Impact of Hypertension Threshold and Goals on Special Populations

National Lipid Association
2015 Annual Scientific Sessions
June 13, 2015
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Professor of Clinical Medicine,
Tulane University School of Medicine
Immediate Past-chair National Forum for Heart Disease and Stroke Prevention

Keith C. Ferdinand, MD

Has disclosed the following affiliations. Any real or apparent COIs related to the presentation have been resolved.

Speaker’s Bureau
- None

Grant/Research Support
- Boehringer Ingelheim, Lilly

Consultant
- Astra Zeneca, Amgen, Sanofi, Boehringer Ingelheim
Learning Objectives

• Describe the impact of hypertension (HTN) in special populations: African American (AA’s), women, patients with diabetes mellitus (DM) and secondary stroke

• Describe controversies and impact in new guidelines and reports, specifically concerning current goals for blood pressure control

Development of Hypertension Guidelines: the JNCs and Therapy

JNC = Joint National Committee  
NHBPEP = National High Blood Pressure Education Program  
ASH/ISH = American Society of Hypertension/International Society of Hypertension  
ESC = European Society of Cardiology  
ACC/AHA/CDC = American College of Cardiology/American Heart Association/Center for Disease Control

Earliest Guidelines

JNC I
- 28 drugs
- Diuretics

JNC II
- 34 drugs
- Diuretics, β-blockers

JNC III
- 43 drugs
- ACEIs, CAs added

JNC IV
- 50 drugs
- β-blockers

JNC V
- 7 options

JNC VI
- 84 drugs

JNC 7
- > 125 drugs

ASH/ISH

ESC

ACC/AHA/CDC

"JNC 8"

BAROREFLEX

BAT and RD Devices?

NHBPEP STARTS

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Baroreflex Activation Therapy

National Cholesterol Education Program 1985

Renal Denervation

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Increasing SBP and Age Elevates Risk Ischemic Heart Disease and Stroke Mortality

One Million Adults, 61 Prospective Studies

Ischemic Heart Disease Mortality

<table>
<thead>
<tr>
<th>Usual Systolic BP (mm Hg)</th>
<th>120</th>
<th>140</th>
<th>160</th>
<th>180</th>
</tr>
</thead>
<tbody>
<tr>
<td>IHD Mortality (Absolute Risk and 95% CI)</td>
<td>256</td>
<td>128</td>
<td>64</td>
<td>32</td>
</tr>
<tr>
<td>Age at Risk (y)</td>
<td>80-89</td>
<td>70-79</td>
<td>60-69</td>
<td>50-59</td>
</tr>
</tbody>
</table>

Stroke Mortality

<table>
<thead>
<tr>
<th>Usual Systolic BP (mm Hg)</th>
<th>120</th>
<th>140</th>
<th>160</th>
<th>180</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stroke Mortality (Absolute Risk and 95% CI)</td>
<td>256</td>
<td>128</td>
<td>64</td>
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</tr>
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<td>Age at Risk (y)</td>
<td>80-89</td>
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<td>50-59</td>
</tr>
</tbody>
</table>


Long-term Anti-HTN Therapy Significantly ↓ CV Events

<table>
<thead>
<tr>
<th>Event</th>
<th>Average Reduction in Events (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stroke</td>
<td>35%-40%</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>20%-25%</td>
</tr>
<tr>
<td>Heart failure</td>
<td>&gt;50%</td>
</tr>
</tbody>
</table>

Hypertension: a common and manageable chronic condition- recent national data

- 51.9% BP controlled <140/90 mm Hg
- Control neither met goal of the HP 2020 (61.2% by 2020)
- Nor the Million Hearts Initiative (65% by 2017).
- “These results provide evidence for continued efforts to improve the management of hypertension in order to attain these goals”

Heart Disease & Stroke Mortality Disparities

- Black men & women much more likely to die of heart disease & stroke than whites
- CHD & stroke not only leading cause of death in the US, but also account for largest proportion of inequality in life expectancy between whites and blacks
- Despite existence of low-cost, highly effective preventive treatment

Avoidable death from heart disease, stroke, and HCVD 2001–2010

Salient Aspects of HBP in Blacks

- Increased incidence of target organ damage, including stroke, MI mortality, LVH, HF, retinopathy and CKD/end-stage renal disease, especially premature
- HTN prevalence in U.S. blacks among the highest in the world
- Compared with whites, blacks develop HTN at an earlier age and average BPs much higher

Mortality From HTN Higher in Blacks

Overall Mortality Rates from Causes Related to HTN, 2010

<table>
<thead>
<tr>
<th></th>
<th>Black Male</th>
<th>Black Female</th>
<th>White Male</th>
<th>White Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>50.2%</td>
<td>37.1%</td>
<td>17.2%</td>
<td>15.0%</td>
</tr>
<tr>
<td>Female</td>
<td>60.2%</td>
<td>41.2%</td>
<td>18.2%</td>
<td>12.0%</td>
</tr>
</tbody>
</table>


Projected HF: Race/ethnicity 2012-2030

Heidenreich, Albert, NM et al Circ Heart Fail. 2013;6:00-00
Complications: Kidney Disease

- ESRD incidence has risen significantly among AAs.

Heart Disease in Women #1 Killer
Prevalence of High Blood Pressure in Adults by Age and Sex: NHANES 2005-2006

Mean BP: Age, Sex & Ethnic Group in US Adults

Blood Pressure Goals: Is Lower always Better?

Incidence of MI and Stroke Stratified by Diastolic Blood Pressure in the INVEST Study

Impact of Achieved BPs on Mortality Risk and ESRD Among a Large, Diverse HTN Population

N=398,419 treated HTN (30%DM)

Kaiser Permanente Southern California

130 -139/60- 79 mm Hg were associated with best outcomes.

J Am Coll Cardiol. 2014;64(6):588-597

BP Targets and Achieved BP: HTN in Elderly

<table>
<thead>
<tr>
<th></th>
<th>SHEP¹</th>
<th>Syst-Eur²</th>
<th>HYVET³</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subjects (n)</td>
<td>4736</td>
<td>4695</td>
<td>3845</td>
</tr>
<tr>
<td>Inclusion BP Criteria (mm Hg)</td>
<td>160-219 / &lt;90</td>
<td>160-219 / &lt;95</td>
<td>160-190 / &lt;110</td>
</tr>
<tr>
<td>Goal SBP (mm Hg)</td>
<td>&lt;160 or ≥20 reduction</td>
<td>&lt;150 or ≥20 reduction</td>
<td>&lt;150</td>
</tr>
<tr>
<td>Mean Achieved BP (mm Hg)</td>
<td>143/68</td>
<td>151/79</td>
<td>144/78</td>
</tr>
<tr>
<td>Follow-up (y)</td>
<td>4.5 (mean)</td>
<td>2.0 (median)</td>
<td>1.8 (mean)</td>
</tr>
</tbody>
</table>

1. SHEP Cooperative Research Group. JAMA. 1991
Effects of Intensive Blood-Pressure Control in Type 2 Diabetes Mellitus

The ACCORD Study Group

Secondary Outcome

Nonfatal Stroke

Total Stroke

HR = 0.63
95% CI (0.41-0.96)

HR = 0.59
95% CI (0.39-0.89)

Hypertension and Stroke

• Hypertension is a major risk factor for stroke and transient ischemic attack, with the risk increasing with every rise in SBP.
• The CV risk can be minimized by persistent correction of the HTN.
• Once the stroke has stabilized, antihypertensive therapy can ↓ rate of recurrent stroke, independent of the baseline BP


Secondary Prevention of Small Subcortical Strokes Trial

Blood-pressure targets in patients with recent lacunar stroke: the SP53 randomised trial

The SP53 Study Group

Summary
Background Lowering of blood pressure prevents stroke but optimum target levels to prevent recurrent stroke are unknown. We investigated the effects of different blood-pressure targets on the rate of recurrent stroke in patients with recent lacunar stroke.

Methods In this randomised-open-label trial, eligible patients lived in North America, Latin America, and Spain and had recent, NEI-defined symptomatic lacunar infarctions. Patients were recruited between March, 2003, and April, 2011, and randomly assigned, according to a two-by-two multifactorial design, to a systolic-blood-pressure target of 130-149 mm Hg or less than 130 mm Hg. The primary endpoint was reduction in all stroke (including ischemic strokes and intracranial haemorrhages). Analysis was done by intention to treat. This study is registered with ClinicalTrials.gov, number NCT00559165.

Findings 3420 enrolled patients, 1510 in the higher-target group and 1910 in the lower-target group, were followed up for a mean of 3.7 (SD 2.4) years. Mean age was 68 (SD 11) years. After 1 year, mean systolic blood pressure was 138 mm Hg (95% CI 132-144) in the higher-target group and 127 mm Hg (95% CI 124-129) in the lower-target group. Non-significant rate reductions were seen for all stroke (hazard ratio 0.91, 95% CI 0.84-0.99), disabling or fatal stroke (0.85, 0.72-1.01) and the composite outcome of myocardial infarction or vascular death (0.64, 0.50-0.81). Among patients with lacunar stroke, the rate of intracranial haemorrhage was reduced significantly (0.37, 0.35-0.95, p=0.03). Treatment-related serious adverse events were infrequent.

Interpretation Although the reduction in stroke was not significant, our results suggest that in patients with recent lacunar stroke, the use of a systolic-blood-pressure target of less than 130 mm Hg is likely to be beneficial.

Funding National Institutes of Health-National Institute of Neurological Disorders and Stroke (NIH-NINDS)
SPS3: Lower vs. Higher BP

- Non-significant rate reductions for all stroke (HR 0.81, 95% CI 0.64–1.03, p=0.08)

- Composite outcome of MI or vascular death (0.84, 0.68–1.04, p=0.32).

- Rate of intracerebral haemorrhage reduced significantly (0.37, 0.15–0.95, p=0.03).

- Treatment-related serious adverse events were infrequent.
Table 4: Side-effects potentially related to blood-pressure management

Table 3: Serious adverse events related to hypotension

Potentially BP-related Side-effects

SPS3 Serious AE’s

SPS3: Interpretation

“Although the reduction in stroke was not significant, our results support that in patients with recent lacunar stroke, the use of a systolic-blood-pressure target of less than 130 mm Hg is likely to be beneficial.”

*Lancet* 2013;382: 507-515

Best Practices:
Recent Guidelines Effective for BP Control 2015 and Beyond
SBP Treatment Goals and Thresholds

• Areas of agreement < 140/90 mmHg for both Goal and Threshold
  - Individuals younger than 60
  - Individuals with diabetes
  - Individuals with CKD without significant proteinuria

Treatment Goals and Thresholds in Older individuals

• Biggest area of diversion is between 60 and 79 years old
• More general agreement for age 80 years and older, particularly if they are fragile: treatment goal should be <150/90 mmHg rather than < 140/90 mmHg
2014 Evidence-Based Guideline for the Management of High Blood Pressure in Adults
Report From the Panel Members Appointed to the Eighth Joint National Committee (JNC 8)

Hypertension is the most common condition seen in primary care and leads to myocardial infarction, stroke, renal failure, and death if not detected early and treated appropriately. Patients want to be assured that blood pressure (BP) treatment will reduce their disease burden, while clinicians want guidance on hypertension management using the best scientific evidence. This report takes a rigorous, evidence-based approach to recommend treatment thresholds, goals, and medications in the management of hypertension in adults. Evidence was drawn from randomized controlled trials, which represent the gold standard for determining efficacy and effectiveness. Evidence quality and recommendations were graded based on their effect on important outcomes.

Box. Recommendations for Management of Hypertension

**Recommendation 1**
In the general population aged ≥60 years, initiate pharmacologic treatment to lower blood pressure (BP) at systolic blood pressure (SBP) ≥150 mm Hg or diastolic blood pressure (DBP) ≥90 mm Hg and treat to a goal SBP <150 mm Hg and goal DBP <90 mm Hg. (Strong Recommendation - Grade A)

**Corollary Recommendation**
In the general population aged ≥60 years, if pharmacologic treatment for high BP results in lower achieved SBP (eg, <140 mm Hg) and treatment is well tolerated and without adverse effects on health or quality of life, treatment does not need to be adjusted. (Expert Opinion - Grade E)
Minority Perspective

- Evidence from trials and observational studies that the panel did not use as part of its review supports the lower goal, especially in high-risk patients.
- Two large meta-analysis supported the < 140 mmHg goal
Minority Perspective

• What is the trial evidence of increase risk of serious adverse events with treatment to < 140 mmHg?
• JATOS, VALISH, and SPS3 all concluded that lower goal was safe.


Misleading Lay Media Reports
For decades during every doctor’s visit, Americans hoped they would hear two magic numbers: 120 over 80. That enviable BP reading is now obsolete.

In December, a report in the Journal of the American Medical Association reset the guidelines for healthy BP to a level below 150 over 90.

**Comparison of Hypertension Guidelines 2011-2014**

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<tbody>
<tr>
<td>Initiate drug therapy with two drugs</td>
<td>Not mentioned</td>
<td>In patients with markedly elevated BP</td>
<td>≥160/100</td>
<td>≥160/100</td>
<td>≥160/100</td>
</tr>
<tr>
<td>BP targets</td>
<td>&lt; 140/90</td>
<td>&lt;140/90</td>
<td>&lt;140/90</td>
<td>&lt;140/90</td>
<td>&lt; 140/90</td>
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<tr>
<td></td>
<td>≥ 80 y. &lt; 150/90</td>
<td>Elderly &lt; 80 y. SBP 140-150</td>
<td>≥ 80 y. &lt; 150/90</td>
<td>Lower targets may be appropriate in some, including the elderly</td>
<td>≥ 60 y. &lt;140/90</td>
</tr>
<tr>
<td></td>
<td>Elderly ≥ 80 y. SBP 140-150</td>
<td></td>
<td></td>
<td></td>
<td>≥ 60 y. &lt;150/90</td>
</tr>
<tr>
<td>BP target in patients with DM</td>
<td>Not addressed</td>
<td>&lt; 140/85</td>
<td>&lt;140/90</td>
<td>&lt;140/90</td>
<td>≤140 /90</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Lower targets may be considered</td>
<td></td>
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Go A. et al. AHA/ACC/CDC 2013

Lindholm LH, Carlberg B. HT News 2014, Opus 35
Standards of Medical Care

- People with diabetes and hypertension should be treated to a SBP goal of < 140 mmHg. A
- Lower systolic targets, such as, < 130 mmHg, may be appropriate for certain individuals, such as younger patients, if they can be achieved without undue treatment burden.
# Treatment Hypertension in Patients with CAD

## Table 3. Summary of BP Goals

<table>
<thead>
<tr>
<th>BP Goal, mm Hg</th>
<th>Condition</th>
<th>Class/Level of Evidence</th>
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<tbody>
<tr>
<td>&lt;150/90</td>
<td>Age &gt;80 y</td>
<td>IIa/B</td>
</tr>
<tr>
<td>&lt;140/90</td>
<td>CAD</td>
<td>I/A</td>
</tr>
<tr>
<td></td>
<td>ACS</td>
<td>IIa/C</td>
</tr>
<tr>
<td></td>
<td>HF</td>
<td>IIa/B</td>
</tr>
<tr>
<td></td>
<td>CAD</td>
<td>IIb/C</td>
</tr>
<tr>
<td>&lt;130/80</td>
<td>Post-myocardial infarction, stroke or TIA, carotid artery disease, PAD, AAA</td>
<td>IIb/C</td>
</tr>
</tbody>
</table>

AAA indicates abdominal aortic aneurysm; ACS, acute coronary syndrome; BP, blood pressure; CAD, coronary artery disease; HF, heart failure; PAD, peripheral arterial disease; and TIA, transient ischemic attack.
Goals for target BP or reduction from pretreatment baseline uncertain and should be individualized

- But it is reasonable to achieve SBP<140 mm Hg and DBP <90 mm Hg (Class IIa;B).

- For patients with a recent lacunar stroke, it might be reasonable to target a SBP of <130 mm Hg (Class IIb;B)
If It Ain't Broke
Don't Fix It
(Charles Wilson Blues Singer 2005)
AHA: Stratified BP Goal May Adversely Affect Community and Public Health Efforts to Reduced HTN

• “We believe that a higher SBP target of less than 150 will adversely affect public health.
• We further believe the higher SBP target in this age group will increase health disparities among populations at greatest risk, especially African Americans, patients with multiple risk factors, including those with existing cardiovascular disease.”

www.heart.org/idc/groups/heartpublic/@wcm/@adv/documents/downloadable/ucm_462146.pdf

THE PRESENT AND FUTURE

STATE-OF-THE-ART REVIEW

2014 Hypertension Recommendations From the Eighth Joint National Committee Panel Members Raise Concerns for Elderly Black and Female Populations

Lawrence R. Kukoff, MD,* Robert L. Gilmore, MD,† Keith C. Ferdinand, MD,‡ Icinma V. Fergus, MD,§ Ola Akinbobe, MD, MBA,∥ Kim A. Williams, MD,¶ Mary Norine Walsh, MD,|| C. Noel Bairey Merz, MD,** Carl J. Pepine, MD††
ASSOCIATION OF BLACK CARDIOLOGISTS
POSITION: POTENTIAL UNINTENDED
ADVERSE CONSEQUENCES

Robert L. Gillespie, MD, Keith C. Ferdinand, MD,
Icilma V. Fergus, MD, Ola Akinboboye, MD, MBA,
Kim A. Williams, MD, on behalf of the Association of
Black Cardiologists’ Board of Directors

WORKING GROUP ON WOMEN’S
CARDIOVASCULAR HEALTH: HYPERTENSION
TREATMENT FOR OLDER ADULTS: RAISING
THE BAR ADVERSELY AFFECTS WOMEN

Keith C. Ferdinand, MD, Mary Norine Walsh, MD,
C. Noel Bairey Merz, MD, Carl J. Pepine, MD
2014 Hypertension Recommendations Raise Concerns for Elderly, Black and Female Populations

• The black-white life expectancy gap remains wide for both men and women
• Driven largely by the adverse effects of poorly controlled hypertension and associated CVD.
• The unacceptable, unintended, adverse consequences of raising SBP goals for older persons may be to worsen these disparities
• JACC Vol.64, No.4, 2014

2014 Hypertension Recommendations Raise Concerns for Elderly, Black and Female Populations

• Prevalence of HTN in the U.S. will continue to increase
• With population growth, population aging, and persistent adverse behavioral risk factors, including high sodium, low potassium dietary patterns, physical inactivity, and increasing obesity.
• Rise in extreme obesity (BMI $>$40 kg/m²) significantly more prevalent among women than men and will further drive a sex-specific rise in hypertension rates.
• JACC Vol.64, No.4, 2014
2014 Hypertension Recommendations Raise Concerns for Elderly, Black and Female Populations

• CVD is the leading cause of death among U.S. women, and hypertension is the major modifiable contributor to CHD, HF, stroke, atrial fibrillation, DM, and CKD.

• Hypertension is a much stronger risk factor for development of HF among women versus men
  • JACC Vol.64, No.4, 2014

2014 Hypertension Recommendations Raise Concerns for Elderly, Black and Female Populations

• “This JNC-8P places high-risk older women, especially African-American women, at unnecessary excess risk, exacerbating existing sex and racial/ethnic CVD disparities.”

JACC Vol.64, No.4, 2014
Parachutes reduce risk of injury after gravitational challenge, but **effectiveness not proved with randomized controlled trials**

*BMJ 2003;327;1459-1461  Smith .G. and Pell,J*

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Is All Medicine all Morbidity, Mortality Endpoints?

- Absence of mortality, hard morbidity endpoints (eg,CV events) does not mean lack of benefit
  - Limited data selection process for guidelines, excluded important considerations
  - Lack of trials in specific populations led to changes in treatment goals
Is All Medicine only Morbidity, Mortality Endpoints?

• Other important factors to consider
  – Drug tolerability
  – Subset analysis from large trials
  – Epidemiology

• Cannot base treatment recommendations solely on whether there is a specific trial, in specific group of patients, with specific outcomes

Take Home Messages
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• Age is a powerful risk factor for hypertension complications, in Blacks, elderly (esp. women) and other high risk groups

• Current recommendation of < 140/90 has been associated with dramatic reductions in HTN complications with BP↓

• There is no evidence of benefit and clear risk of harm if BP targets > 140/90 are recommended (e.g. SBP< 150 ), esp in Blacks and other higher risk groups >/=60 years old

Take Home Messages

• The 2014 JAMA HTN Guideline is currently the only guideline in the world recommending looser BP control in pts as young as 60 yrs

• In the meantime, efforts to control HTN, particularly in Blacks, older women and high risk (CAD,DM,CKD,secondary stroke prevention), should continue to focus on increasing the number of hypertensives controlled to <140/90 mmHg
Thank You!