was 28. His office-based BP, measured by the medical assistant using the appropriately sized cuff and proper positioning, was 128/78 mm Hg. Findings of his cardiovascular examination were otherwise normal.

How certain is it that these patients do or do not have hypertension?

Background

Accurate measurement of BP is important, yet challenging. 1,2 With mercury sphygmomanometers removed from practice, offices use either aneroid manual sphygmomanometers or automatic oscillometric devices. Manual measurement is particularly prone to errors, including rapid cuff deflation, auscultatory gap, and terminal digit preference.²⁻⁴ Proper technique (including brief rest before measurement, proper positioning, and correct cuff size) is also required during oscillometric measurement, but is seldom followed.²⁻⁴ Even when BP is measured with no technical errors, isolated BP readings may not represent a person's usual BP because of many factors that influence BP variability. $^{2\text{-}5}$ An initially elevated BP in the office setting (which can be considered a positive screening measurement) calls for follow-up BP measurements to confirm or refute the presence of hypertension.

Although newer guidelines recommend out-of-office measurements of BP, preferably by 24-hour ambulatory blood pressure monitoring (ABPM), to confirm a suspected diagnosis of hypertension, 1,6 the practice of obtaining such measurements in the US is limited in part due to lack of health care centers and clinicians offering the services.⁷ Additionally, in current practice, a nonelevated office BP measurement has typically not been an indication for further testing. The combined effect of this approach is that it can lead to misclassification (Table 1), assigning an elevated BP status to a person whose BP is usually not elevated (a falsepositive) or assigning a "normal" BP status to a person whose BP is usually elevated (false-negative).

Key Points

Question How can clinicians best identify adult patients likely to have hypertension?

Findings Conventional office blood pressure (BP) measurements from a single visit or home BP monitoring performed over a few days each have limited sensitivity and specificity for diagnosing hypertension, especially when the pretest probability is low. The combination of elevated mean office BP plus elevated mean BP on home BP monitoring is most indicative of hypertension, using 24-hour ambulatory BP monitoring as the reference standard.

Meaning Out-of-office BP measurements should be obtained to complement office BP before diagnosing hypertension in adults.

Another contemporary method of BP assessment (Table 2) is automated office BP (AOBP) measurement, an in-office alternative in which the oscillometric device is programmed to take multiple readings sequentially (with or without an observer present) and the device provides a mean BP measurement.³ Currently, 24-hour ABPM is considered the reference standard because of the large evidence base demonstrating its strong association with future cardiovascular events, as noted in the 2021 US Preventive Services Task Force (USPSTF) Recommendation Statement on Screening for Hypertension in Adults, which reaffirmed the 2015 USPSTF recommendation.⁶

This review was conducted to summarize the literature on the accuracy of these current methods of BP measurement compared with ABPM as the reference standard for diagnosing hypertension in patients receiving no treatment for hypertension.

Methods

Search Strategy

PubMed/MEDLINE, Embase, Cochrane Library, Clinical Trials.gov, and DARE databases and the American Heart Association website were searched from inception to April 28, 2021, using a combination of MeSH (Medical Subject Headings) terms and keywords (eTable 1 in the Supplement). The reference lists of included articles were also searched. An experienced medical librarian (C.E.V.) with expertise in systematic reviews developed the search strategy and conducted the searches.

Article Eligibility

Articles were eligible for inclusion if they described results of an analysis designed to compare conventional office oscillometric BP measurement with 24-hour ABPM, HBMP with 24-hour ABPM, or AOBP with 24-hour ABPM. HBPM was defined as self-performed serial measurements of BP using an oscillometric device at the person's home. Additionally, eligible articles had to indicate that analyzed participants (or precise subsets) were not receiving BP-lowering medication at the time of measurement, and the study had to include participants with both elevated and nonelevated office or home BP measurements in its analysis, applying the reference standard (24-hour ABPM) to both groups. Articles had to report data (directly or calculable) on the number of individuals classified as having or not having hypertension based on the reference standard. The

Table 1. Blood Pressure (BP) Classifications Based on Concordance Between Office and Out-of-Office Measurements

	Out-of-office BP					
Office BP	Not elevated	Elevated				
Not elevated	Sustained normotension (true negative office)	Masked hypertension (false-negative office)				
Elevated	White-coat hypertension (false-positive office)	Sustained hypertension (true positive office)				

reference standard for hypertension was defined by either mean BP during 24-hour ABPM or mean BP while awake during ABPM.¹

Exclusion of Articles

On agreement by 2 authors working independently, articles were excluded for any of the following reasons: non-English language, not original research, ineligible study design (no comparison directly to 24-hour ABPM), unable to calculate sensitivity and specificity from data, use of mercury or aneroid sphygmomanometry, exposure to BP-lowering medication, or ineligible population for this review (eg, children, individuals with kidney failure, pregnant women). Studies comparing kiosk or pharmacy-type monitors or wrist cuff devices were excluded.

Data Abstraction

Data were abstracted into separate tables (by one author and verified by a second author) by category of types of BP measurement methods, noting author, year, sample size/population, BP measurement technique, and the parameters for the comparison with 24-hour ABPM. The number of individuals with and without hypertension confirmed by 24-hour ABPM was recorded along with the number who would then be considered to have true positive results (comparator technique also showed BP elevation), true negative results (comparator technique also showed no BP elevation), false-positive results (comparator technique showed BP elevation when 24-hour ABPM did not), and false-negative results (comparator technique showed no BP elevation when 24-hour ABPM showed BP elevation).

Quality Assessment

Articles meeting inclusion criteria were independently evaluated by 2 reviewers to assess methodological quality using the QUADAS-2 (Quality Assessment of Diagnostic Accuracy Studies, version 2)⁸ tool and *The Rational Clinical Examination*⁹ levels of evidence. Any differences were resolved by discussion or assessment by a third reviewer. Level 1 studies included those that provided an independent blinded comparison to 24-hour ABPM among at least 100 consecutive participants. Level 2 studies provided an independent blinded comparison to 24-hour ABPM among a smaller number of consecutive participants. Level 3 studies provided a comparison to 24-hour ABPM among a nonconsecutive sample.

Diagnostic Thresholds Between Studies

Included studies used an office threshold of at least 140 mm Hg for systolic BP and at least 90 mm Hg for diastolic BP. Studies varied in the number of measurements used for office (during a single visit) or HBPM assessment (across multiple days). Consistent with guideline based recommendations, home BP threshold was a mean systolic BP of at least 135 mm Hg or mean diastolic BP of at least

Table 2. Current Blood Pressure (BP) Assessment Techniques

Technique	Description
Office aneroid	BP is measured manually by inflating a brachial cuff and listening for Korotkoff sounds as a spring device and metal membrane translates the column of air into signals that operate a needle in the gauge; manometer is subject to easy miscalibration and manual technique is subject to observer biases
Office oscillometric	BP measurement is estimated using an algorithm that translates a pressure waveform from a brachial cuff into systolic and diastolic; relies on proper technique but mitigates observer biases
Automated office BP measurement	Provides repeated oscillometric brachial cuff measurements automatically and averages them; can be attended or unattended (no observer present); may mitigate white coat effect
Home BP monitoring (oscillometric)	Patient measures BP using an oscillometric device, typically multiple times per day over several days
Ambulatory BP monitoring (oscillometric)	Device is worn over a 24-h period and automatically (via programming) provides repeated measurements throughout the day and night (including during sleep); ideally should have a minimum of 20 awake readings and 7 nighttime (sleep) readings ³

85 mm Hg for all included studies. ¹ To define hypertension, all studies used either mean systolic BP of at least 130 mm Hg or mean diastolic BP of at least 80 mm Hg during 24-hour ABPM or mean systolic BP of at least 135 mm Hg or mean diastolic BP of at least 85 mm Hg while awake during ABPM. ¹

Analysis

The sensitivity, specificity, and likelihood ratios (LRs) for each study were calculated, followed by a meta-analysis (if >2 studies) to calculate the random-effects bivariable summary measures (Proc NLMixed, SAS 9.4 TS Level 1M4 [SAS Institute]). These bivariable summary measures for office vs home measures were compared, and estimates of the positive and negative predictive values were made using random-effects bivariable measures that took the correlation between prevalence and predictive value into account. To address heterogeneity, the methods and study populations of the data are described using bivariable random-effects methods when combining results, and width of the CIs provides insights into the precision of the parameters.

Results

The searches identified 12 604 titles, of which 17 articles ultimately met the inclusion criteria (**Table 3** and **Table 4**; eFigure in the Supplement). ¹³⁻²⁹ Nine studies (n = 4368) compared office or home measures with mean BP while awake during ABPM as the reference standard, ^{13,16,18-20,22,24,25,27} 5 studies (n = 3191) compared results with mean BP during 24-hour ABPM, ^{14,15,17,21,26} and 2 studies (n = 1183) compared results with both mean BP while awake during ABPM and mean BP during 24-hour ABPM. ^{23,28}

The summary prevalence of hypertension by 24-hour ABPM was 49% (95% CI, 39%-60%) in the studies that evaluated conventional office measures and 54% (95% CI, 39%-69%) in the studies that evaluated home measures. Two studies of AOBP vs 24-hour ABPM among untreated patients across the spectrum of office BP measurements were found, with prevalence of hypertension of 16% and 35%. ^{27,28} Only 3 studies were level 1 and provided comparison

JAMA July 27, 2021 Volume 326, Number 4

Table 3. Studies Comparing Conventional Office Oscillometric Blood Pressure With Ambulatory Blood Pressure Monitoring (ABPM)

	c	Sample size (% with hypertension	Mean	Female	Country	Race and/or	Mean ABPM threshold,	No. of office
Source	Setting	on ABPM)	age, y	sex, %	of study	ethnicity	mm Hg	measurements
Gill et al, ¹³ 2017	General practices	211 (41)	56	53	UK	46% White; 26% South Asian; 27% African Caribbean	Awake: ≥135/85	1
Ishikawa et al, ¹⁴ 2010	Clinic visit	129 (34)	60	53	Japan	Not reported	24-h: ≥130/≥80	2
Kang et al, ¹⁵ 2015	Specialty clinic visit	573 (64)	50	44	China	Not reported	24-h: ≥130/≥80	3
Kim et al, ¹⁶ 2011	Research visit	121 (54)	35	28	South Korea	Not reported	Awake: >135/>85	≥2
Ommen et al, ¹⁷ 2007	Clinic	178 (25)	41	60	US	61% White; 31% Black; 30% Hispanic	24-h: ≥130/≥80	2
Poudel et al, ¹⁸ 2019	Research visit	432 (38)	55	56	US	52% Black	Awake: >135/>85	3 (mean of second and third taken)
Selenta et al, ¹⁹ 2000	Research visit	319 (27)	27	52	US	70% White; 30% Asian	Awake systolic: >135	5
Shin et al, ²⁰ 2015	Specialty clinic visit	1262 (61)	52	48	Korea	Not reported	Awake: >135/>85	2
Tocci et al, ²¹ 2018	Specialty clinic visit	2209 (67)	53	47	Italy	Not reported	24-h: ≥130/≥80	3
Viera et al, ²² 2014	Research visit	411 (76)	48	56	US	75% White; 21% Black	Awake: ≥135/≥85	3 (mean of second and third taken)
Wojciechowska et al, ²³ 2016	Research visit	201 (33)	41	Not reported	Poland	Not reported	24-h: ≥130/≥80; awake: >135/85; or nighttime: >120/70	5
Zhang et al, ²⁴ 2015	Secondary care	831 (62)	51	50	China	Not reported	Awake: ≥135/≥85	3

Table 4. Studies Comparing Home Blood Pressure Monitoring With Ambulatory Blood Pressure Monitoring

Source	Setting	Sample size (% with hypertension on ABPM)	Mean age, y	Female sex, %	Country	Race and ethnicity	Mean ABPM threshold, mm Hg	No. of home measurements
Gill et al, ¹³ 2017	General practices	211 (41)	56	53	UK	46% White; 26% South Asian; 27% African Caribbean	Awake: ≥135/85	12 minimum from ≥4 d (mean excluded day 1 measurement)
Ishikawa et al, ¹⁴ 2010	Research visit	129 (34)	60	53	Japan	Not reported	24-h: ≥130/80	12 (mean of all measurements)
Kang et al, 15 2015	Specialty clinic visit	573 (64)	50	44	China	Not reported	24-h: ≥130/80	12-70
Nunan et al, ²⁵ 2015	Research visit	203 (54)	56	47	UK	90% White	Awake: ≥135/85	12-24 (mean excludes the 4 readings taken on day 1)
Zhang et al, ²⁴ 2015	Outpatient clinic	831 (62)	51	50	China	Not reported	Awake: ≥135/85	42 (mean of 24 readings)
Zhuo et al, ²⁶ 2009	Community volunteers	102 (71)	54	57	China	Not reported	24-h: ≥130/80 ^a	6 (mean of 4 readings)

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to 24-hour ABPM using a consecutive sample 21,24,27; the remainder of the studies were level 3 (eTable 2 in the Supplement).

Conventional Office Oscillometric BP vs 24-Hour ABPM

A total of 12 studies compared office oscillometric BP measurements with 24-hour ABPM, including both initially elevated BP levels as well as nonelevated office BP levels (Table 3). $^{13-24}$ Sample sizes ranged from 117 to 2209 participants. Four studies were conducted in the US. 17-19,22 For a threshold of at least 140/90 mm Hg, the summary sensitivity of oscillometric office BP (mean of 1-5 measures from single visit) for diagnosing hypertension was 51% (95% CI, 36%-67%), specificity was 88% (95% CI, 80%-96%), positive

LR was 4.2 (95% CI, 2.5-6.0), and negative LR was 0.56 (95% CI, 0.42-0.69) (Table 5).

HBPM vs 24-Hour ABPM

A total of 6 studies compared home oscillometric BP measurements with 24-hour ABPM, including both initially elevated BP levels and nonelevated office BP levels (Table 4). 13-15,21,25,26 Sample sizes ranged from 102 to 831 participants. None of the studies were conducted in the US. For a threshold of at least 135/85 mm Hg, HBPM (mean of multiple measurements) had a summary sensitivity of 75% (95% CI, 65%-86%), specificity of 76% (95% CI, 65%-86%), positive LR of 3.1 (95% CI, 2.2-4.0), and negative LR of 0.33 (95% CI, 0.20-0.47) (Table 5).

JAMA July 27, 2021 Volume 326, Number 4

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^a Used awake mean \geq 135/85 for the false-positive assessment.

Table 5. Sensitivity, Specificity, and Likelihood Ratios of Office Oscillometric and Home Blood Pressure Monitoring Compared With Ambulatory Blood Pressure Monitoring^a

Screening				Likelihood ratio (95% CI)		
test	No. of studies	Sensitivity (95% CI), %	Specificity (95% CI), %	Positive	Negative	
Office	12 ¹³⁻²⁴	51 (36-67)	88 (80-96)	4.2 (2.5-6.0)	0.56 (0.42-0.69)	
Home	6 ^{13,14,21-23}	75 (65-86)	76 (65-86)	3.1 (2.2-4.0)	0.33 (0.20-0.47)	

^a See eTable 3 in Supplement for results from individual studies.

Table 6. Studies Comparing Automated Office Blood Pressure (AOBP) Monitoring With Ambulatory Blood Pressure Monitoring (ABPM)

Source	Setting	Sample size (% with hypertension on ABPM)	Mean age, y	Female sex, %	Country	Race and/or ethnicity	Mean ABPM threshold, mm Hg	No. of AOBP measurements averaged
Armanyous et al, ²⁷ 2019	Healthy volunteers at a clinic	578 (16)	43	56	US	11% Black	Awake: ≥135/85	5
Etyang et al, ²⁸ 2019	Random sample recruited to research clinics	982 (35)	42	60	Kenya	Not reported	Awake: ≥135/85	3
Michea et al, ²⁹ 2021	Cohort referred from primary health care centers	309 (65)	54	50	Chile	Not reported	24-hour: ≥130/≥80; awake: >135/85; nighttime: >120/70	2

Office Oscillometric Measurement vs HBPM

Office BP had low sensitivity for diagnosing hypertension, whereas HBPM had higher sensitivity (51% vs 75%; P = .04) and no significant difference in specificity (76% vs 88%; P = .15). The positive LRs were not significantly different for office BP vs HBPM (P = .37), whereas the negative LR was lower for HBPM (P = .04). The thresholds for defining hypertension and the prevalence of hypertension were similar in office BP measurement and home BP measurement studies, and the estimated predictive values of office oscillometric BP measures and HBPM were numerically nearly identical (office BP: positive predictive value, 78% [95% CI, 67%-85%]; negative predictive value, 68% [95% CI, 59%-76%]; HBPM: positive predictive value, 78% [95% CI, 69%-86%]; negative predictive value, 71% [95% CI, 60%-80%]).

Office Measurement and HBPM as a Composite Measure

One study 24 had an adequate sample size and provided enough data that allowed calculating the serial LR for each combination of office and home BP measurements compared with 24-hour ABPM (eTable 4 in the Supplement). There was a stepwise lower LR for the office HBPM hypertension statuses in Table 1, suggesting higher diagnostic accuracy when home measures are added to office measures for sustained hypertension (LR, 10.0 [95% CI, 5.3-20.0]), masked hypertension (LR, 3.6 [95% CI, 2.4-5.4]), white coat hypertension (LR, 1.6 [95% CI, 0.91-2.7]), and normotension (LR, 0.41 [95% CI, 0.36-0.47]).

AOBP Monitoring vs 24-Hour ABPM

Two studies from 2019 assessed unattended automated office (AOBP) measurement compared with 24-hour ABPM among untreated participants (Table 6). ^{27,28} In a study of a consecutive sample of 578 adults, AOBP (using a cutoff of 135/85 mm Hg) had a sensitivity of 48% (95% CI, 38%-58%) and specificity of 91% (95% CI, 88%-93%) compared with mean BP while awake during ABPM (positive LR, 5.3 [95% CI, 3.4-7.2]; negative LR, 0.57 [95% CI, 0.46-0.69]).²⁷ In another study of 982 adults from a general population in Kenya, mean AOBP had a sensitivity of 51% (96% CI, 46%-57%) and specificity of 80% (95% CI, 77%-83%) compared with BP while awake during ABPM (positive LR, 2.6 [95% CI, 2.2-3.2]; negative LR, 0.60 [95% CI, 0.50-0.70]).²⁸ Compared with the 24-hour mean, AOBP had a similar sensitivity (55% [96% CI, 49%-60%]) and specificity (81% [95% CI, 77%-84%]). 28 The studies differed in how they calculated the mean AOBP, with the first study using 5 readings and the second using 3 readings. One study (n = 309) compared attended AOBP (using a cutoff of 140/90 mm Hg from the mean of the second and third reading) with 24-hour ABPM.²⁹ In this study, sensitivity of AOBP was 87.6% (95% CI, 83.0%-92.1%) and specificity was 24.1% (95% CI, 16.0%-32.2%).

Discussion

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Due to limited sensitivity and specificity, conventional office BP measurements should not be relied on for making a diagnosis of hypertension or for definitively ruling out a diagnosis of hypertension. Although currently available data are more limited, AOBP does not appear to have sufficiently high sensitivity and specificity for this measurement to serve as a replacement for conventionally measured office BP performed with careful attention to recommended technique. HBPM performed over a few days also has limited sensitivity and specificity for diagnosing hypertension. HBPM is an important complement to office BP, because when office BP and HBPM measurements are concordant, the clinician can be more confident that the diagnosis is correct. When office and HBPM measurements are not in agreement and diagnostic clarification is needed, 24-hour ABPM should be considered.

The USPSTF issued a reaffirmation in April 2021 of its recommendation to screen adults for hypertension with office BP measurement and obtain BP measurements outside of the clinical setting to confirm the diagnosis before initiating treatment.⁶ The task force noted that ABPM provides the most evidence-based risk information for subsequent cardiovascular events. 6,30

ABPM is not widely available in the US, so HBPM is recommended by both the USPSTF and the American College of Cardiology/ American Heart Association (ACC/AHA) guidelines as an alternative. 1,6 Home BP level is a more reliable predictor of cardiovascular outcomes than office BP. 3,31 In addition to its usefulness in clarifying the diagnosis of hypertension, HBPM offers the additional

JAMA July 27, 2021 Volume 326, Number 4

Box. Implementation of Ambulatory Blood Pressure Monitoring (ABPM)

Define need and establish goals

Estimate the anticipated number of patients requiring monitoring per week and whether home BP monitoring will be asked of a patient before proceeding to ABPM.

Purchase devices and software

Choose a device that has been independently validated; considerations include cost and ease of use of software for programming, retrieving data, and generating reports. Order the number of devices based on anticipated need. Batteries will also be needed and should be replaced or recharged between sessions.

Create team and define roles

A dedicated coordinator will be needed to schedule patients and counsel them ahead of time about the procedure (expectations, wearing the monitor, troubleshooting). The interpreting clinician (or another team member) will need to preprogram the monitor. A medical assistant or nurse can place the monitor the day of the appointment and provide additional guidance about wearing the monitor for the 24 hours (including during sleep), how to reposition the cuff if needed, how to keep a diary during the session, and when/where to return the next day.

Train staff on scheduling, fitting, and retrieving monitors

The monitor is worn by the patient for 24 hours, so consider implications for scheduling. A well-prepared patient is key to successful ABPM. Staff must be trained on cuff selection and placement, assisting the patient in wearing the device (belt or harness), and positioning the tubing. The return of the monitor is straightforward; the patient can be instructed to remove it and drop it off or can have the device removed by office staff. Have a phone number patients can call to ask questions if any issues arise.

Ensure interpreting clinicians are familiar with software and ABPM interpretation

The retrieved monitor must then be provided to the interpreting clinician who will download the data, render an interpretation (including assessing quality of data), and generate a report to send to the ordering clinician. The monitor can then be prepared for the next scheduled session.

Mean thresholds for ABPM

Daytime/awake

Stage 1 hypertension: 130/80 mm Hg Stage 2 hypertension: 135/85 mm Hg

Nocturnal/asleep

Stage 1 hypertension: 110/65 mm Hg Stage 2 hypertension: 120/70 mm Hg

24-hour

Stage 1 hypertension: 125/75 mm Hg Stage 2 hypertension: 130/80 mm Hg

advantages of ongoing monitoring of BP, possibly also promoting improved BP control.³² Patients should use proper technique for HBPM and should be instructed on the frequency, timing, and recording of measurements.³

A diagnosis of hypertension is generally not pursued when the office BP is within normal range. However, clinicians should be aware that individuals with masked hypertension have nearly the same risk for target organ damage and cardiovascular disease events as pa-

tients with sustained hypertension. ^{1,33} To date, no randomized trials have evaluated the management of masked hypertension, but given its risks and its progression to sustained hypertension, identification and management may have significant public health implications. ¹ Although some risk factors for masked hypertension have been identified, the most robust predictor appears to be office BP level. ³⁴ Patients with office BP level closer to the threshold for office hypertension are more likely to have masked hypertension. ³⁴

The 2017 ACC/AHA guideline lowered the threshold for hypertension to systolic BP of at least 130 mm Hg or diastolic BP of at least 80 mm Hg. The 2017 guideline also noted out-of-office BP monitoring to be critical in the diagnosis and management of hypertension, with HBPM suggested as an alternative to 24-hour ABPM. For patients with an office BP (untreated) in the elevated, but not hypertensive, range (120-129 mm Hg systolic or 75-79 mm Hg diastolic), the guideline states that obtaining out-of-office measurements to evaluate for masked hypertension is reasonable.

The current review focused on screening for undiagnosed hypertension using oscillometric methods and thus excluded evaluations of patients already receiving treatment, studies using mercury or aneroid sphygmomanometry, and analyses for which the reference standard was used only for individuals with elevated office BP. Multiple studies have evaluated the use of out-of-office BP measurements for both confirming elevated office BP and for comparing BP assessment methods among treated patients. ^{1,3,35} These studies are consistent in showing the importance of out-of-office BP measures in assessing overall BP pattern.

The Centers for Medicare & Medicaid Services recently expanded coverage for 24-hour ABPM (maximum once per year) to include masked hypertension as well as white coat hypertension. Current Procedural Terminology 2020 also includes codes for self-measured BP that support patient education and collection of data. It remains to be seen whether updated payment structures will lead to increased use of HBPM and 24-hour ABPM.

Practices interested in offering 24-hour ABPM will need to purchase the devices and software, develop a protocol for testing procedures, and train staff (Box). ^{3,36,37} The cost is typically \$2000 to \$2500 per device. ³⁶ Each manufacturer has its own accompanying software. A variety of cuff sizes is typically included. Cuffs can be washed between uses. Clinic staff involved in the service must be trained to fit 24-hour ABPM devices and to counsel patients. Clinicians interpreting data and generating reports must become familiar with the software as well as 24-hour ABPM protocols and thresholds.

Scenario Resolutions

Case 1

The diagnostic dilemma is whether this patient has white coat hypertension, (ie, BP is elevated in the office setting but below diagnostic thresholds outside the office). This patient's systolic BP in the office setting of 155/83 mm Hg was greater than 140 mm Hg, which has a positive LR of 4.2 for hypertension. The magnitude of the BP elevation raises the concern about true (sustained) hypertension rather than white coat hypertension. However, the studies in this review did not include data that allowed the estimation of LR as a function of the degree of hypertension. The prevalence of hypertension

(using office BP threshold of \geq 140/90 mm Hg) in individuals aged 40 to 59 years is approximately 33%. Thus, the likelihood that 24-hour ABPM could confirm hypertension is at least 67%, and possibly higher given this patient's measured office systolic BP. HBPM that confirms the elevation of systolic BP would support the diagnosis and allow proceeding to treatment. However, the HBPM measurement suggests white coat hypertension. The combination of an elevated office BP and a normal HBPM level has an LR of 1.6 for true hypertension, which places this patient at approximately 44% probability of having hypertension. If available, 24-hour ABPM should be used before making a diagnosis. Carefully repeating the patient's BP measurement at subsequent office visits, while potentially a reasonable approach, is still subject to the possibility of white coat (false-positive) hypertension.

Case 2

The diagnostic dilemma is whether this patient has masked hypertension, (ie, BP is below the diagnostic threshold in the office setting, but BP measurement outside the office setting would reveal elevated BP). This patient's BP in the office of 128/78 mm Hg has an LR of 0.56 for hypertension. The prevalence of hypertension in those aged 18 to 39 years is approximately 7.5%. ³⁸ Thus, the belowthreshold office BP suggests a probability of hypertension of approximately 4%. However, this patient's BP level is close to the ACC/AHA guideline threshold of 130/80 mm Hg for hypertension, ¹ and HBPM could be useful to decide whether to pursue 24-hour ABPM. HBPM levels that suggest hypertension is present (LR of 3.6 for the combination of normal office BP and elevated home BP) would increase the probability of hypertension to approximately 23%. In such an instance, 24-hour ABPM could be used to clarify this patient's status, particularly given his other cardiovascular risk factors.

Limitations

This review has several limitations. First, a limited number of studies that tested the diagnostic accuracy of oscillometric office BP measurement among untreated adults proceeded to conduct further 24hour ABPM testing of patients with nonelevated office or home BP levels. Second, studies varied in the number and type of measurements used to calculate mean office or home BP. Third, few studies were conducted in the US, and only a small number of studies included Black participants. Fourth, some studies used clinic visit BP for office measurement, whereas other studies used research study visit BP for office measurement, and research visit BP measurements tend to be lower than actual clinical visit measurements.³⁹ Fifth, some eligible articles may have been missed, and non-English-language publications were not considered in the review. However, other major systematic reviews support the recommendations of this review. $^{\rm 30,31,35}$ Sixth, although it is the accepted reference standard, 24-hour ABPM does not perform perfectly. 3,6,30 In addition, although mean awake BP has been used commonly as the reference, 24-hour data (which includes sleep BP measures) may be preferred.³

Seventh, only 3 studies were included that involved untreated participants for whom AOBP measurement at a single visit was compared with 24-hour ABPM among participants with elevated and nonelevated office BP measurements. ²⁷⁻²⁹ Another study that compared 3 days of AOBP to 24-hour ABPM found that 3 days of AOBP had a higher sensitivity than a single-visit office BP measurement, but lower sensitivity than HBPM. ¹³ Studies of patients with hypertension have

consistently shown that AOBP on average provides BP measurements that correlate more closely with mean BP while awake during ABPM and mitigate the white coat effect. ⁴⁰⁻⁴² The optimal threshold for hypertension using unattended AOBP may be different than that of conventional office BP.³

Eighth, the available studies consistently used 140/90 mm Hg as the office BP threshold, with an HBPM threshold of 135/85 mm Hg, both compared with the reference standard of 130/80 mm Hg for mean BP during 24-hour ABPM and 135/85 mm Hg for mean BP while awake during ABPM. Clinicians should keep these thresholds in mind (as well as prevalence) when applying the LRs. New office and out-of-office BP thresholds, as defined in the ACC/AHA guideline, may alter the prevalence of masked hypertension and white coat hypertension. One study that compared the new ACC/AHA thresholds to the aforementioned thresholds found that the prevalence of white coat hypertension and masked hypertension increased only slightly, while there was a substantial increase in sustained hypertension (from 9% to 27%) and decrease in sustained normotension (from 61% to 39%). 18

Ninth, because hypertension is not truly a dichotomous state, applying standard diagnostic test operating characteristics, while useful, is inherently limited. None of the included studies evaluated the consistency of BP classification solely by 24-hour ABPM across multiple sessions. However, mean BP (both awake and 24-hour) measured via 24-hour ABPM has demonstrated good reproducibility in most studies, although regression to the mean also occurs. ^{3,43} The decision to initiate medical treatment for hypertension must consider not only the average BP level measured in the most accurate and feasible manner, but also the patient's overall risk for cardiovascular disease and the potential benefits vs harms of treatment.

Clinical Bottom Line

All forms of BP measurement should be performed with validated devices using proper positioning and correct cuff size. ³ Health care personnel and individuals performing BP measurements should be trained, even when using oscillometric devices. However, even when performed correctly, office BP measurements alone may not be sufficient to establish a diagnosis of hypertension for most individuals, particularly age groups with lower pretest probability. For diagnosing hypertension in adults, out-of-office BP assessment should be considered for most patients with elevated BP and for individuals who have upper-level "normal" office BP measurements. The combination of results from office BP measurement and HBPM has better diagnostic accuracy than the independent results alone, and when concordant, is likely sufficient for diagnosis. However, 24-hour ABPM should be considered when results are discordant, especially for patients with a higher pretest probability of hypertension.

Conclusions

Office measurements of BP may not be accurate enough to rule in or rule out hypertension; HBPM may be helpful to confirm a diagnosis. When there is uncertainty around threshold values or when office and HBPM are not in agreement, 24-hour ABPM should be considered to establish the diagnosis.

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346

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