



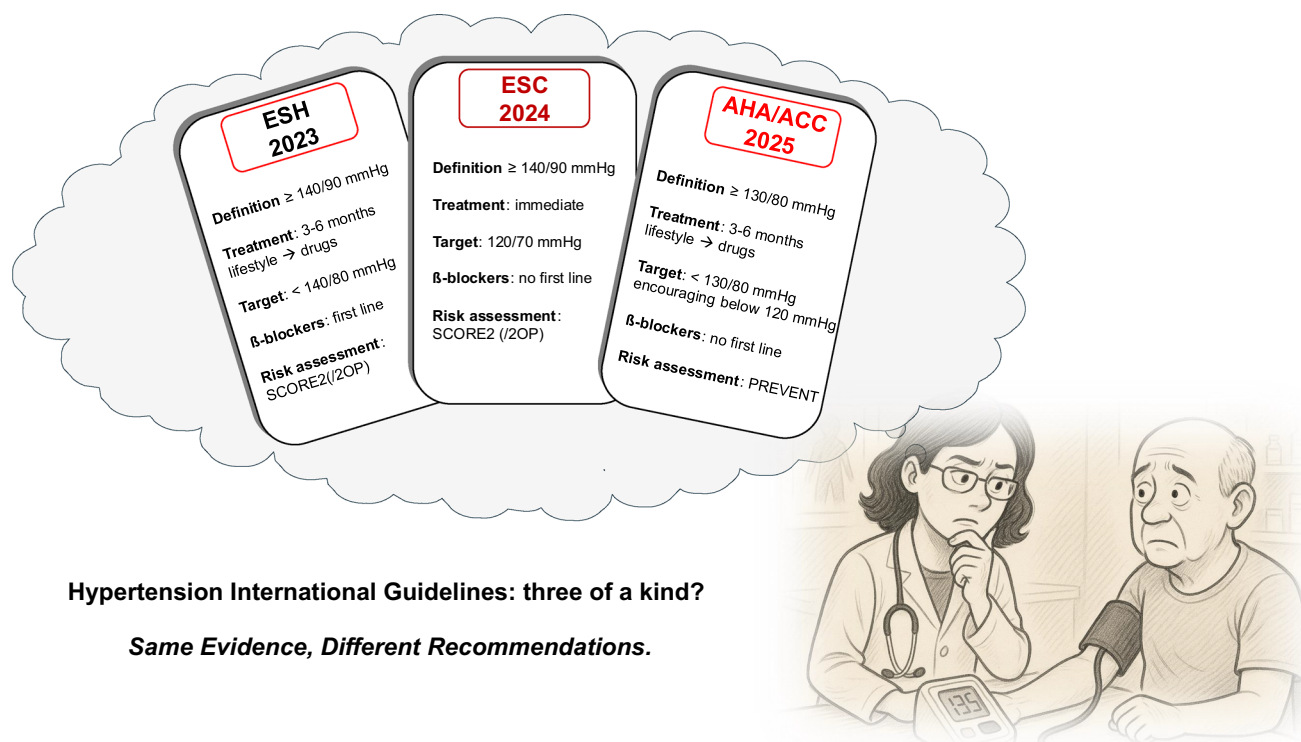
Hypertension International Guidelines: Three of a Kind?

Agostino Virdis¹ · Maria Lorenza Muiesan² · Guido Grassi³ · Massimo Volpe^{4,5}

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Graphical Abstract



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Same Evidence, Different Recommendations.

1 Introduction

In August 2025, the new “Guidelines for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults” [1], as a result of a joint effort by the American Heart Association (AHA)/American College of Cardiology (ACC)/American Association of Nurse Practitioners/American Academy of Physician Assistants/Association of Black Cardiologists/American Association of Colleges of Pharmacy/ American College of Preventive Medicine/American Geriatrics Society/American Medical Association/American Society for Preventive Cardiology were published on Circulation and Hypertension [1]. The US guidelines follow the 2023 European “Guidelines for the management of arterial hypertension” from the European Society of Hypertension (ESH)

✉ Agostino Virdis
agostino.virdis@unipi.it

¹ Department of Clinical and Experimental Medicine and Geriatric Unit, University of Pisa, Via Paradisa 2, Ospedale Cisanello, 56124 Pisa, Italy

² Department of Clinical and Experimental Sciences, University of Brescia, and ASST Spedali Civili Brescia, Brescia, Italy

³ Department of Medicine, Surgery University Milano-Bicocca, Milan, Italy

⁴ IRCCS San Raffaele Roma, Rome, Italy

⁵ University of Rome Sapienza, Rome, Italy

[2], endorsed by the European Renal Association (ERA) and the International Society of Hypertension (ISH), and the 2024 “Guidelines for the management of elevated blood pressure and hypertension” [3] of the European Society of Cardiology (ESC) endorsed by the European Society of Endocrinology (ESE) and the European Stroke Organisation (ESO). At the pace of one major international guideline per year, it appears clear the relevance that arterial hypertension holds in the global healthcare landscape. On the other hand, these multitude of documents may generate confusion especially when they deliver different recommendations. Diseases partially driven by environmental factors, lifestyle habits and stressors, such as hypertension, may certainly imply geographical differences. Indeed, using the same blood pressure (BP) diagnostic criteria (the European ones), the prevalence of arterial hypertension in Europe is 37% [4], while in the US it is 46% [5]. Thus, the development of new US guidelines is definitely appropriate, especially when considering that the previous document was issued 8 years before [6]. Nevertheless, it is interesting to see if, and where, these new guidelines compared to the two almost contemporary European documents differ in their general approach and in a number of recommendations. In fact, it appears puzzling why, in the presence of the same available scientific evidence, the documents produced may produce multiple relevant differences and deliver different recommendations to the medical community.

2 Definition of Arterial Hypertension: Who, How and When

From the title onwards, it is interesting to note the different choices made by the task-forces in the three guidelines. The ESH and AHA/ACC remain consistent with the style of previous guidelines. While the ESH is focused on the disease, the AHA/ACC also emphasizes the importance of “prevention, detection and evaluation” as well as “management”. The ESC, on the other hand, introduce the new category of “elevated blood pressure” in the title. Turning to the definitions, the AHA/ACC adopted a systolic blood pressure (SBP) threshold of 130 mmHg and a diastolic blood pressure (DBP) threshold of 80 mmHg, which is consistent with that of the 2017 guidelines [6]. This is different from both the ESH and ESC and is based on the need for a more urgent and aggressive prevention and intervention strategy, as advocated by US physicians. This substantial change, indeed, halted the decline in BP control observed between 2013 and 2016, although the level of BP control has remained stable ever since [7]. In terms of classification, the AHA/ACC remains consistent with the 2017 guidelines by using the “elevated blood pressure” category, which was also adopted by the ESC in 2024, albeit with different

cut-offs, as well as stages 1 and 2. Hypertension grading at three levels is present only in the ESH guidelines.

Some nuances are present regarding when to start pharmacological treatment. All three guidelines emphasize the need for lifestyle changes, regardless of BP control. As a general rule, all three guidelines recommend initiating treatment at 140/90 mmHg. However, the ESH takes a more conservative approach, recommending 3–6 months of lifestyle changes before starting treatment, unless BP is above 160/100 mmHg, the cardiovascular risk is high, or an established cardiovascular disease is present. In the last case, ESH recommends immediate treatment at BP levels of $\geq 130/80$ mmHg. The ESC and AHA/ACC bypass lifestyle intervention alone for BP $\geq 140/90$ mmHg. The AHA/ACC recommends immediate intervention when BP is $\geq 130/80$ mmHg in cases of previous cardiovascular events and high CV risk, in line with the ESH.

3 Treatment: Targets and Interventions

In terms of BP targets, the AHA/ACC guidelines do not explicitly state the ALARA (As low as Reasonably Achievable) principle as the ESC does. However, they substantially adhere to this principle by encouraging the achievement of a SBP below 120 mmHg. The ESH takes a more gradual approach based on age, but does not advocate a reduction SBP below 120 mmHg.

Also the recommended way to measure BP shows significant differences among the Guidelines since office BP measurement remains the reference measure in ESH and US Guidelines, whereas ESC Guidelines surprisingly endorse out-of-office measures (home and 24-hour ambulatory BP) as the main reference approach [8].

Recommendations for lifestyle changes are broadly similar among the three different guidelines. All of them mention potassium intake and salt substitutes as a strategy to reduce both BP and cardiovascular risk. Surprisingly, the AHA/ACC guidelines barely mention smoking (except in the section on renal artery stenosis) or the need to restrict sugar-sweetened beverages [9]. On the other hand, unlike ESC but in line with ESH, AHA/ACC also discusses stress management as a lifestyle intervention. In terms of pharmacological choice, all three guidelines substantially support dual fixed-dose single-pill combinations and ACE inhibitors, ARBs, CCBs and thiazide or thiazide-like diuretics as first-choice drugs. The AHA/ACC and ESC relegate beta-blockers only to conditions when compelling indications are present. It is interesting to note that AHA/ACC included not only drug classes but also a comprehensive list of FDA-approved agents for each class; this choice is consistent with their previous edition [6] but not shared by ESH and ESC.

Finally, the approach to resistant hypertension is substantially similar, with renal denervation being endorsed, but not as a first-line intervention (class IIA), and only in specialized centers following a shared decision-making process between the patient and a multidisciplinary team with recognized expertise.

4 Secondary Hypertension, Comorbidities, and Organ Damage

Secondary hypertension screening is recommended by all three guidelines when clinical suspicion is present. Nevertheless, the AHA/ACC guidelines particularly emphasize screening for primary aldosteronism, with one minor difference: while the ESC guidelines recommend screening all newly diagnosed hypertensive patients, the AHA/ACC guidelines focus more on ruling out primary aldosteronism in adults with resistant hypertension. In terms of comorbidities and conditions associated with high/very high cardiovascular risk, there are no major differences except that the ESH also includes atrial fibrillation. However, the AHA/ACC guidelines do not discuss hypertension-mediated organ damage (HMOD), which is accurately detailed in the other two guidelines. This reflects AHA/ACC more pragmatic approach but leaves a key aspect of hypertension management in a grey area.

5 Risk Assessment and Risk-Based Approach

The risk assessment in the AHA/ACC guidelines differs in two major ways from European Guidelines. First, it uses the PREVENT risk calculator [10], which appears to be more comprehensive than the SCORE2/SCORE2-OP [11] as it also takes into account renal function and body mass index. Secondly, the risk calculation is also used to determine when and if to initiate pharmacological treatment for stage 1 AHA/ACC hypertension (i.e. 130–139/80–89 mmHg). This has three consequences: (i) formal risk analysis is required for all hypertensive patients. Although this is less pragmatic than other ACC/AHA recommendations, it aligns with the need to promote cardiovascular prevention and raise individual awareness of cardiovascular risk; (ii) it delays drug initiation to 3–6 months after a lifestyle intervention for most hypertensive patients, which substantially goes along with the ESH guidelines, as discussed above; (iii) it formally recommends pharmacological treatment for low-risk patients with BP below 140/90 mmHg. However, there is no direct evidence to support this, and given that a lower absolute risk reduction is expected in low-risk patients, the

cost-effectiveness of the intervention in terms of healthcare expenses and patient compliance may be low. Although risk calculation must be integrated into clinical routines, and cardiometabolic prevention must focus on global rather than disease-specific risk reduction, current tools and evidence require further refinement and confirmation, particularly when influencing treatment initiation in hypertension. The ESH guidelines contain a dedicated paragraph (“9.1 *Should treatment initiation be based on total CV risk?*”) that addresses this issue accurately and aligns with a recent editorial on the AHA/ACC guidelines [12].

6 Older Adults

Unlike the ESH and ESC, the AHA/ACC does not have a dedicated section for older adults. In fact, in line with the ESC guidelines, they generally propose an age-independent management of hypertension, unless certain circumstances apply. For instance, they adopt a more cautious approach to initiating drug treatment for stage 1 AHA/ACC hypertension in patients over 80 years old, and advocate monotherapy for frail patients. The ESC approach is age-independent until the age of 85, at which point they support the use of a clinical frailty scale to categorize patients as either non-frail or frail, and to inform intervention strategies based on these categories. Of the three, the ESH provides a more granular approach, adopting a more extensive stratification for age (18–64, 65–79, 80+) and frailty (fit, slowed but autonomous, severely dependent). Nevertheless, the AHA/ACC guidelines are the only ones to mention dementia and cognitive decline not only as comorbidities of hypertension, but also as a target for prevention, providing a precise BP target supported by evidence (i.e. SBP <130 mmHg). It is worth noting that sarcopenia, another geriatric syndrome which is already having an impact on the healthcare system worldwide and is set to worsen [13], is not mentioned in any of the three guidelines.

7 Conclusions

The AHA/ACC guidelines fulfill their expectations. They are consistent with previous editions and evidence-based. The most notable new features are the emphasis on screening for secondary hypertension and the prevention of cognitive decline. Their tighter definition of hypertension is a consequence of the national healthcare policy in US. From a practical perspective, the three guidelines are similar in several aspects, and it is important that they take a new approach to assessing global individual risk rather than relying on blood pressure levels alone. This tentative paradigm shift towards a risk-driven approach is particularly apparent in the AHA/

Table 1 Back to back comparisons between the AHA/ACC, ESC and ESH guidelines

	ESH 2023	ESC 2024	AHA/ACC 2025
Definition of hypertension (BP threshold)	SBP ≥ 140 or DBP ≥ 90 , or both; further stratified into grades for severity: Grade 1: 140–159 or 90–99 Grade 2: 160–179 or 100–109 Grade 3: ≥ 180 or ≥ 110 Uncontrolled hypertension: ≥ 140 or ≥ 90 (varies by age-specific goal)	SBP ≥ 140 or DBP ≥ 90 , or both; no formal BP stage/grade: 140–159 or 90–99: confirm by HBPM/ABPM 160–179 or 100–109: confirm by HBPM/ABPM within 1 month ≥ 180 or ≥ 110 : exclude hypertensive emergency Uncontrolled hypertension: ≥ 140 or ≥ 90	SBP ≥ 130 or DBP ≥ 80 , or both; Uncontrolled hypertension: ≥ 130 or ≥ 80
BP categories	Grade 1: 140–159 or 90–99 Grade 2: 160–179 or 100–109 Grade 3: ≥ 180 or ≥ 110 High normal: 130–139 or 85–89 Normal: 120–129 and 80–84 Optimal: <120 and <80	Hypertension SBP ≥ 140 or DBP ≥ 90 , Elevated: 120–139 or 70–89 Non elevated: <120 and <70 (no “normal” definition)	Stage 1: 130–139 or 80–89 Stage 2: ≥ 140 or ≥ 90 Elevated: 120–129 and <80 Normal: <120 and <80
Severe hypertension ($>180/120$ mm Hg) without evidence of acute target organ damage	Hypertensive urgency	Hypertensive urgency	Uncontrolled HT
Drug choice	ACE-inhibitors, ARBs, CCB, thiazide or thiazide-like diuretics, beta-blockers. Dual fixed dose single pill combination for most patients with BP ≥ 140 or ≥ 90 mmHg	ACE-inhibitors, ARBs, CCB, thiazide or thiazide-like diuretics. Beta-blockers (only if compelling indications: post AMI, CAD, HF, angina, heart rate control). Low dose dual fixed dose single pill combination for most patients with BP ≥ 140 or ≥ 90 mmHg	ACE-inhibitors, ARBs, CCB, thiazide or thiazide-like diuretics. Beta-blockers (only if compelling indications: post AMI, CAD, HF, angina, heart rate control). Dual fixed-dose single pill combination for stage 2 hypertension or non-frail with BP $\geq 20/10$ mm Hg above goal
Drugs combination to start	Start with ACE-inhibitors or ARBs, + CCB or diuretic	Start with ACE-inhibitors or ARBs, + CCB or diuretic	Start with ACE-inhibitors or ARBs, + CCB or diuretic
Monotherapy choice	Grade 1 HT and low CV risk, High normal BP and high CV risk, Frailty, Advanced age	Elevated BP, Frailty, Age ≥ 85 years, Symptomatic orthostatic hypotension	Stage 1 hypertension
Target BP	General target: <140 and 80 mm Hg in most patients <u>Age-related targets</u> 18–64: 120–129 and 70–79 65–79: <140 and <80 , but a lower BP target of 120–129 and 70–79>: may be considered if well-tolerated ≥ 80 : SBP of 140–150; a lower SBP target of 130–139 may be considered if well tolerated Frailty: individualize treatment target	General target: 120–129 and 70–79; Age ≥ 85 y with moderate to severe frailty, orthostatic hypotension, or a life expectancy <3 y: SBP <140 or ALARA	General target: <130 and <80 with encouragement to achieve SBP <120 ; No different target for elderly or frail patients but use clinical judgment (avoid side effects; individualize higher if needed)
Lifestyle measures initiation	Always (high normal and above)	Always (elevated and above)	Always (elevated and above)
Body weight	In adults with overweight or obesity, weight reduction is recommended to reduce BP and the risk of CVD	A stable and healthy BMI (20–25 kg/m ²) and waist circumference (<94 in men and <80 cm in women) is recommended to reduce BP and the risk of CVD	In overweight or obesity adults, weight loss is recommended with a goal of at least 5% of body weight reduction to prevent or treat elevated BP and hypertension

Table 1 (continued)

	ESH 2023	ESC 2024	AHA/ACC 2025
Diet	Mediterranean or DASH diet or, in general, a healthy dietary pattern including more plant-based and less animal-based food is recommended; preferred dietary products include vegetables, fruits, beans, nuts, seeds, vegetable oils, and fish and poultry among meat products; fatty meats, full-fat dairy, sugar, sweetened beverages and sweets should be limited.	Adopting Mediterranean or DASH diet, is recommended to help to reduce BP and the risk of CVD	DASH eating plan is recommended to prevent or treat elevated BP and hypertension
Sodium intake	Dietary salt (sodium chloride) restriction to < 5g (2 g Na) per day	Dietary salt (sodium chloride) restriction to < 5 g (2 g Na) per day	Dietary sodium intake < 2300 mg/d, an ideal limit of < 1500 mg/day
Potassium intake	Increased potassium consumption, preferably via dietary modification, is recommended, except for patients with advanced CKD; in adults consuming a high-sodium diet (most Europeans), salt substitutes replacing part of the sodium chloride with potassium chloride is recommended to reduce BP and the risk of CVD	In patients with hypertension without moderate-to-advanced CKD and with high daily sodium intake, an increase in potassium intake by 0.5–1.0 g per day, for example, through sodium substitution with potassium-enriched salt (comprising 75% sodium chloride and 25% potassium chloride) or through diets rich in fruits and vegetables, should be considered	Aim for 3500–5000 mg/d, ideally by consumption of a diet rich in potassium; or alternative use of moderate-dose pharmacological potassium supplementation
Physical activity and exercise	Daily physical activity and structured exercise are recommended for adults with elevated BP to reduce BP and the risk of CVD; patients should strive for ≥150–300 min of aerobic exercise per week of moderate intensity, or 75–150 min per week of aerobic exercise of vigorous intensity or an equivalent combination; sedentary time should be reduced and supplemented with dynamic resistance exercise (2–3 times per week)	Moderate-intensity aerobic exercise of ≥150 min per week (≥30 min, 5–7 days per week) or alternatively 75 min of vigorous-intensity aerobic exercise per week over 3 days is recommended and should be complemented with low-intensity or moderate-intensity dynamic or isometric resistance training (2–3 times per week) to reduce BP and the risk of CVD	Aerobic exercise: 90–150 min/wk 65–75% heart rate reserve Dynamic resistance: 90–150 min/wk 50–80% 1 rep maximum 6 exercises, 3 sets/exercise, 10 repetitions/set Isometric resistance: 4 × 2 min (hand grip), 1 min rest between exercises, 30–40% maximum voluntary contraction, 3 sessions/wk
Sugar consumption	Consumption of sugar, sweetened beverages and sweets should be limited (included in general dietary recommendations).	Patients are recommended to restrict free sugar consumption, in particular sugar-sweetened beverages, to max 10% of energy intake; consumption of sugar-sweetened beverages is discouraged, starting from young age.	No specific recommendation
Smoking	Smoking cessation, supportive care and referral to smoking-cessation programmes are recommended for all smokers to avoid increases in ambulatory BP, reduce the risk of masked hypertension and improve CVD outcomes.	Tobacco smoking cessation, supportive care and referral to smoking-cessation programmes are recommended, because tobacco use strongly and independently causes CVD, CVD events and all-cause death.	No specific recommendation
Alcohol	Adults who currently consume alcohol (≥3 drinks per day) should be advised that reduction of alcohol intake close to abstinence will lower their BP; alcohol consumption should not be recommended for CVD prevention, because previous studies linking moderate consumption to a lower risk of CVD were likely to have been confounded; patients should avoid excessive (binge) drinking to reduce BP and the risks of haemorrhagic stroke and premature death	Adults are recommended to drink less alcohol than the upper limit (approximately 100 g per week of pure alcohol); the number of drinks depends on portion size (most drinks contain 8–14 g of alcohol); patients are recommended to avoid alcohol to achieve the best health outcomes	Optimal goal is abstinence for all adults for best health outcomes; in patients who consume alcohol, aim for >50% reduction in daily intake to no more than 2 drinks/d in men or 1 drink/d in women
Stress management	Reduced stress via controlled breathing exercises, mindfulness-based exercise and meditation can be considered	none	Training by a professional, followed by 2 × 20 min sessions/d while seated comfortably with eyes closed Device-guided session to decrease respiration

Table 1 (continued)

	ESH 2023	ESC 2024	AHA/ACC 2025
Drug therapy initiation	Grade 2 or 3: regardless of age and cardiovascular risk; or Grade 1: BP level 140–159 or 90–99 with high risk; BP level 150–159 or 95–99 with low risk; or high normal BP ≥ 130 or ≥ 80 with established CVD (CAD)	P ≥ 140 or ≥ 90 , regardless of age and cardiovascular risk	BP ≥ 140 or ≥ 90 , regardless of age and cardiovascular risk; or Stage 1: 130–139 or 80–89 with high risk (previous CVD event, diabetes, CKD, or 10-y CVD risk of $\geq 7.5\%$)
Drug treatment delayed	BP level 140–149 or 90–94: after 3–6 months of lifestyle intervention if BP remains ≥ 140 or ≥ 90 Age ≥ 80 y: SBP ≥ 160 or SBP 140–159 after individualized consideration	Elevated BP: 130–139 or 80–89 with high risk (previous CVD event, diabetes, CKD, HMOD, or 10-y CVD risk of $\geq 10\%$, or 10-y CVD risk of 5%–10% with risk modifier) After 3 months of lifestyle intervention if BP remains ≥ 130 or 80 Elevated SBP 130–139 with low risk and 10-y CVD risk $< 10\%$ and no risk modifier; lifestyle measures only; monitor BP and CVD risk yearly Elevated BP 120–129; lifestyle measures only; monitor BP and CVD risk yearly Age ≤ 85 y: similar to younger patients for hypertension and elevated BP Age ≥ 85 y, or orthostatic hypotension, frailty, or limited lifespan (< 3 y): BP ≥ 140 or ≥ 90 after individualized consideration	Stage 1: 130–139 or 80–89 with low risk (without CVD and with estimated 10-y CVD risk $< 7.5\%$) After 3–6 months of lifestyle intervention if BP remains ≥ 130 or ≥ 80 Age ≥ 80 y: BP ≥ 130 or ≥ 80 after individualized consideration
Renal denervation	Resistant Hypertension: can be considered if drug treatment elicits serious side effects and poor quality of life	Resistant hypertension: can be considered if the risk of cardiovascular disease is increased, but it is not recommended as a first-line intervention	Resistant Hypertension (carefully selected patients with systolic and diastolic hypertension and eGFR ≥ 40 mL/min/1.73 m ²): despite optimal treatment, or intolerable side effects to additional antihypertensive drug therapy, as an adjunct treatment to BP medications and lifestyle modification to reduce BP
Secondary hypertension	Screening for secondary hypertension is advised when there is high clinical suspicion, (++) before the age of 40 years or in resistant hypertension)	Screening for secondary hypertension is advised when there is high suspicion, (++) before the age of 40 years or in resistant hypertension) Screening (with testing for plasma renin and aldosterone levels) for all patients with newly diagnosed hypertension.	Screening for specific forms of secondary hypertension is recommended when clinical suspicion is present In adults with resistant hypertension, screening for primary aldosteronism is recommended regardless of whether hypokalaemia is present
Conditions associated with high or very high risk of CVD	Atherosclerotic CVD Heart failure Chronic kidney diseases Diabetes mellitus Familial hypercholesterolaemia Atrial fibrillation	Atherosclerotic CVD Heart failure Chronic kidney disease Diabetes mellitus Familial hypercholesterolaemia	Diabetes or CKD Heart failure CAD Post AMI Stroke

Table 1 (continued)

	ESH 2023	ESC 2024	AHA/ACC 2025
Hypertension mediated organ damage	Detailed description Cardiac: LVH (electrocardiography, echocardiography), diastolic dysfunction, global longitudinal strain Vascular: carotid plaque, carotid intima-media thickness, carotid-femoral pulse wave velocity and brachial-ankle pulse wave velocity, ankle-brachial pressure index, coronary artery calcium score, retinopathy, pulse pressure >60 mmHg (in older people) Renal: chronic kidney disease (eGFR <60 ml/min/1.73 m ² or urinary albumin-to-creatinine ratio >30 mg/g), resistive index Brain: cognitive function, imaging	Detailed description Cardiac: LVH (electrocardiography, echocardiography), diastolic dysfunction, high-sensitivity cardiac troponin T or troponin I and N-terminal pro-B-type natriuretic peptide levels Vascular: carotid plaque, carotid-femoral pulse wave velocity and brachial-ankle pulse wave velocity, coronary artery calcium score, femoral plaque Renal: chronic kidney disease (eGFR <60 ml/min/1.73 m ² or urinary albumin-to-creatinine ratio >30 mg/g)	No detailed description since screening and management of different types of target organ damage beyond hypertension treatment are lacking.
Risk assessment	SCORE 2 (age 40–70) and SCORE 2OP (age 70–89)	SCORE 2 (age 40–70) and SCORE 2OP (age 70–89)	PREVENT score
Cognitive impairment	Mentioned in the guidelines without specific recommendations. Used in frailty stratification to individualize treatment.	Mentioned in the guidelines without specific recommendations.	SBP < 130 mmHg to prevent cognitive impairment and dementia.
Frailty	Three groups (fit, slowed but autonomous for most activities, severely dependent) based on ADL, MMSE and walking activities	Two groups based on CFS (1–5 vs. 6–9).	Used to modulate treatment strategies but not specified how to assess it.

ABPM Ambulatory blood pressure monitoring, *ACE* angiotensin-converting enzyme, *ADL* activities of daily living, *ALARA* as lower as reasonably achievable, *AMI* acute myocardial infarction, *ARB* angiotensin receptor blocker, *BMI* body mass index, *BP* Blood pressure, *CAD* coronary artery disease, *CCB* calcium-channel blocker, *CFS* clinical frailty scale, *CKD* chronic kidney disease, *CV* cardiovascular risk, *CVD* cardiovascular disease, *DBP* diastolic blood pressure, *HBPM* home blood pressure monitoring, *HF* heart failure, *LVH* left ventricular hypertrophy, *MMSE* mini mental state examination, *SBP* systolic blood pressure

ACC guidelines. Despite the limitations discussed above, it represents a small yet significant step towards managing cardiometabolic disease. This management must focus on cardiovascular prevention and refine risk prediction tools to effectively enable a risk-driven treatment approach. It cannot ignore the involvement of healthcare professionals on a larger scale, including not only general practitioners, but also pharmacists and nurses, as well as non-healthcare professionals, to increase public awareness of cardiometabolic disease.

On the other hand, the numerous relevant differences described in this article and reported in Table 1 may raise major uncertainties and different interpretations in the clinical practice, especially at the general practitioner level. In particular, the differences in the definition and classification of hypertension and BP categories, as well as the thresholds to start treatment or the targets to achieve have important implications for the management of hypertension, the most diffuse disease in the planet. In this view, any effort to achieve universal agreement on these aspects should be endorsed and promoted [14].

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Declarations

Conflict of interest The authors declare that they have no conflict of interest.

Ethical Approval No request to local Ethic Committee has been made, given the descriptive nature of the manuscript (Editorial).

Human and Animal Rights This article does not contain any studies involving human participants performed by any of the authors. All procedures performed in clinical trials discussed in this manuscript and involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants involved in the clinical trials, according to the study protocols.

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