



# Importance of reconfirming the validity of the revised blood pressure categories

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The 2017 American College of Cardiology/American Heart Association (ACC/AHA) Guidelines [1] impacted clinical practice because it proposes to reduce the criteria for diagnosis of hypertension from 140/90 mmHg or more, which other major guidelines have followed, to  $\geq 130/\geq 80$  mmHg (Fig. 1A). The primary evidence came from the Systolic Blood Pressure Intervention Trial (SPRINT) [2], and the recent Strategy of Blood Pressure Intervention in the Elderly Hypertensive Patients (STEP) Chinese trial [3] supported the rationale of this threshold. Although various discussion is still in dispute, one cannot overlook the enormity of the revised threshold by the united 11 authorities [1], even aimed at a patient outside the US. Nevertheless, the revised thresholds have not become dominant worldwide. The 2018 European Society of Cardiology/European Society of Hypertension (ESC/ESH) Guidelines [4] kept the hypertension thresholds as 140/90 mmHg, and kept the optimal, normal, and high-normal subcategory of non-hypertensive range unchanged (Fig. 1B). The 2019 Japanese Society of Hypertension (JSH) Guidelines [5] proposed an eclectic classification, i.e., the more intensive subcategory for people with non-hypertension but still use the same thresholds for hypertension (Fig. 1C). The International Society of Hypertension recently proposed another classification of hypertension (Fig. 1D) in which the

generally-accepted criteria, 140/90 mmHg or more, was kept while the category definition was simplified to align therapeutic approaches with blood pressure (BP) levels [6]. A guideline shall be applied for each targeted population; however, which BP classification is best suited for a specific population to prevent cardiovascular disease and other significant diseases should be individually validated.

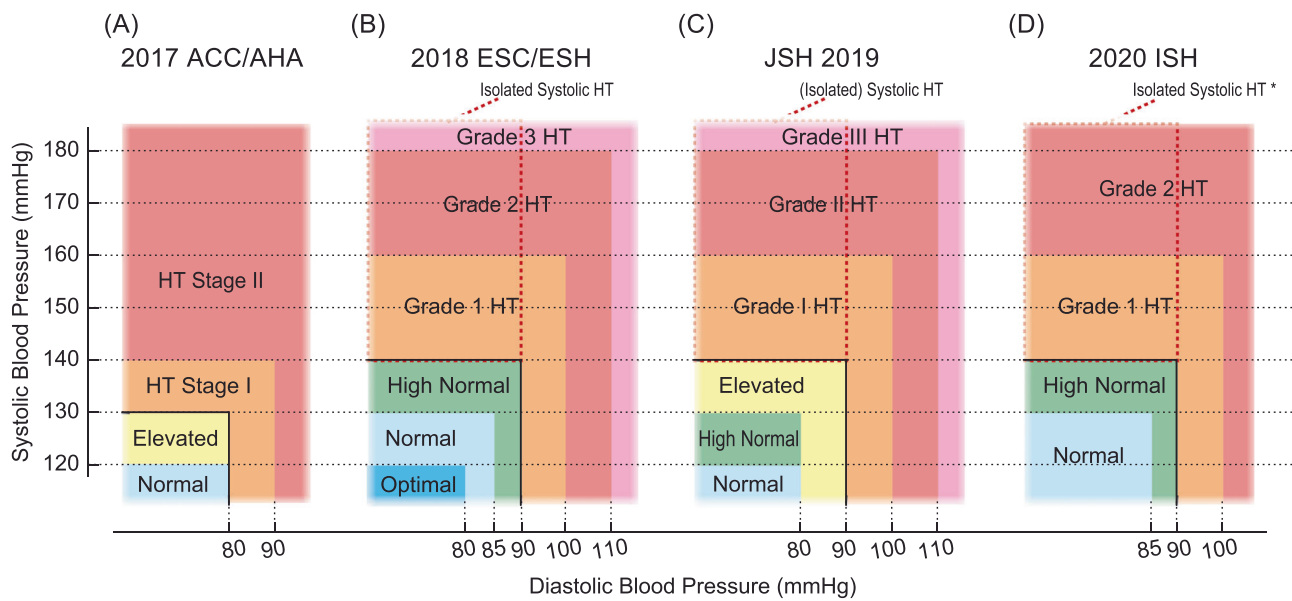
The Suita study is known as a Japanese urban-sided prospective cohort study [7]. Arafa and colleagues investigated the usefulness of BP categories by the 2019 JSH Guidelines [5] for predicting cardiovascular diseases among 7,643 Suita Study participants (53.6% women; average age, 55.3 years, age range, 30–84 years) [8]. During the median 16.6 years of follow-up, 690 participants developed cardiovascular diseases, encompassing 411 strokes and 279 coronary heart diseases. When based on a fully-adjusted model including antihypertensive drug therapy, high-normal and elevated BPs had significantly higher cardiovascular diseases compared with normal BP, as hazard ratios (HR) were 1.49 (95% confidence intervals [CI], 1.08–2.05) and 1.72 (CI, 1.34–2.20), respectively. A significantly higher risk for coronary heart disease was also observed in participants with high-normal BP (HR, 1.99; 95% CI, 1.18–3.36), while that for stroke did not reach the significance (HR, 1.29, 95% CI, 0.86–1.93). Surprisingly, in contrast to Japanese individual participant-level meta-analysis [9], the less steep cardiovascular risk increase as a BP category increment was observed when 889 patients with antihypertensive medication were excluded [8]. However, because only 2 of 110 cardiovascular events occurred among these patients with normal BP [8], the main driver for the less steep risk increment is likely to be the elimination of high-risk patients with high-normal and upper BP categories who took antihypertensive drug treatment. Meanwhile, the association between BP categories and cardiovascular disease risk was attenuated among older adults aged  $\geq 65$  years [8], which is confirmatory. In another

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**Fig. 1** Classification of conventional office blood pressure levels according to the (A) 2017 ACC/AHA, (B) 2018 ESC/ESH, (C) JSH 2019, and (D) 2020 ISH Guidelines. The vertical axis indicates systolic blood pressure (mmHg), and the horizontal axis indicates diastolic blood pressure (mmHg) across the 4 Guidelines. \*Isolated systolic hypertension was referred to in the main text but not used for the classification of the 2020 ISH. HT, ACC/AHA 2017, ESC/ESH

2018, JSH 2019, and 2020 ISH denote hypertension, the 2017 American College of Cardiology/American Heart Association Guidelines, the 2018 European Society of Cardiology/European Society of Hypertension Guidelines, the Japanese Society of Hypertension Guidelines for the Management of Hypertension (JSH 2019), and the 2020 International Society of Hypertension Global Hypertension Practice Guidelines, respectively

report [10], they further focused on heart failure by investigating the risk judged by the B-type natriuretic peptide (BNP) levels  $\geq 100$  pg/mL according to the BP categories based on the 2017 ACC/AHA [1] and 2018 ESC/ESH [4] Guidelines. Among the 2,809 Suita population who measured BNP, significant risk increases were observed in participants with hypertension stage I according to the 2017 ACC/AHA Guidelines and in those with high-normal BP according to the 2018 ESC/ESH Guidelines, when compared both with the lowest categories.

The increasing trend of cardiovascular diseases, including stroke, coronary heart disease, and heart failure per BP categories increase, was constantly observed across the analysis [8, 10]. A significance likely depends on the person-year follow-up period of a population and risk in reference categories in these studies. Nevertheless, significant risk increases among participants without hypertension but higher than the lowest BP category were observed, even based on a comparably small sample of under a dozen of thousand population. The reports call our attention to these high-normal/elevated BP populations. The calculated population attributable fraction among the Suita participants with high-normal and elevated BPs, based on the JSH 2019 Guidelines [5], were 2.7% (95% CI, 0.6–4.2%) and 3.8% (95% CI, 2.3–4.9%) [8], which seems not significantly impacted at a glance. However, considering that 34.9% of the study participants belonged to these categories, intensive treatment, regardless of pharmacological approach or lifestyle

improvement, to this massive population must be essential for a population strategy to reduce cardiovascular risk worldwide.

The BP classification and the target BP levels for anti-hypertensive treatment are confusing and sometimes mixed up. The former is mainly used for treatment-naïve individuals; in contrast, physicians should consider the target BP according to the condition of each patient who initializes and continues antihypertensive medication. Nevertheless, meta-analyses of trials demonstrated that BP-lowering treatment reduced cardiovascular diseases irrespective of the initial BP level before the treatment [11, 12]. Therefore, primarily aiming to shift down to the one lower BP category may be a widely acceptable treatment strategy for most patients as the first step. It can break down clinical inertia on a patient side. Overcoming clinical inertia on a clinician's side is also essential; clinicians shall not neglect their effort to tighten the treatment to stringently achieve the target BP level for those who need more risk reduction, as the recent trials confirmed the benefit [2, 3].

Like other risk factors, amendment of BP thresholds affects succeeding risk estimation and classification established by the previously used values, particularly when absolute risk and population attributable fraction are calculated [13]. Furthermore, the different thresholds may affect the prospective association in a population where the classical BP category-based risk stratification has already been established [13, 14]. To maintain and expand the

usefulness of such risk stratification, we should reassess and update it whenever needed. At the same time, we should pay great attention to the surrounding conditions that can alter the established guidelines, e.g., medical and social advancement through changing times and emerging critical outcomes such as dementia and frailty. The measurement methodology is also indispensable, as office BP shall be measured according to the guidelines proposing BP classification. Moreover, considering the evidence that supports the more prognostic ability of out-of-office BP compared with conventional office BP [15], utilization of out-of-office BP would also be a fundamental approach.

### Compliance with ethical standards

**Conflict of interest** KA received research support from Omron Healthcare.

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