Use of 2003 European Society of Hypertension–European Society of Cardiology guidelines for predicting stroke using self-measured blood pressure at home: the Ohasama study

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Aims To evaluate the predictive power of the risk stratification system proposed in the 2003 European Society of Hypertension–European Society of Cardiology (2003 ESH–ESC) guidelines and to compare self-measured blood pressure at home (HBP) with casual-screening blood pressure (CBP) for prediction of first stroke among a general Japanese population.

Methods and results HBP and CBP were measured in 1702 subjects (≥40 years) who had no history of stroke and who were followed for an average of 11 years. The subjects were assigned to one of five groups with differential risk stratification according to the 2003 ESH–ESC criteria: average risk, low added risk, moderate added risk, high added risk, and very high added risk. Even in the low risk group a significantly high risk for stroke was observed, and there was a linear step up of stroke risk based on HBP, as well as on CBP. On the basis of HBP classification, a higher stroke incidence was observed in the high and very high groups compared with CBP classification.

Conclusion The risk stratification system proposed in the 2003 ESH–ESC guidelines is valid for the prediction of stroke in this Japanese study population, and has a stronger predictive power when based on HBP than on CBP. The results indicate the usefulness of HBP for the prediction of stroke risk in individuals.

KEYWORDS Blood pressure; Home measurement; Screening measurement; Stroke; ESH-ESC guidelines; Risk stratification

Introduction Hypertension is an important risk factor for cardiovascular disease (CVD), which is the second leading cause of death in Japan. Although overall reduction of absolute risk factors for CVD is the goal, blood pressure (BP) management remains a key factor. Thus, accurate diagnosis and treatment of hypertension is necessary for better individual prognosis.

High reproducibility and reliability of self-measurement of BP at home (HBP) have been reported. HBP monitoring is well accepted by patients1,2 and encourages active participation in the management of personal health conditions.

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2003 ESH–ESC guidelines emphasized the importance of individualized medications. Although the 2003 ESH–ESC guidelines would possibly be applicable even for populations outside Europe,7 the usefulness of the guidelines in non-European countries has not yet been established. Also, the advantages of HBP measurements when compared with CBP have not been established, especially in terms of predicting first onset of stroke.

One aim of the present study was to examine whether the 2003 ESH–ESC classification was applicable to predict the risk of first stroke incidence, particularly because there is a high incidence of stroke observed among the Japanese.8 Another aim was to compare the predictive power of HBP and CBP for stroke risk with the stratification system of the 2003 ESH–ESC guidelines. Finally, we compared the prediction of first stroke based on the simplified risk stratification suggested by JNC-79 with prediction based on the comprehensive risk stratification from the 2003 ESH–ESC guidelines.

Methods

Study population

The present study was a part of the longitudinal observational study. Subjects have been participating in our HBP measurement project in Ohasama, a rural community in the northern part of Japan, since 1987. The study protocol was approved by the Institutional Review Board of Tohoku University School of Medicine and by the Department of Health of the Ohasama Town Government and complies with the Declaration of Helsinki. Informed consent was obtained from each subject.

The socio-economic and demographic characteristics of this region and the details of the selection procedure of study populations have been previously described.4,10–12 Briefly, HBP measured three times or more and CBP measurements were obtained from 1789 representative individuals of the 1989 eligible individuals aged 40 years or over. As 87 individuals had a previous history of stroke, they were excluded from the present analysis in order to examine the relationship between the first onset of stroke and the risk stratification system of the 2003 ESH–ESC guidelines. Therefore, the study population consisted of 1702 individuals. The mean (SD) age was 60.6 (10.7) years.

Blood pressure measurements

Physicians and well-trained public health nurses conducted health education classes to inform the subjects on how to measure and record HBP. After their ability to measure HBP was verified, subjects were asked to measure their own HBPs in the sitting position every morning within 1 h after waking and after ≥2 min of rest and to record the measurements for 4 weeks. All subjects were instructed to position their cuff-covered arms at heart level during HBP measurements. If individuals were taking antihypertensive medications, HBP was measured before taking medications. These procedures were described in detail in our previous report,10 and were developed according to the guidelines for self-monitoring of HBP.2 CBP was measured using the HEM 401C (Omron Healthcare Co. Ltd, Kyoto, Japan), a semi-automatic device based on the cuff-oscillometric principle, which generates a digital display of both systolic and diastolic BP.13

Annual health check-ups are available to all Japanese citizens aged 40 or over. Subjects are seated at rest for at least 2 min, then CBP is consecutively measured two times by nurses or technicians. A semi-automatic BP measuring device (UM700F; Ueda Electronic Work Co., Ltd, Tokyo, Japan) based on the microphone method was used.

The average arm circumference for subjects was typically <34 cm, so we used a standard arm cuff for both HBP and CBP measurements. The devices for measurement of CBP and HBP were calibrated before the start of the study.12 All devices met the criteria set by the Association for the Advancement of Medical Instrumentation.14

Classification of groups

On the basis of the 2003 ESH–ESC risk stratification system, the subjects were first classified into six BP categories as shown in Table 1. HBP-based and CBP-based criteria were defined as follows: optimal (HBP <115/75 mmHg, CBP <120/80 mmHg); normal (HBP 115/75–124/79 mmHg, CBP 120/80–129/84 mmHg); high normal (HBP 125/80–134/84 mmHg, CBP 130/85–139/89 mmHg); Grade 1 (mild hypertension: HBP 135/85–149/94 mmHg, CBP 140/90–159/99 mmHg); Grade 2 (moderate hypertension: HBP 150/95–164/104 mmHg, CBP 160/100–179/109 mmHg); Grade 3 (severe hypertension: HBP ≥165/105, CBP ≥180/110 mmHg). When a systolic or diastolic BP was in a different category, the subject was assigned to the higher category. The CBP classification was equal to the 2003 ESH–ESC criteria. In the present analysis, hypertension was defined as HBP ≥135/85 mmHg, according to the JNC-VI, JNC-7, and 2003 ESH–ESC guidelines; HBP of 135/
85 mmHg is equivalent to CBP of 140/90 mmHg. To define other BP levels based on HBP, we postulated that 75, 80, 95, and 105 mmHg of diastolic HBP were equivalent to 80, 85, 100, and 110 mmHg of diastolic CBP, respectively. Then systolic BP levels for HBP were introduced from the rate of subjects from each level of CBP classification. In the present analysis, we did not include the concept of pure systolic hypertension.

The individuals were then stratified into four classes based on the extent of cardiovascular risks: Class 1 (no risk factors), Class 2 (one or two risk factors), Class 3 (more than two risk factors or diabetes mellitus), and Class 4 (past history of CVD). Risk factors were defined as follows: age ≥55 for males, age ≥65 for females, body mass index (BMI) >25 kg/m², habitual smoking, and hypercholesterolaemia. Finally, study subjects were assigned to one of five groups, according to the 2003 ESH-ESC criteria: average risk, low added risk, moderate added risk, high added risk, and very high added risk (Table 1). Subjects with an optimal BP (optimal) who were not described in the risk stratification table of the original ESH-ESC guidelines were assigned to the average, low, or moderate risk group according to their classes. The average risk group was used as the reference group in the analysis. Subjects classified according to CBP and HBP were analysed separately.

In addition to these criteria, we also used the classification system based on the JNC-7 guidelines as previously reported. Briefly, the subjects were classified into four groups based on HBP or CBP according to the JNC-7 criteria: Group 1 (normotension: HBP <115/75 mmHg, CBP <120/80 mmHg); Group 2 (prehypertension: HBP 115/75–134/84 mmHg, CBP 120/80–139/89 mmHg); Group 3 (Stage 1 hypertension: HBP 135/85–149/94 mmHg, CBP 140/90–159/99 mmHg); Group 4 (Stage 2 hypertension: HBP ≥150/95 mmHg, CBP ≥160/100 mmHg). After classification of BP values, Groups 2–4 were divided into two subgroups—‘a’ and ‘b’—indicating those without and those with CVD risks (diabetes, hypercholesterolaemia, habitual smoking, or history of CVD), respectively. All subjects were assigned to one of seven categories (Groups 1, 2a, 3a . . . 4b) based on the JNC-7 classification.

Follow-up and risk ascertainment

We accumulated follow-up data until 31 December 2001. The subjects’ residence status in Ohasama was confirmed by registration cards. These cards are accurate and reliable because they are used for pensions and social security benefits in Japan. Twenty-seven subjects (1.8%) had moved away and were eliminated from follow-up, and 209 deaths (14.0%) were identified from the residents’ registration cards.

The incidence and past history of stroke were investigated through the Stroke Registration System of Iwate Prefecture, death certificates, receipt of National Health Insurance, and questionnaires sent to each household at the time of HBP measurement. The information was then confirmed by checking the medical records of Ohasama hospital where >90% of the subjects had their regular check-ups. We used computed tomography (CT) scans and magnetic resonance imaging (MRI) reports to determine the clinical definition of stroke. For 3% of stroke cases, death certificates were the only source of information. The analysis included only the first event in those who had multiple non-fatal events. The diagnostic criteria of stroke and their subtypes were based on the system for the Classification of Cerebrovascular Disease III by the National Institute of Neurological Disorders and Stroke.

Other information for individuals such as height, weight, habitual smoking, use of antihypertensive medication at baseline, history of heart disease, hypercholesterolaemia, or diabetes mellitus was obtained from questionnaires sent to each household at the time of HBP measurements, from records of annual health check-ups, and from medical records at Ohasama Hospital. Subjects using lipid-lowering drugs or those with serum cholesterol levels of ≥5.68 mmol/L (220 mg/dL) were considered to have hypercholesterolaemia. Subjects with a fasting glucose level of ≥7.77 mmol/L (140 mg/dL) or non-fasting glucose level of ≥11.11 mmol/L (200 mg/dL), or those using insulin or oral antihyperglycaemic drugs were defined as having diabetes mellitus. A past history of CVD included a history of myocardial infarction, angina pectoris, atrial fibrillation, or cardiac failure.

Data analysis

The HBP values were the average of all home measurements per subject. CBP of each subject was the average of two consecutive CBP readings taken at the beginning of the study.

The risk of the first stroke was examined using the Cox proportional hazards model. The dependent variable was the number of days from the initial HBP measurement to the date of stroke or censoring. Stroke-free survivors as of December 31, 2001 were censored. The independent variables were the groups of the risk stratification system using the 2003 ESH-ESC guidelines in which factors of age and sex were included. In further analysis, the risk in relation to the JNC-7 guideline-based classification was examined by the Cox model adjusted for age and sex. When we analysed the incidence of stroke, we censored cases of death from causes other than fatal stroke events.

The estimated relative hazard (RH) and the 95% confidence interval (95% CI) of variables were derived from the coefficient and standard error determined by the Cox proportional hazards model. The RH is expressed relative to Group 1 (average risk; RH = 1). Separate models were used for HBP classification and CBP classification after verification of the assumption of proportionality for the Cox proportional hazards models. The predictive values of HBP classification and CBP classification were evaluated using the comparison of corresponding regression coefficients and log likelihoods in the Cox model. We also assessed the interaction between antihypertensive medication and the five risk groups using the Cox model with stroke as the endpoint. All data are shown as mean (SD) unless otherwise stated. A P-value <0.05 (two-sided test) was accepted as indicative of statistical significance. The SAS system (Version 8.2, SAS Institute Inc., Cary, NC, USA) was used for all statistical calculations.

Results

The subjects were followed up for a median of 10.9 (interquartile 8.9–13.9) years, to a maximum of 13.9 years. We obtained 149 incident cases of first stroke among the 1702 individuals: 106 (69%) cerebral infarction, 28 (18%) intracerebral haemorrhage, 12 (8%) subarachnoid haemorrhage, and 3 (2%) unknown causes. In addition to 149 stroke cases, four incidences of transient ischaemic attack were observed, and excluded from the analysis. There was no interaction between the use of antihypertensive medication and the five risk groups (HBP, P = 0.7; CBP, P = 0.4).

The characteristics of the subjects are shown in Table 2. Of the 1702 study subjects, 370 (22%) were classified as current or ex-smokers; 507 (30%) were treated with antihypertensive medication at baseline; 16 (1%) had a history of heart disease; 218 (13%) had diabetes mellitus, and 207 (12%) had hypercholesterolaemia. The mean number of HBP measurements from each individual was 23.0 (7.1). The mean systolic and diastolic HBP of all subjects were 125.2 (15.0) and 74.9 (10.1) mmHg, respectively.

The risk of first stroke of the five groups in HBP classification and CBP classification is shown in Figure 1A and B. Stroke risk was increased linearly, with the increase in the grade of stratified risk based on HBP, as well as on CBP. Even in the low risk group, the risk for stroke was
Table 2  Clinical characteristics among groups

<table>
<thead>
<tr>
<th>Variables</th>
<th>Average</th>
<th>Low</th>
<th>Moderate</th>
<th>High</th>
<th>Very high</th>
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<tr>
<td>Number of subjects</td>
<td>584</td>
<td>543</td>
<td>377</td>
<td>160</td>
<td>38</td>
</tr>
<tr>
<td>Age (years)</td>
<td>54.9±9.1</td>
<td>61.5±9.8</td>
<td>65.5±10.6</td>
<td>64.5±9.1</td>
<td>68.2±11.0</td>
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<td>Male (%)</td>
<td>23.8</td>
<td>42.2</td>
<td>52.5</td>
<td>50.0</td>
<td>63.2</td>
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<tr>
<td>BMI (kg/m²)</td>
<td>22.4±2.4</td>
<td>23.7±3.1</td>
<td>23.6±3.2</td>
<td>25.0±3.3</td>
<td>24.1±4.7</td>
</tr>
<tr>
<td>PH CVD (%)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>3.8</td>
<td>26.3</td>
</tr>
<tr>
<td>Diabetes (%)</td>
<td>0</td>
<td>8.3</td>
<td>11.9</td>
<td>75.6</td>
<td>18.4</td>
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<tr>
<td>Smoking (%)</td>
<td>8.9</td>
<td>27.8</td>
<td>26.8</td>
<td>33.1</td>
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<td>Hypercholesterolaemia (%)</td>
<td>3.1</td>
<td>12.7</td>
<td>11.9</td>
<td>43.1</td>
<td>15.8</td>
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<tr>
<td>Use of antihypertensive medication (%)</td>
<td>11.8</td>
<td>26.2</td>
<td>46.9</td>
<td>60.0</td>
<td>60.5</td>
</tr>
<tr>
<td>Home SBP (mmHg)</td>
<td>112.6±8.8</td>
<td>123.5±8.2</td>
<td>138.8±11.5</td>
<td>137.2±10.1</td>
<td>157.1±16.8</td>
</tr>
<tr>
<td>Home DBP (mmHg)</td>
<td>72.0±10.5</td>
<td>74.9±10.8</td>
<td>80.0±11.9</td>
<td>79.8±12.7</td>
<td>83.4±13.3</td>
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</table>

Casual blood pressure based groups

<table>
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<th>Variables</th>
<th>Average</th>
<th>Low</th>
<th>Moderate</th>
<th>High</th>
<th>Very high</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of subjects</td>
<td>529</td>
<td>564</td>
<td>408</td>
<td>158</td>
<td>43</td>
</tr>
<tr>
<td>Age (years)</td>
<td>55.1±8.5</td>
<td>61.3±10.7</td>
<td>64.9±10.7</td>
<td>63.6±9.3</td>
<td>65.2±12.3</td>
</tr>
<tr>
<td>Male (%)</td>
<td>24.0</td>
<td>45.2</td>
<td>46.1</td>
<td>51.3</td>
<td>44.2</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>22.3±2.2</td>
<td>23.5±3.1</td>
<td>24.0±3.4</td>
<td>24.8±3.5</td>
<td>24.0±3.1</td>
</tr>
<tr>
<td>PH CVD (%)</td>
<td>0</td>
<td>0</td>
<td>1.0</td>
<td>1.3</td>
<td>23.3</td>
</tr>
<tr>
<td>Diabetes (%)</td>
<td>0</td>
<td>5.9</td>
<td>11.8</td>
<td>82.3</td>
<td>16.3</td>
</tr>
<tr>
<td>Smoking (%)</td>
<td>11.3</td>
<td>27.3</td>
<td>24.5</td>
<td>29.7</td>
<td>20.9</td>
</tr>
<tr>
<td>Hypercholesterolaemia (%)</td>
<td>2.6</td>
<td>11.2</td>
<td>15.4</td>
<td>36.1</td>
<td>23.3</td>
</tr>
<tr>
<td>Use of antihypertensive medication (%)</td>
<td>14.2</td>
<td>26.1</td>
<td>45.8</td>
<td>47.5</td>
<td>53.5</td>
</tr>
<tr>
<td>Home SBP (mmHg)</td>
<td>115.5±11.2</td>
<td>124.8±13.0</td>
<td>133.9±14.3</td>
<td>132.3±14.5</td>
<td>140.6±15.1</td>
</tr>
<tr>
<td>Home DBP (mmHg)</td>
<td>70.1±8.6</td>
<td>75.0±8.9</td>
<td>78.9±10.4</td>
<td>78.6±10.2</td>
<td>82.0±11.7</td>
</tr>
</tbody>
</table>

See Table 1 for definitions of groups. Values are expressed as mean ± SD. CVD, cardiovascular disease; SBP, systolic blood pressure; DBP, diastolic blood pressure.

Figure 1  Risk of first stroke based on HBP or CBP values and cardiovascular risks. (A) and (B) demonstrate RH and 95% CI for first stroke plotted on a log scale among all groups classified by CBP (A) and HBP (B) values. Ave.: average risk group, Low: low added risk group, Mod.: moderate added risk group, High: high added risk group, Very High: very high added risk group. (C) demonstrates RH and 95% CI for first stroke according to JNC-7 classification based on HBP values. Absolute risks display incidence per 1000 person-years. Group definitions are shown in Table 1 and in the Methods section. The average group (2003 ESH–ESC) or Group 1 (JNC-7) is treated as the reference category. Solid squares indicate the RH point and are sized in proportion to the number of events observed. Vertical lines extending from squares represent 95% CI. Trend P-values express the linearity among groups.
significantly higher than in the average risk group. In the low risk group, there was no difference in the stroke risk between HBP classification and CBP classification (HBP: RH = 2.24, 95% CI 1.32–3.80, P = 0.003; CBP: RH = 2.76, 95% CI 1.63–4.66, P = 0.0001). The stroke risk in the very high risk group was extremely high when subjects were classified by HBP (RH = 14.4, 95% CI 6.92–29.8, P < 0.0001). The predictive power decreased when subjects were classified by CBP (RH = 5.30, 95% CI 2.23–12.6, P = 0.0002). The statistically significant linearity among the groups was observed for both HBP and CBP classifications (trend P < 0.0001). When we designated the low risk group as a reference category in the Cox model, the stroke risk in the moderate risk group was significantly high for HBP (RH = 2.04, 95% CI 1.34–3.09, P = 0.0009), whereas the moderate risk group was not significantly different from the low risk group using the CBP classification (RH = 1.33, 95% CI 0.90–1.97, P = 0.2). When both classifications were treated as continuous variables and were simultaneously included in the model, only HBP classification was significantly related with stroke risk (HBP classification: RH = 1.88, 95% CI 1.55–2.28, P < 0.0001; CBP classification: RH = 0.98, 95% CI 0.81–1.20, P = 0.9). The model, including both HBP and CBP classifications, lost ‘goodness of fit’ when HBP was removed (likelihood ratio 40.2, P < 0.001), whereas no significant changes occurred when CBP was removed (likelihood ratio 0.028, P = 0.9). The same results were observed when transient ischaemic attack was included in the stroke incidence (data not shown).

We conducted further analysis by comparing the JNC-7 guideline-based classification (including subarachnoid haemorrhage and excluding transient ischaemic attack which was a modified analysis from our previous study) and the 2003 ESH–ESC guideline-based classification (Figure 1B and C based on HBP). The stroke risk in Group 4b (highest) was significantly elevated for HBP classification (RH = 4.54, 95% CI 2.16–9.54, P < 0.0001) as well as for CBP (RH = 2.81, 95% CI 1.31–6.04, P = 0.008). However, for the magnitude of RH, the stroke risk based on the 2003 ESH–ESC classification was clearly more dramatic than that based on the JNC-7 classification.

**Discussion**

The 2003 ESH–ESC guidelines for treating hypertension emphasize a composite risk stratification system based on CBP categories and other risk factors. In this prospective cohort study, we found that the 2003 ESH–ESC classification was useful and applicable for a general Japanese population in predicting future stroke incidence. Furthermore, the risk stratification system became extremely powerful for the prediction of stroke incidence when HBP was used instead of CBP. These results were based on a comprehensive follow-up system in the Ohasama cohort as described previously and the high reliability of diagnoses of stroke and subtypes according to CT/MRI. Although some of the stroke cases were determined by death certificates only, these were limited to 3% of the total cases. Although some of the risk parameters from the 2003 ESH–ESC guidelines were not evaluated, it is a reasonable assumption that the predictive power of HBP as well as CBP would be emphasized if those unmeasured parameters were included in our analysis. Thus, the results support the usefulness of the 2003 ESH–ESC guidelines for the general Japanese population, especially when information on BP is based on HBP.

In comparison with the 2003 ESH–ESC guidelines, the JNC-7 classification adopts a simplified risk stratification that consists of four grades based on CBP. Individuals who have hypertension and at least one risk factor are considered to be candidates for antihypertensive drugs and intensive treatment. Thus their cardiovascular risks are not thoroughly considered in JNC-7. We reported in the previous study that the JNC-7 classification is applicable for the general Japanese population. However, when based on the risk stratification system proposed in the 2003 ESH–ESC guidelines, the measurements of HBP as well as CBP would predict the first stroke incidence more accurately than those based on the simplified risk stratification in JNC-7 as shown in the current study (refer to Asayama et al.5). It is a reasonable assumption that a comprehensive risk stratification system could be used for individualized BP management. Furthermore, we would like to emphasize that in this study, the stroke risk in the moderate risk group was significantly higher than that in the low risk group when based on HBP, whereas no significant differences were observed between two risk groups when based on CBP; these findings support the assertion that BP management should be based on HBP information.

The 2003 ESH–ESC guidelines set the reference value of hypertension using HBP at 135/85 mmHg. In the present study, hypertension was also defined as HBP at 135/85 mmHg, then HBP was classified by the percentage distribution of subjects according to the corresponding ratio of CBP. A stepwise increase of stroke risk in the stratification system was observed when based on HBP as well as CBP in the current study. It should be noted that high-normal individuals and prehypertension have relatively high CVD risk when compared with individuals with optimal17 or normal BP. Hypothetically speaking, the lower the BP, the better the stroke prevention.19

Approximately one-quarter of our subjects with high-normal BP (23.5% based on HBP and 22.5% based on CBP) were classified as average risk according to the 2003 ESH–ESC guidelines. There were 89 high-normal BP subjects among 584 (HBP-based) and 89 high-normal subjects among the 529 (CBP-based) average risk subjects. A major difference between the 2003 ESH–ESC and JNC-7 guidelines is that the latter advises pharmacological or non-pharmacological intervention in all prehypertensives (high-normal or normal BP), whereas the former suggests intervention only for those who are in the low added risk but not in the average risk category.20 According to our results, it was obvious that individuals in the low risk group needed treatment even though their BP was within normal limits, whereas treatment for the average risk individuals remains a matter for debate.

Although HBP measurement is now acknowledged worldwide in the major guidelines as a useful tool for clinical practice, lack of information on the prognostic significance has limited its use in clinical decision-making. In the present study, we demonstrated that HBP measurements provide more useful prognostic information in cerebrovascular disease than CBP measurements. Information on BP in relation to the time of day, as well as an increased number of measurements, improves the quality of data. Furthermore, HBP is usually measured under more
controlled conditions than CBP. The average of multiple values of HBP obtained under controlled conditions provides individual BP information without biases such as white-coat effect, regression dilution biases, and time effect. In conclusion, the risk stratification system proposed in the 2003 ESH-ESC guidelines was valid for the prediction of stroke incidence in populations outside Europe, and we found that the stratification based on HBP measurements is a valuable tool for predicting the incidence of stroke. Guidelines based on individualized medications, such as the 2003 ESH-ESC guidelines, are more useful and applicable than those based on simple BP-oriented medications, such as the JNC-7. HBP measurement is a useful tool to improve awareness of hypertension and to predict future incidence of cerebrovascular disease.

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