Using Cardiovascular Risk to Guide Antihypertensive Treatment – Implications For The Pre-elderly and Elderly

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Disclosures

• Funding
  – Amgen, Inc.
  – National Institutes of Health
  – American Heart Association

• Dr. Muntner is a member of the writing committee for the ACC/AHA Guideline for the Management of Hypertension. Today’s presentation represents his opinion and does not reflect the views of the ACC, AHA or Guideline Committee.
• Antihypertensive treatment – recommendations in current guidelines.

• Cardiovascular disease (CVD) risk prediction.

• Using CVD risk to guide antihypertensive treatment:
  − Data from clinical trials.
  − Simulations of the population-level benefits.
  − Considerations for the pre-elderly and elderly.
## Antihypertensive Treatment Recommendations – Current Guidelines

<table>
<thead>
<tr>
<th></th>
<th>Systolic BP, mm Hg</th>
<th>Diastolic BP, mm Hg</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>JNC7</strong></td>
<td>≥ 140</td>
<td>≥ 90</td>
</tr>
<tr>
<td><strong>JAMA 2014</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>recommendation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 60 years of age</td>
<td>≥ 140</td>
<td>≥ 90</td>
</tr>
<tr>
<td>≥ 60 years of age</td>
<td>≥ 150</td>
<td>≥ 90</td>
</tr>
<tr>
<td><strong>2013 ESH guideline</strong></td>
<td></td>
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</tr>
<tr>
<td>&lt; 80 years of age</td>
<td>≥ 140</td>
<td>≥ 90</td>
</tr>
<tr>
<td>≥ 80 years of age</td>
<td>≥ 160</td>
<td>≥ 90</td>
</tr>
</tbody>
</table>

Chobanian 2003; James 2014; Mancia 2013
Which Person Would You Initiate on Antihypertensive Medication?

- White male
- 60 years old
- Total cholesterol: 220 mg/dL
- HDL cholesterol: 40 mg/dL
- Diabetes
- Current smoker
- SBP: 136 mm Hg

- White male
- 60 years old
- Total cholesterol: 160 mg/dL
- HDL cholesterol: 60 mg/dL
- No Diabetes
- Non-smoker
- SBP: 154 mm Hg
What is the main objective of prescribing antihypertensive medication?

- To reduce the absolute risk for premature death and morbidity, primarily cardiovascular disease (CVD) and renal disease.

- Do benefits outweigh the potential adverse effects?
Background on CVD Risk Prediction
• Insurance companies have been using lifetables for centuries.

• In 1967, a CVD risk score was developed in the Framingham Heart Study

• This equation has been modified and refined over the past five decades.
The ACC/AHA cholesterol management guideline recommends using the Pooled Cohort risk equations to estimate 10-year risk for CVD.
Predicting CVD Risk May Seem Complicated

<table>
<thead>
<tr>
<th></th>
<th>( S_0(t) ) at 5 years†</th>
<th>( S_0(t) ) at 10 years †</th>
<th>Mean score</th>
<th>Equations parameters*</th>
<th>Individual score‡</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Participants not taking antihypertensive medications</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black women</td>
<td>0.98194</td>
<td>0.9533</td>
<td>86.61</td>
<td>( 17.114 \times \ln(\text{age}) + 0.94 \times \ln(\text{TC}) - 18.92 \times \ln(\text{HDL-C}) + 4.475 \times \ln(\text{age}) \times \ln(\text{HDL-C}) + 27.82 \times \ln(\text{SBP}) - 6.087 \times \ln(\text{age}) \times \ln(\text{SBP}) ) (+ 0.691 if current smoker)</td>
<td></td>
</tr>
<tr>
<td>White women</td>
<td>0.98898</td>
<td>0.9665</td>
<td>-29.18</td>
<td>( -29.799 \times \ln(\text{age}) + 4.884 \times \ln(\text{age})^2 + 13.54 \times \ln(\text{TC}) - 3.114 \times \ln(\text{age}) \times \ln(\text{TC}) - 13.578 \times \ln(\text{HDL-C}) + 3.149 \times \ln(\text{age}) \times \ln(\text{HDL-C}) + 1.957 \times \ln(\text{SBP}) ) (+ 7.574 - 1.665 \times \ln(\text{age}) if current smoker)</td>
<td></td>
</tr>
<tr>
<td>Black men</td>
<td>0.95726</td>
<td>0.8954</td>
<td>19.54</td>
<td>( 2.469 \times \ln(\text{age}) + 0.302 \times \ln(\text{TC}) - 0.307 \times \ln(\text{HDL-C}) + 1.809 \times \ln(\text{SBP}) ) (+ 0.549 if current smoker)</td>
<td></td>
</tr>
<tr>
<td>White men</td>
<td>0.96254</td>
<td>0.9144</td>
<td>61.18</td>
<td>( 12.344 \times \ln(\text{age}) + 11.853 \times \ln(\text{TC}) - 2.664 \times \ln(\text{age}) \times \ln(\text{TC}) - 7.99 \times \ln(\text{HDL-C}) + 1.769 \times \ln(\text{age}) \times \ln(\text{HDL-C}) + 1.764 \times \ln(\text{SBP}) ) (+ 7.837 - 1.795 \times \ln(\text{age}) if current smoker)</td>
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</tr>
</tbody>
</table>

ASCVD: atherosclerotic cardiovascular disease; HDL-C: high-density lipoprotein cholesterol; REGARDS: REasons for Geographic And Racial Differences in Stroke; SBP: systolic blood pressure; TC: total cholesterol.

* Final risk estimation is calculated as:

\[
\text{Predicted ASCVD risk} = 1 - S_0(t)^{\text{(Individual score - Mean score)}}
\]

† Obtained from the ACC/AHA Guideline on the Assessment of Cardiovascular Risk working group (S. Coady, Personal Communication).

‡ For clarity, coefficients for diabetes are not shown since REGARDS participants with diabetes were excluded from calculations.
CVD Risk Prediction Does Not Need To Be Complicated

This patient has a 10-year ASCVD risk of 10.2%.


<table>
<thead>
<tr>
<th>Patient Data</th>
</tr>
</thead>
</table>
| Gender                | \( \bigcirc \) Male \( \bigcirc \) Female  
| Patient Age           | 62 years  
| Ethnicity             | \( \bigcirc \) white (non-black) \( \bigcirc \) black  

<table>
<thead>
<tr>
<th>Labs</th>
</tr>
</thead>
</table>
| Cholesterol (S)       | 170 mg/dL  
| HDL (S)               | 50 mg/dL  
| SP                    | 139 mmHg  
| On HTN meds           | \( \bigcirc \) No \( \bigcirc \) Yes  
| DM                    | \( \bigcirc \) No \( \bigcirc \) Yes  
| Smoking               | \( \bigcirc \) No \( \bigcirc \) Yes  

There are Multiple CVD Risk Prediction Models

<table>
<thead>
<tr>
<th>Risk score</th>
<th>End points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Framingham 1998</td>
<td>CHD – CHD death, MI, angina</td>
</tr>
<tr>
<td>ATP-III risk estimator</td>
<td>Hard CHD – CHD death, nonfatal MI</td>
</tr>
<tr>
<td>Framingham global CVD</td>
<td>CVD – CVD death, CHD, stroke, heart failure, etc.</td>
</tr>
<tr>
<td>PROCAM</td>
<td>Hard CHD - CHD death and non-fatal MI</td>
</tr>
<tr>
<td>QRISK</td>
<td>CVD – CHD, stoke, TIA</td>
</tr>
<tr>
<td>Reynolds risk score (women)</td>
<td>CVD – CVD death, MI, stroke, revascularization</td>
</tr>
<tr>
<td>Reynolds risk score (men)</td>
<td>CVD – CVD death, MI, stroke, revascularization</td>
</tr>
<tr>
<td>SCORE</td>
<td>CVD death – CVD death only</td>
</tr>
<tr>
<td>Pooled Cohort risk equations</td>
<td>CVD – fatal and non-fatal stroke, non-fatal MI and CHD death</td>
</tr>
</tbody>
</table>

Lloyd-Jones *Circulation* 2011, Goff *JACC* 2013
Why Use CVD Risk Prediction to Guide Treatment?
(1) Trials Often Enroll High Risk Patients

<table>
<thead>
<tr>
<th>Study</th>
<th>Age group</th>
<th>CVD risk criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACCORD</td>
<td>40 to 79</td>
<td>History of clinical CVD, Albuminuria, PAD, LVH, ≥50% stenosis, 2+ risk factors</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(e.g., high LDL, smoking)</td>
</tr>
<tr>
<td>ALLHAT</td>
<td>55+ years</td>
<td>Previous (&gt;6 months) MI or stroke, Left ventricular hypertrophy, Diabetes, current</td>
</tr>
<tr>
<td></td>
<td></td>
<td>cigarette smoking, HDL-C &lt; 35 mg/dL, Documentation of other atherosclerotic CVD</td>
</tr>
<tr>
<td>SPRINT</td>
<td>50+ years</td>
<td>Age ≥ 75 years, History of CHD, Estimated GFR 20 – 59 ml/min/1.73 m²,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Framingham 10-year predicted risk ≥ 15%</td>
</tr>
</tbody>
</table>
(2) CVD Risk Can Differ Substantially for People With the Same BP Level

Low risk – 50 year old, white woman, non-smoker, without diabetes, not taking antihypertensive medication, total cholesterol of 180 mg/dL and HDL-cholesterol of 54 mg/dL

Intermediate risk – 60 year old, black man, non-smoker, with diabetes, not taking antihypertensive medication, total cholesterol of 240 mg/dL and HDL-cholesterol of 50 mg/dL

High risk – 70 year old, white man, smoker, with diabetes, not taking antihypertensive medication, total cholesterol of 240 mg/dL and HDL-cholesterol of 40 mg/dL
(3) Patients with High CVD Risk Experience the Greatest Benefit from Treatment

(3) Treating High Risk People Would Prevent More Events

Events prevented per 1,000 people treated for one year

- <11%: 14
- 11% to 15%: 20
- 15% to 21%: 24
- >21%: 38

(4) Who is Having CVD Events?

% of all CHD and stroke events

<table>
<thead>
<tr>
<th>Blood Pressure (mm Hg)</th>
<th>% of All Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;120/80</td>
<td>19.5%</td>
</tr>
<tr>
<td>120-129/80-84</td>
<td>24.4%</td>
</tr>
<tr>
<td>130-139/85-89</td>
<td>23.1%</td>
</tr>
<tr>
<td>&gt;=140/90</td>
<td>33.0%</td>
</tr>
</tbody>
</table>

Systolic/diastolic blood pressure, mm Hg
(4) Who is Having CVD Events?

Predicted 10-year ASCVD risk
- <5%
- 5% to <7.5%
- 7.5% to <10%
- ≥10%

Muntner JAMA 2014
(5) BP varies substantially between visits but CVD risk is stable

Data from NHANES III (n=808 participants who completed two clinic visits, ~18 days apart)

Adapted from Ye, JASH 2015
(5) BP varies substantially between visits but CVD risk is stable

<table>
<thead>
<tr>
<th></th>
<th>Predicted 10-year CVD Risk at Visit 1</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt;5%</td>
</tr>
<tr>
<td>10-year CVD risk</td>
<td>&lt;5%</td>
</tr>
<tr>
<td>at Visit 2</td>
<td>5% to &lt;7.5%</td>
</tr>
<tr>
<td></td>
<td>7.5% to &lt;10%</td>
</tr>
<tr>
<td></td>
<td>≥10%</td>
</tr>
</tbody>
</table>

Data from NHANES III (n=808 participants who completed two clinic visits, ~18 days apart)

10-year CVD risk concordant between visits

- Yes (95.7%)
- No (4.3%)
(6) Risk-based versus BP-based Treatment Approaches Are More Efficient

- **Treatment Strategy**
  - TTT
  - BTT

- **Indications for Intensification**
  - Low risk patient: SBP > 140 or DBP > 90
  - If patient has diabetes treat if SBP > 130 or DBP > 85
  - 5-year expected event reduction > 1.7% or SBP > 150 mmHg

- **Intensification Strategy**
  1. No treatment
  2. Add thiazide
  3. Add ACEI
  4. Add beta-blocker
  5. Add CCB

- **Assessment**
  1. Calculate SBP and DBP
  2. Calculate event rates
  3. Calculate QALYs

Sussman *Circulation*, 2014
(6) Risk-based versus BP-based Treatment Approaches Are More Efficient

<table>
<thead>
<tr>
<th>Risk score</th>
<th>Treat-to-target</th>
<th>Risk-based treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number treated, millions</td>
<td>78.8</td>
<td>62.6</td>
</tr>
<tr>
<td>Initial SBP among treated, mm Hg</td>
<td>145.3</td>
<td>148.2</td>
</tr>
<tr>
<td>Final SBP among treated, mm Hg</td>
<td>124.0</td>
<td>128.5</td>
</tr>
<tr>
<td>5-year CVD risk among treated, %</td>
<td>5.5</td>
<td>8.0</td>
</tr>
<tr>
<td>Events prevented over 5 years, millions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coronary heart disease</td>
<td>2.0</td>
<td>2.7</td>
</tr>
<tr>
<td>Stroke</td>
<td>1.3</td>
<td>1.5</td>
</tr>
<tr>
<td>Total</td>
<td>3.3</td>
<td>4.2</td>
</tr>
<tr>
<td>QALYs saved, millions</td>
<td>19.3</td>
<td>22.2</td>
</tr>
</tbody>
</table>

Sussman *Circulation, 2014*
Using CVD risk to Guide Treatment – Considerations for the Pre-elderly / Elderly
Why to Consider a Risk-Based Treatment Approach For Older Adults

• Age is unquestionably the most important determinant of CVD risk.

• Almost all adults ≥ 60 years of age have a high CVD risk.

• Trials have shown the benefit of antihypertensive medication for older adults.
Age-specific Incidence of CVD, CHD and stroke

Unpublished data from the REGARDS study

Incidence rates per 1,000 person-years

- Cardiovascular disease: 5.0 (Age <65), 14.6 (Age >= 65)
- Coronary heart disease: 3.2 (Age <65), 8.0 (Age >= 65)
- Stroke: 1.8 (Age <65), 6.8 (Age >= 65)
Distribution of 10-year Predicted Risk by Age Grouping

Unpublished data from the REGARDS study
Percentage of CVD Events Among Adults ≥ 65 years with High BP vs. High CVD Risk

Not taking antihypertensive medication

- Cardiovascular disease: 32.8%
- Coronary heart disease: 33.8%
- Stroke: 30.6%

Tajeu (Circulation 2017)
## Benefit of Intensive BP Management in Adults ≥ 75 years

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Incidence (95% CI) per year</th>
<th>HR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intensive Tx</td>
<td>Standard Tx</td>
</tr>
<tr>
<td>CVD</td>
<td>2.59 (2.13 – 3.14)</td>
<td>3.85 (3.28 – 4.53)</td>
</tr>
<tr>
<td>MI</td>
<td>0.92 (0.67 – 1.27)</td>
<td>1.34 (1.02 – 1.75)</td>
</tr>
<tr>
<td>Stroke</td>
<td>0.67 (0.46 – 0.97)</td>
<td>0.85 (0.61 – 1.19)</td>
</tr>
<tr>
<td>Heart Failure</td>
<td>0.86 (0.62 – 1.20)</td>
<td>1.41 (1.09 – 1.83)</td>
</tr>
<tr>
<td>Mortality</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All-cause</td>
<td>1.78 (1.41 – 2.24)</td>
<td>2.63 (2.17 – 3.18)</td>
</tr>
<tr>
<td>CVD</td>
<td>0.44 (0.28 – 0.70)</td>
<td>0.72 (0.50 – 1.03)</td>
</tr>
</tbody>
</table>

Williamson *JAMA*, 2016
Which Person Would You Initiate on Antihypertensive Medication?

- White male
- 60 years old
- Total cholesterol: 220 mg/dL
- HDL cholesterol: 40 mg/dL
- Diabetes
- Current smoker
- SBP: 136 mm Hg
- 10-year CVD risk: 33.5%

- White male
- 60 years old
- Total cholesterol: 160 mg/dL
- HDL cholesterol: 60 mg/dL
- No Diabetes
- Non-smoker
- SBP: 154 mm Hg
- 10-year CVD risk: 9.0%
<table>
<thead>
<tr>
<th>Person 1</th>
<th>Person 2</th>
</tr>
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<tbody>
<tr>
<td>White male</td>
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</tr>
<tr>
<td>Diabetes</td>
<td>No Diabetes</td>
</tr>
<tr>
<td>Current smoker</td>
<td>Non-smoker</td>
</tr>
<tr>
<td>SBP: 136 mm Hg</td>
<td>SBP: 154 mm Hg</td>
</tr>
<tr>
<td>10-year CVD risk: 33.5%</td>
<td>10-year CVD risk: 9.0%</td>
</tr>
<tr>
<td>Post-tx risk: 26.5%</td>
<td>Post-tx risk: 7.2%</td>
</tr>
</tbody>
</table>
• There are benefits with using risk prediction to guide antihypertensive and statin treatment:

- It is relevant to populations included in trials.
- It is a patient-centered treatment approach.
- Most CVD events occur in high risk individuals including the elderly.
- We avoid treatment in people who are likely to receive little benefit.
- It is cost effective.
Acknowledgements

• UAB
  - Suzanne Oparil
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  - Siqin Ye

• Tulane University
  - Marie Krousel-Wood
  - Paul Whelton

• University of Utah
  - Adam Bress
EXTRA SLIDES
Using CVD risk To Guide Treatment is Patient-centered.
Using CVD Risk to Guide Treatment is Patient-centered.

![Graph showing cumulative % of subjects prepared to take the drug over hypothetical 5 year absolute risk reduction of cholesterol-lowering drug (%)]

- **Group 1**: Not on therapy
- **Group 2**: Statin users
- **Group 3**: Post-hospital discharge for MI

Trewby, Clinical Medicine 2002
What is the minimum number of deaths avoided among 5,000 people treated with antihypertensive or statin treatment of 10 years to justify its use?
Select Population – Young Adults

All US Adults: 219.4 million

Age < 50 years: 124.3 million

SBP ≥ 130 mm Hg: 16.6 million

High CVD risk: 2.0 million

SBP – systolic blood pressure, CVD – cardiovascular disease
The circles are proportional to the population sizes
Estimated 10-year versus 30-year CVD risk for 45 year old women

- Dyslipidemia
- Hypertension
- Smoking
- Diabetes

Pencina, Circulation 2009
Most people are concerned about short-versus long-term benefits of treatment.

Meaningful comparisons of life-years lost from CVD at different ages require weighting that gives less value to years in the distant future than in the near future.

Economic analyses account for this through discounting (e.g., 3% per year).

Jackson, The Lancet 2005
### Table 2: Effect of discounting and 30-day case fatality on life years lost after a cardiovascular disease event in men

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Average life expectancy (years)</th>
<th>Average life expectancy discounted at 3% per year (years)</th>
<th>30-day case fatality after a major CVD event* (%)</th>
<th>Average discounted life-years lost after a CVD event, attributable to 30-day case fatality (years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>80</td>
<td>6.8</td>
<td>6.2</td>
<td>60</td>
<td>3.7</td>
</tr>
<tr>
<td>70</td>
<td>12.2</td>
<td>10.3</td>
<td>50</td>
<td>5.2</td>
</tr>
<tr>
<td>60</td>
<td>19.2</td>
<td>14.8</td>
<td>40</td>
<td>5.9</td>
</tr>
<tr>
<td>50</td>
<td>27.6</td>
<td>18.9</td>
<td>30</td>
<td>5.7</td>
</tr>
<tr>
<td>40</td>
<td>36.8</td>
<td>22.4</td>
<td>25</td>
<td>5.6</td>
</tr>
</tbody>
</table>

*Coronary heart disease case fatality used as a proxy for cardiovascular disease case fatality⁵⁶ (note that the model does not account for morbidity after a cardiovascular disease event).
High BP is a Risk Factor For Many Outcomes

- Left ventricular hypertrophy
- Atrial fibrillation
- Heart failure
- Dementia
- Peripheral artery disease
- Retinopathy
- Peripheral neuropathy
- Chronic kidney disease/ESRD
Most People With Low CVD Risk Will Not Develop These Outcomes

- Hypertension Detection Follow-up Program

- Subset of 600 participants, 30 to 49 years of age followed for 5 years

- Stepped care versus referred care prevented:
  - 1 death
  - 1 stroke
  - 2 cases of incident left ventricular hypertrophy

Ramsay, JAMA 1997
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