Pragmatic Method Using Blood Pressure Diaries to Assess Blood Pressure Control

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ABSTRACT

PURPOSE Twenty-four–hour ambulatory blood pressure (ABP) is the reference standard of blood pressure control. Home blood pressure (HBP) is superior to clinic blood pressure for assessing control, but a barrier to its use is the need for physicians to calculate average blood pressure from patient diaries. We sought to develop a quick and pragmatic method to assess blood pressure control from patients' HBP diaries.

METHODS Seven-day HBP and 24-hour ABP were measured in 286 patients with uncomplicated treated hypertension (aged 64 ± 8 years; 53% female). We determined the optimal ratio of home systolic blood pressure readings above threshold (≥ 135 mm Hg) for the last 10 recorded that would best predict elevated 24-hour ABP. Uncontrolled blood pressure was defined as 24-hour ABP systolic blood pressure ≥ 130 mm Hg or 24-hour ABP daytime systolic blood pressure ≥ 135 mm Hg. Validation by corroborative evidence was tested by association with markers of end-organ disease.

RESULTS The best predictor of 24-hour ABP systolic blood pressure above treatment/target threshold was having 3 or more ($\geq 30\%$) of the last 10 home systolic blood pressure readings ≥ 135 mm Hg (area under the receiver operating characteristic curve = 0.71). Importantly, patients meeting this criterion had evidence of target organ disease, with significantly higher aortic stiffness, left ventricular relative wall thickness, and left atrial area, and lower left ventricular ejection fraction, compared with those who did not meet this criterion.

CONCLUSIONS To facilitate uptake of HBP monitoring, we propose that physicians can determine the percentage of the last 10 home systolic blood pressure values ≥ 135 mm Hg for a patient and tailor management accordingly.

INTRODUCTION

Clinic blood pressure is widely used for patient management, but the method has some limitations that may result in inaccurate assessment of true underlying blood pressure.[1] Methods to assess out-of-clinic blood pressure using self-measured home blood pressure (HBP, the average blood pressure over 7 days) or 24-hour ambulatory blood pressure (ABP) have demonstrated superior prognostic utility with respect to target organ disease (eg, cardiac hypertrophy),[2-4] cardiovascular events, and cardiovascular and all-cause mortality.[5-9] HBP has an advantage of already being in wide use, even if not in a standardized fashion.[10,11] It also helps to reduce health system costs, improve adherence to therapy, and achieve better blood pressure control.[12-17] Accordingly, use of HBP as a tool to help guide management of high blood pressure is advocated in many countries.[18-25]

A disadvantage of HBP is the requirement for manual calculation of the average of multiple values from patient diaries (eg, up to 28 recordings over 7 days) when using blood pressure devices that do not have storage memory, which currently predominate the market. If the patient has not calculated the average (which has its own reliability issue), the physician is

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unlikely to do so because of time constraints in the standard consultation. Indeed, the average number of problems managed at a clinical encounter in primary care in Australia is 1.6, and it is increasing because of aging of the population and concomitant multimorbidity.[26] This rise emphasizes the need for a pragmatic alternative for physicians to assess blood pressure control from patient HBP diaries if they are to be used reliably in practice. One such method could involve quickly viewing the blood pressure diary to determine the percentage of home systolic blood pressure values above threshold (≥135 mm Hg)[19,23,24] that would have predictive value as good as that of true blood pressure control.

To the best of our knowledge, a study to determine the optimal percentage of HBP values above threshold to denote blood pressure control has never been performed and was our primary aim. We also sought to test the validity of this approach by determining associations with a variety of markers of target organ disease—aortic stiffness, left ventricular relative wall thickness, left ventricular ejection fraction, left ventricular mass index, left atrial area, and left ventricular filling pressure as estimated by the ratio of mitral inflow to mitral annular early diastolic velocity (E/e′)—in patients above the optimal percentage of values compared with those below that percentage. We hypothesized that participants with at least 20% of the last 10 home systolic blood pressure readings ≥135 mm Hg would be more likely to have uncontrolled blood pressure (confirmed using 24-hour ABP) and evidence of target organ disease compared with participants below the 20% cut point.

METHODS

Participants

A total of 286 patients being treated for hypertension by their primary care physicians were recruited in 3 Australian centers as part of a randomized clinical trial (Australia New Zealand Clinical Trial Registry number ACTRN12608 000041358).[27,28] Recruitment was conducted through general practice clinics and community advertisement. For our analysis, we used baseline data collected before the intervention. Patient were eligible for inclusion if they were nonpregnant adults receiving antihypertensive therapy for noncomplicated essential hypertension and taking no more than 3 antihypertensive drugs, with compliance checked by the study nurse viewing each patient's medication packet(s) at the clinic visit. Exclusion criteria were as follows: severely abnormal left ventricular mass index (women >59 g/m$^{2.7}$ and men >64 g/m$^{2.7}$); clinical history of coronary artery disease or renal disease; serum creatinine exceeding 1.6 mg/dL; secondary causes of hypertension; uncon-

trolled hypertension (clinic brachial blood pressure >180/100 mm Hg); aortic valve stenosis; or upper limb obstructive atherosclerosis. All patients provided written informed consent, and the work was conducted in accordance with the Declaration of Helsinki.

Protocol

All patients performed HBP recording over 7 days and had measures of 24-hour ABP, aortic stiffness, left ventricular mass and function, and left atrial area assessed at the baseline examination on study enrollment. The aim was for all measures to be consecutively acquired in the shortest time frame possible (approximately 10 days). Uncontrolled blood pressure was defined as 24-hour ABP systolic blood pressure ≥130 mm Hg or 24-hour ABP daytime systolic blood pressure ≥135 mm Hg. We determined the optimal number of home systolic blood pressure readings ≥135 mm Hg (from the last 10 recorded) to predict the presence of uncontrolled blood pressure using statistical tests of model calibration and classification. Restriction to the last 10 systolic blood pressure readings was tested because this measure would be a pragmatic, rapid, and simple way for physicians to calculate proportions from the HBP diaries. This approach is also supported by data showing that 5 days of recording (omitting the first 2 days) is a reliable estimate of usual blood pressure.[29]

Measures

To determine clinic blood pressure, we used an automated oscillometric device (HEM-907; OMRON Europe BV [OMCE]) to measure blood pressure in duplicate (average values presented) after patients had 5 minutes of seated rest in the clinical research laboratory.

Patients recorded 7-day HBP using a valid device with correct cuff size owned by the patient or with a machine (UA 767, A&D Mercury) that we provided if patients did not have their own device.[30] They were instructed to measure blood pressure in duplicate (1 minute apart) 3 times per day—in the morning (between 6 AM and 10 AM), at noon, and in the evening (between 6 PM and 10 PM)—after 5 minutes of seated rest, with feet flat on the floor, legs uncrossed, back supported, and the arm supported at the level of the heart, as per guidelines.[19] Patients were instructed to disregard the first reading and record the second reading.[29] We used only the morning and evening readings for our analyses.[19,21,23,24]

To record 24-hour ABP, we used a validated device with correct cuff size (TM-2430, A&D Mercury),[31] with measures acquired every 30 minutes during the day (between 6 AM and 10 PM) and every 60 minutes overnight (between 10 PM and 6 AM).

Target organ disease was assessed from various cardiovascular measures. We measured aortic stiffness[23,32] using the reference standard of tonometric carotid-to-femoral pulse wave velocity (SphygmoCor 8.0, AtCor Medical) as per expert consensus.[33] Allometric left ventricular mass (indexed to m[2.7]) and left ventricular ejection fraction were measured using real time 3-dimensional echocardiography as previously described.[34] Left atrial volume was assessed using 2-dimensional method of disks area-length biplane, according to American Society of Echocardiography guidelines.[35] For the approximation of left ventricular filling pressure by E/e′, mitral inflow velocity (E) was measured by pulsed-wave Doppler at the tips of the mitral valve leaflets, and early diastolic tissue velocity (e′) was measured by pulsed wave tissue Doppler at the septal and lateral portion of the mitral annulus in the apical 4-chamber view. We used the average value of e′ from both sites to calculate E/e′.[36]

Statistical Analysis

We estimated and compared risk of the outcome (uncontrolled blood pressure) at each binary classification of the predictor (number of home SBP readings ≥135 mm Hg among the last 10 recorded) using log binomial regression analysis.[37] To compare accuracy of prediction at different binary classifications, we calculated sensitivity and specificity[38] and area under the receiver operating characteristic curve[39] together with 2 alternatives to this analysis described by Pencina et al[40] that have become popular in recent years for evaluating improvement in prediction: the net reclassification index and the integrated discrimination improvement. Because model calibration should be improved by adding a covariate for an additional marker of risk, we report the deviance of the fitted model. Following the approach recommended by Pepe et al,[41] we report the P values from testing the null hypothesis about its regression coefficient. We explored multiple binary classification possibilities of the predictor (eg, ≥1, ≥2, ≥3, ≥4… elevations of home SBP among the last 10 recorded) to determine the best cut points for optimal diagnostic accuracy. Only data with the best diagnostic accuracy are presented.

RESULTS

Patient Characteristics

Table 1 presents the characteristics of study patients, as well as blood pressure and markers of target organ disease related to hypertension. In the study sample, 34% of patients had controlled blood pressure based on HBP <135 mm Hg, whereas 44% had controlled blood pressure based on the average 24-hour ABP daytime systolic blood pressure <135 mm Hg.

Optimal Percentage of HBP to Predict Blood Pressure Control

Table 2 presents the cut points that provide the optimal values of area under the curve, net reclassification index, integrated discrimination improvement, and model deviance. The cut points differed for the outcomes of mean 24-hour ABP systolic blood pressure ≥130 mm Hg (for which ≥3 elevations among the last 10 home recordings was the optimal cut point for all but the category-free version of net reclassification index) and 24-hour ABP daytime systolic blood pressure ≥135 mm Hg (for which ≥2 elevations among the last 10 home recordings was the optimal cut point). The positive and negative predictive values of ≥3 elevations were 0.85 (95% CI, 0.78-0.91) and 0.56 (95% CI 0.48-0.64), respectively, for 24-hour ABP systolic blood pressure ≥130 mm Hg, and 0.79 (95% CI 0.72-0.86) and 0.63 (95% CI 0.55-0.71), respectively, for 24-hour ABP daytime systolic blood pressure ≥135 mm Hg.

Repeating the analyses with all 14 morning and afternoon HBP readings taken over 7 days resulted in an optimal cut point of ≥4 elevations for each of 24-hour ABP ≥130 mm Hg systolic blood pressure and 24-hour ABP daytime systolic blood pressure ≥135 mm

Table 1. Clinical Characteristics of Study Participants (N = 286)

Characteristic	Value, Mean (SD) [range][a]
Age, y[b]	64 (8) [24-78]
Sex, female, % (No.)	53 (152)
Body mass index, kg/m²	29.4 (4.8)
Waist-hip ratio	0.95 (0.48)
Antihypertensive medications (daily defined dose), No.	2.4 (1.4)
Measures of target organ disease	
Aortic stiffness, m/s	9.4 (2.1)
Left ventricular relative wall thickness, cm	0.47 (0.20)
Left ventricular mass index, g/m[2.7]	31.3 (5.5)
Left ventricular ejection fraction, %	62 (5)
Left atrial area, cm²	20.4 (4.2)
Left ventricular filling pressure, E/e′	11.6 (3.6)
Clinic blood pressure, mm Hg	
Systolic	134 (14)
Diastolic	78 (10)
24-hour ambulatory blood pressure, mm Hg	
Systolic	133 (12)
Diastolic	77 (8)
7-day home blood pressure, mm Hg	
Systolic	128 (13)
Diastolic	74 (8)

E/e′ = the ratio of mitral inflow to mitral annular early diastolic velocity.

[a] Unless otherwise noted.

[b] Eighty percent were aged 60 years or older.

Hg. This cut point of ≥4 elevations among the last 14 home readings is consistent with the cut point of ≥3 elevations among the last 10 home readings. Additionally, the mean (±SD) values of 24-hour ABP daytime systolic blood pressure and the last 10 HBP readings were 132.7 ± 11.1 mm Hg and 120.4 ± 9.8 mm Hg, respectively, for those with <3 elevations, and 143.4 ± 11.2 mm Hg and 147.4 ± 10.5 mm Hg, respectively, for those with ≥3 elevations. Furthermore, the means of the last 14 home readings—120.4 ± 9.7 mm Hg for those with <3 elevations, and 147.1 ± 10.2 mm Hg for those with ≥3 elevations—were almost identical to the respective means of the last 10 readings above.

Validation Analysis by Association With Target Organ Disease

To examine whether ≥2 or ≥3 elevations provides the most clinically relevant cut point, Table 3 shows mean values of aortic stiffness, left ventricular relative wall thickness, left ventricular ejection fraction, left ventricular mass index, left atrial area, and E/e′ for groups of patients classified by the number of elevations (≥135 mm Hg) in the last 10 home recordings of systolic blood pressure. On the basis of a criterion of greatest discrimination between groups, a cut point of ≥3 eleva-

tions was optimal for these 6 markers of end organ disease related to hypertension. This approach produces differences in mean values that are either similar to or greater than those for ≥2 elevations, and only for E/e′ does ≥3 elevations provide a classification with a greater prognostic value. Sensitivity and specificity of the ≥3 cut point were 62.1% and 80.2%, respectively, for mean 24-hour ABP systolic blood pressure ≥130, and 64.6% and 77.2%, respectively, for 24-hour ABP daytime systolic blood pressure ≥135 mm Hg.

DISCUSSION

The use of patient HBP diaries is recommended in blood pressure management guidelines and by international expert committees.[18-24] Averaging all HBP values to assess blood pressure control is impractical in busy clinical practice, however. We therefore sought to determine if it was possible to reliably determine blood pressure control and likely underlying target organ disease by quick assessment of patient HBP diaries. We found that if at least 30% of the last 10 home systolic blood pressure readings were ≥135 mm Hg (the threshold for elevated blood pressure based on HBP), there was propensity toward having uncontrolled blood pressure according to 24-hour ABP, as well as greater risk for target organ disease associated with hypertension (increased aortic stiffness, left ventricular relative wall thickness, and left atrial area, and reduced left ventricular ejection fraction). These data suggest that in patients who do not use HBP devices with storage memory, this pragmatic approach using a summary statistic is a valid aid for physicians to assess blood pressure control and help facilitate greater use of HBP monitoring in clinical practice.

Clinicians lack confidence in clinic blood pressure as a diagnostic tool because of the high prevalence of readings that conflict with out-of-clinic readings, thus potentially producing erroneous diagnosis.[42] Uncertainty as to the true blood pressure based on clinic blood pressure has also been reported as a prominent reason for not intensifying therapy.[43] Although ignored as a clinical tool in the United States, at least

Table 2. Indices of the Diagnostic Accuracy of Classification of Patients as Having vs Not Having Uncontrolled Blood Pressure Based on the Number of SBP Elevations

Definition of Uncontrolled Blood Pressure and Index	Unadjusted		Adjusted[a]	
	Cut Point	Value	Cut Point	Value
24-hour ABP SBP ≥130 mm Hg				
AUC[b]	≥3 elevations	0.712	≥3 elevations	0.722
NRI[c]	≥3 elevations	0.005	≥3 elevations	0.004
Category-free NRI[c]	≥3 elevations	0.010	≥2 elevations	0.192
rIDI[d]	≥3 elevations	1.021	≥3 elevations	1.018
Deviance[e]	≥3 elevations	321.9	≥3 elevations	321.1
24-hour ABP daytime SBP ≥135 mm Hg				
AUC[b]	≥2 elevations	0.717	≥2 elevations	0.724
NRI[c]	≥2 elevations	0.072	≥2 elevations	0.072
Category-free NRI[c]	≥2 elevations	0.144	≥2 elevations	0.137
rIDI[d]	≥2 elevations	1.306	≥2 elevations	1.237
Deviance[e]	≥2 elevations	331.9	≥2 elevations	330.3

ABP = ambulatory blood pressure; AUC = area under the receiver operating characteristic curve; NRI = net reclassification index; rIDI = relative integrated discrimination improvement; SBP = systolic blood pressure.

[a] For age, sex, and body mass index.

[b] Criterion: largest value for receiver operating characteristic curve produced from all 10 cut points (≥1 elevations, ≥2 elevations, ≥3 elevations, …, ≥9 elevations, 10 elevations).

[c] Criterion: last classification before that producing first negative value.

[d] Criterion: last classification before that producing first value below unity.

[e] Model deviance, criterion: last classification before that producing first higher value.

Note: Elevated systolic blood pressure was defined as 24-hour ABP SBP ≥130 mm Hg or 24-hour ABP daytime SBP ≥135 mm Hg. Number of elevations was defined as number of elevations ≥135 mm Hg among the last 10 recordings of morning and evening home SBP.

in the guidelines,[44] HBP monitoring is frequently used in clinical practice in this country,[45] and it has gained acceptance in Europe, Japan, and Canada.[12,19,21-23] Not all patients may be committed to undertaking HBP, but several motivating factors potentially contribute to participation, including self-empowerment and engagement in their own medical management to achieve lower blood pressure.[25] Indeed, a large survey of UK primary care physicians recently reported that 90% of practitioners have patients who use HBP, with about one-third of practitioners lending blood pressure monitors to patients and providing training on self-monitoring.[10] High levels of HBP use in primary care have also been reported in China.[11] In Australia, general practitioners report a lack of confidence that clinic blood pressure readings provide an accurate assessment of true underlying blood pressure, and that HBP was a method being used to address clinical uncertainty around diagnosis.[46,47]

Despite wider use of HBP, there remains a lack of concordance with respect to clinical interpretation of HBP values. Individual patient variability in the method of recording HBP (eg, several readings on a scrap of paper with no times or dates vs highly detailed spreadsheets of blood pressure and other clinical information) contributes to this discordance. The possible practical value of our findings is that regardless of the HBP recording method the patient uses, it may still be possible to apply a quick assessment to determine the percentage of blood pressure readings above the 135–mm Hg threshold. Having said this, our findings may have been influenced by the HBP protocol that we used, and may not be generalizable to different HBP recording methods, or to patients with very high clinic blood pressure (>180/100 mm Hg) as we excluded this group. Also, we did not standardize the timing of anti-hypertensive medication relative to HBP (other than asking patients to measure morning blood pressure before taking medication), nor attempt to control other daily life activity that may affect consistency of HBP (ie, exercise habits, food and drink intake). Nonetheless, better reproducibility and confidence in underly-

Table 3. Differences in Indicators of Target Organ Disease for Patients Not Attaining vs Attaining the Cut Point in Number of SBP Elevations During Home Blood Pressure Monitoring

Target Organ Disease Indicator and Cut Point	Value, Mean (SD)		Unadjusted Difference (95% CI)[a]	Adjusted Difference (95% CI)[a,b]
	Did Not Attain Cut Point	Attained Cut Point		
Aortic stiffness, m/s				
≥2 elevations	8.82 (1.79)	9.87 (2.25)	1.05 (0.57 to 1.54)[c]	0.72 (0.27 to 1.18)[d]
≥3 elevations	8.92 (1.87)	9.94 (2.26)	1.02 (0.53 to 1.51)[c]	0.71 (0.25 to 1.17)[d]
Relative wall thickness in cm × 10				
≥2 elevations	4.49 (0.75)	4.74 (0.63)	0.26 (0.09 to 0.04)[d]	0.26 (0.09 to 0.43)[d]
≥3 elevations	4.51 (0.74)	4.75 (0.63)	0.02 (0.01 to 0.04)[d]	0.25 (0.07 to 0.42)[d]
Left ventricular ejection fraction, %				
≥2 elevations	62.57 (5.18)	60.46 (5.40)	−2.11 (−3.48 to −0.74)[d]	−2.00 (−3.43 to −0.56)[d]
≥3 elevations	62.54 (5.28)	60.11 (5.22)	−2.43 (−3.83 to −1.03)[d]	−2.34 (−3.80 to −0.89)[d]
Left ventricular mass, g/m[2.7]				
≥2 elevations	30.91 (5.11)	31.60 (5.83)	0.69 (−0.64 to 2.03)	0.71 (−0.61 to 2.35)
≥3 elevations	30.71 (5.17)	31.99 (5.83)	1.28 (−0.05 to 2.61)	1.03 (−0.29 to 2.35)
Left atrial area, cm[2]				
≥2 elevations	19.91 (3.78)	20.72 (4.57)	0.80 (−0.23 to 1.84)	0.28 (−0.75 to 1.32)
≥3 elevations	19.72 (3.84)	21.08 (4.56)	1.36 (0.33 to 2.39)[d]	0.77 (−0.26 to 1.79)
≥4 elevations	19.86 (3.87)	21.14 (4.69)	1.28 (0.22 to 2.34)[e]	0.76 (−0.29 to 1.80)
Left ventricular filling pressure, E/e'				
≥2 elevations	11.36 (3.17)	11.84 (3.79)	0.48 (−0.39 to 1.36)	0.81 (−0.05 to 1.67)
≥3 elevations	11.28 (3.22)	12.04 (3.87)	0.76 (−0.11 to 1.63)	1.10 (0.24 to 1.95)[e]
≥4 elevations	11.12 (3.28)	12.48 (3.93)	1.36 (0.47 to 2.25)[d]	1.63 (0.77 to 2.49)[c]

E/e' = the ratio of mitral inflow to mitral annular early diastolic velocity; SBP = systolic blood pressure.

[a] Difference in means between patients who did vs did not attain cut point.

[b] Adjusted for age, sex, and body mass index.

[c] $P < .001$.

[d] $P < .01$.

[e] $P < .05$.

Note: Number of elevations ≥135 mm Hg among the last 10 recordings of morning and evening home SBP. Results are shown for ≥4 elevations only if the difference between means is similar to or higher than that for ≥3 elevations.

ing blood pressure is achievable when HBP is recorded by a standardized method,[48,49] such as that used in this current study and recommended in guidelines.[19,21] Overall, the best clinical approach would be using a validated blood pressure monitor with a memory function and automated averaging, and a standard method taking into account timing of antihypertensive medications. The demonstrated association of inadequate blood pressure control with markers of target organ disease supports the validity of our approach and might suggest that the problem with a suboptimal hypotensive effect may not be limited to a recent period, but possibly is a more general phenomenon covering longer time spans. This issue could have been examined further if we had accurate detail on the duration of hypertension, but these data were not available.

In summary, we analyzed HBP diaries from patients with treated hypertension (and clinic blood pressure ≤180/100 mm Hg) to determine whether a summary blood pressure statistic could be derived to assess blood pressure control. Although not a perfect discriminator of true blood pressure control, we found that patients with at least 30% of the last 10 home systolic blood pressure readings ≥135 mm Hg were more likely to have uncontrolled blood pressure as defined by 24-hour ABP. Validity of the test was corroborated by a higher prevalence of hypertension-related cardiac and large artery end-organ disease in patients with at least 30% of the last 10 home systolic blood pressure readings ≥135 mm Hg. Overall, this pragmatic summary statistic approach may be helpful for physicians to quickly assess data from HBP diaries in clinical practice.

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