Overview of the 2013 ACC/AHA Guidelines on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults And Young Adults

Hany Ragy MD, FSCAI
NHI, Egypt
Cardio Arab 2015

History of U.S. Dyslipidemia Guideline Development

<table>
<thead>
<tr>
<th>Year</th>
<th>ATP I</th>
<th>ATP II</th>
<th>ATP III</th>
<th>ATP III Update</th>
<th>ACC/AHA Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>1988</td>
<td>• Exclusive focus on LDL-C</td>
<td>• Risk assessment guides therapy</td>
<td>• Lower LDL-C threshold for therapy initiation in high risk patients</td>
<td>• Lower LDL-C threshold for therapy initiation in very high risk patients</td>
<td>• Use of moderate- or high-intensity statin therapy for patients across 4 major groups at risk for ASCVD*</td>
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<td>1993</td>
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<td>2001</td>
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<td>2004</td>
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<tr>
<td>2013</td>
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</tr>
</tbody>
</table>

*ASCVD, Atherosclerotic Cardiovascular Disease

What remains the same

- Ultimate goals: prevent ASCVD and improve the management of patients with ASCVD
- Heart-healthy lifestyle habits are the foundation for ASCVD prevention
- LDL-C is key treatment target
- Evidence supports that lowering LDL-C with statins reduces CV morbidity and mortality
- Benefit / Risk assessments are necessary

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2013 ACC/AHA Cholesterol Treatment Guideline Recommendations

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Third report of the National Cholesterol Education Program (NCEP) expert panel on detection, evaluation, and treatment of high blood cholesterol in adults (Adult Treatment Panel III) final report. Circulation. 2002;106:3143.

Focus on ASCVD Risk Reduction: 4 statin benefit groups*

Clinical ASCVD†
LDL-C level ≥190 mg/dL

Diabetes, aged 40-75 years, with LDL-C 70-189 mg/dL
Estimated 10-year risk of ASCVD of ≥7.5%,‡ 40-75 years of age, and with LDL-C 70-189 mg/dL

* Moderate- or high-intensity statin therapy recommended for these 4 groups
† Clinical ASCVD defined as acute coronary syndromes, history of MI, stable or unstable angina, coronary or arterial revascularization, stroke, transient ischemic attacks, or peripheral artery disease
‡ Estimated using Pooled Cohort Risk Assessment Equations

### Intensity of Statin Therapy

<table>
<thead>
<tr>
<th>High-Intensity Statin Therapy</th>
<th>Moderate-Intensity Statin Therapy</th>
<th>Low-Intensity Statin Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>LDL–C ↓ ≥50%</td>
<td>LDL–C ↓ 30% to &lt;50%</td>
<td>LDL–C ↓ &lt;30%</td>
</tr>
</tbody>
</table>

- **Atorvastatin (40†)–80 mg**
- **Rosuvastatin 20 (40) mg**

- **Atorvastatin 10 (20) mg**
- **Rosuvastatin (5) 10 mg**
- **Simvastatin 20–40 mg‡**
- **Pravastatin 40 (80) mg**
- **Lovastatin 40 mg**
- **Fluvastatin XL 80 mg**
- **Fluvastatin 40 mg bid**
- **Pitavastatin 2–4 mg**

- **Simvastatin 10 mg**
- **Pravastatin 10–20 mg**
- **Lovastatin 20 mg**
- **Fluvastatin 20–40 mg**
- **Pitavastatin 1 mg**

Lifestyle modification remains a critical component of ASCVD risk reduction, both prior to and in concert with the use of cholesterol lowering drug therapies.

Statins/doses that were not tested in randomized controlled trials (RCTs) reviewed are listed in italics
†Evidence from 1 RCT only: down-titration if unable to tolerate atorvastatin 80 mg in IDEAL
‡Initiation of or titration to simvastatin 80 mg not recommended by the FDA due to the increased risk of myopathy, including rhabdomyolysis.

Secondary Prevention

**Clinical ASCVD and ≤75 years old**

- *Moderate-intensity* statin therapy is recommended for patients with clinical ASCVD age >75 years, or in those patients who are not candidates for high-intensity statin therapy due to safety or tolerability considerations.
LUNAR
Efficacy on atherogenic Lipids in ACS Patients

Patients (n=825)
18–75 years with CAD
Hospitalized for ACS (STEMI, NSTEMI, UA) within 48 hrs of ischemic symptoms
LDL-C >70 mg/dL and TG <500 mg/dL within 72 hrs of symptom onset

Average time from symptom onset to randomization of study drug treatment = 3.9 days

Visit: 1 2 3 4 5
Week: 0 2 6 12

Symptom Onset
Screening / baseline blood analysis
Lipids Safety
Lipids hsCRP Safety

Rosuvastatin 20 mg (n=277)
Rosuvastatin 40 mg (n=270)
Atorvastatin 80 mg (n=278)


LUNAR
Primary End Point
LDL-C Averaged Over Measurements at Weeks 6 and 12

Average Change in LDL-C from Baseline (%)

RSV 20 mg n=246
RSV 40 mg n=251
ATV 80 mg n=257

-42.0
-46.6
-42.7

*p< 0.05 versus ATV 80 mg

Similar results were achieved in all subcategories of ACS (unstable angina, non-STEMI, and STEMI)
LUNAR
Secondary End Point
Values Averaged Over Measurements at Weeks 6 and 12

HDL-C

Average Change from Baseline (%)

RSV 20 mg (n=246)
RSV 40 mg (n=251)
ATV 80 mg (n=257)

† 9.7
11.9
5.6

LUNAR
Safety and Tolerability

<table>
<thead>
<tr>
<th>Variable</th>
<th>RSV 20 mg/day (n=249)</th>
<th>RSV 40 mg/day (n=249)</th>
<th>ATV 80 mg/day (n=257)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alanine aminotransferase &gt;3× ULN at 2 consecutive visits, n (%)</td>
<td>1 (0.4%)</td>
<td>0</td>
<td>1 (0.4%)</td>
</tr>
<tr>
<td>Creatine kinase &gt;10× ULN, n (%)</td>
<td>0</td>
<td>1 (0.4%)</td>
<td>0</td>
</tr>
<tr>
<td>Serum creatinine increased &gt;30% from baseline and &gt;ULN at maximum, n (%)</td>
<td>2 (0.9%)</td>
<td>0</td>
<td>3 (1.2%)</td>
</tr>
</tbody>
</table>

Primary Prevention

Patients ≥21 years old with LDL-C ≥190 mg/dL

- If high-intensity statin not tolerated, use maximum tolerated statin intensity
- After maximum statin intensity has been achieved, addition of a non-statin drug to further lower LDL-C may be considered


Application of Pediatric and young Adult Guidelines for Treatment of Lipid Levels Among US Adolescents Transitioning to Young Adulthood

Design, Setting, and Participants:
A cross-sectional analysis of the National Health and Nutrition Examination Survey (NHANES) population. Surveys were administered from January 1, 1999, through December 31, 2012, and the analysis was performed from June through December 2014. Participants included 6338 individuals aged 17 to 21 years in the United States.

Results:

- Of the 6338 young people aged 17 to 21 years in the NHANES population, **2.5%** would qualify for statin treatment under the pediatric guidelines compared with **0.4%** under the adult guidelines.

- Participants who met pediatric criteria had lower mean (SD) LDL-C levels (167.3 [3.8] vs 210.0 [7.1] mg/dL) but higher proportions of other cardiovascular risk factors, including hypertension (10.8% vs 8.4%), smoking (55.0% vs 23.9%), and obesity (67.7% vs 18.2%) compared with those who met the adult guidelines.

- **483 500** young people would be eligible for treatment of LDL-C levels if the pediatric guidelines were applied compared with only **78 200** if the adult guidelines were applied.
Conclusions and Relevance:
Application of pediatric vs adult guidelines for lipid levels, which consider additional cardiovascular risk factors beyond age and LDL-C concentration, might result in statin treatment for more than 400,000 additional adolescents and young adults.

Rosuvastatin versus Comparators:
LDL-C Efficacy at 10mg Dose
The STELLAR Study

<table>
<thead>
<tr>
<th>Change in LDL-C from baseline (%)</th>
<th>0</th>
<th>-5</th>
<th>-10</th>
<th>-15</th>
<th>-20</th>
<th>-25</th>
<th>-30</th>
<th>-35</th>
<th>-40</th>
<th>-45</th>
<th>-50</th>
<th>-55</th>
<th>-60</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rosuvastatin 10 mg</td>
<td>10</td>
<td>20</td>
<td>40</td>
<td>60</td>
<td>80</td>
<td>100</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Atorvastatin 10 mg</td>
<td>10</td>
<td>20</td>
<td>40</td>
<td>60</td>
<td>80</td>
<td>100</td>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Simvastatin 10, 20, 40 mg</td>
<td>10</td>
<td>20</td>
<td>40</td>
<td>60</td>
<td>80</td>
<td>100</td>
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</tr>
<tr>
<td>Pravastatin 10, 20, 40 mg</td>
<td>10</td>
<td>20</td>
<td>40</td>
<td>60</td>
<td>80</td>
<td>100</td>
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</tbody>
</table>

*p<0.002 vs atorvastatin 10 mg; simvastatin 10, 20, 40 mg; pravastatin 10, 20, 40 mg
†p<0.002 vs atorvastatin 20, 40 mg; simvastatin 20, 40, 80 mg; pravastatin 20, 40 mg
‡p<0.002 vs atorvastatin 40 mg; simvastatin 40, 80 mg; pravastatin 40 mg

Adapted from Jones P et al. Am J Cardiol 2003; 92: 152–160
Primary Prevention

Patients with Diabetes and LDL-C 70-189 mg/dL (age 40-75 years) without clinical ASCVD

Moderate-Intensity Statin

High-Intensity Statin if ≥7.5% estimated 10-year ASCVD risk*

* Estimated using Pooled Cohort Risk Assessment Equations


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CORALL Study design

Patients (n=263)
Type 2 diabetes mellitus (HbA1c <10%)
LDL-C ≥3.36 mmol/l (statin-naive) or >2.99 – ≤5.00 mmol/l (previous statin treatment within 4 weeks)
TG ≤4.52 mmol/l
≥18 years

End points:
Apo B/apoA-1
LDL-C
LDL-C goals
Lipids and lipoproteins

RSV=rosuvastatin; ATV=atorvastatin
Franken et al. Atheroscler Suppl 2004; 5: 118

© AstraZeneca 2013
Change in LDL-C with Rosuvastatin and Atorvastatin in High-Risk Patients
The CORALL Study

![Graph showing change in LDL-C with Rosuvastatin and Atorvastatin over different time periods (6, 12, 18 weeks) and doses (10 mg, 20 mg, 20 mg, 40 mg, 40 mg, 80 mg). The graph includes mean change from baseline (%) data for Rosuvastatin and Atorvastatin. Significant differences are indicated with * (p<0.05 vs ATV) and ** (p<0.01 vs ATV).](image)


Primary Prevention

- Patients with LDL-C 70-189 mg/dL without diabetes and without clinical ASCVD
- Estimated 10 year ASCVD risk ≥7.5%

- Yes
  - Moderate- to high-intensity statin therapy

- No
  - Consider additional factors to inform treatment decision

JUPITER – study design

No history of CAD
- men ≥50 yrs
- women ≥60 yrs
- LDL-C <130 mg/dL
- CRP ≥2.0 mg/L

Placebo run-in
- Rosuvastatin 20 mg (n=8901)
- Placebo (n=8901)

Visit:
- 1
- 2
- 3
- 4
- 6-monthly
- Final

Week:
- −6
- −4
- 0
- 13

Lipids
- Randomisation
- Lipids
- Lipids
- Lipids

CRP
- Tolerability
- Tolerability
- Tolerability

Tolerability
- HbA1c

Median follow-up 1.9 years

CAD=coronary artery disease; LDL-C=low-density lipoprotein cholesterol; CRP=C-reactive protein; HbA1c=glycated haemoglobin


JUPITER

Effects on LDL-C, HDL-C, TG and hsCRP at 12 months;

Percentage change between rosuvastatin and placebo

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Change from baseline (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>LDL-C</td>
<td>50%</td>
</tr>
<tr>
<td>HDL-C</td>
<td>4%</td>
</tr>
<tr>
<td>TG</td>
<td>17%</td>
</tr>
<tr>
<td>hsCRP</td>
<td>37%</td>
</tr>
</tbody>
</table>

p<0.001

*P-value at study completion (48 months) = 0.34

JUPITER: Primary Endpoint

Cumulative incidence, %

<table>
<thead>
<tr>
<th>Years</th>
<th>Number of events</th>
<th>Rosuvastatin</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td></td>
<td>142 (1.6%)</td>
<td>252 (2.8%)</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>173</td>
<td>156</td>
</tr>
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<td>2</td>
<td></td>
<td>44%</td>
<td></td>
</tr>
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<td>3</td>
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<td>9</td>
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<tr>
<td>10</td>
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</tbody>
</table>

HR 0.56 (95% CI 0.46-0.69)  
P = <0.00001

Number at risk

<table>
<thead>
<tr>
<th>Years</th>
<th>Rosuvastatin</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>8901</td>
<td>8901</td>
</tr>
<tr>
<td>1</td>
<td>8412</td>
<td>8353</td>
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<tr>
<td>2</td>
<td>3892</td>
<td>3872</td>
</tr>
<tr>
<td>3</td>
<td>1352</td>
<td>1333</td>
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<tr>
<td>4</td>
<td>543</td>
<td>534</td>
</tr>
<tr>
<td>5</td>
<td>156</td>
<td>173</td>
</tr>
</tbody>
</table>

JUPITER: Fatal or Nonfatal Myocardial Infarction

Cumulative Incidence

<table>
<thead>
<tr>
<th>Follow-up Years</th>
<th>Number of events</th>
<th>Rosuvastatin</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.5</td>
<td></td>
<td>31</td>
<td>68</td>
</tr>
<tr>
<td>1</td>
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<tr>
<td>1.5</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>2</td>
<td></td>
<td></td>
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<tr>
<td>2.5</td>
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<td>3</td>
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<tr>
<td>3.5</td>
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<tr>
<td>4</td>
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</tbody>
</table>

HR 0.46 (95% CI 0.30-0.70)  
P = <0.0002

- 54 %
JUPITER: Fatal or Nonfatal Stroke

HR 0.52 (95% CI 0.34-0.79)  
P=0.002

- 48%

Reported any serious adverse events were similar in the Crestor and placebo groups.¹

% of any serious adverse event

Crestor 20 mg (n 8901)  
Placebo (n 8901)
Sub-analysis of JUPITER in High Risk Patients (SCORE ≥ 5%; Framingham > 20%)

Analyses requested by the European Health Authorities

Post hoc analyses of JUPITER in High Risk Patients

Reduction in major CV events† with rosuvastatin 20 mg compared to placebo

Relative Risk Reduction in event rate

- Framingham score >20%
- EU score ≥5%

<table>
<thead>
<tr>
<th>Event Rate</th>
<th>Framingham score &gt;20%</th>
<th>EU score ≥5%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absolute risk reduction in event rate:</td>
<td>5.1 per 1000 patient years</td>
<td>8.8 per 1000 patient years</td>
</tr>
<tr>
<td>CV death, stroke and MI</td>
<td>P=0.0003 (vs placebo)</td>
<td>P=0.028 (vs placebo)</td>
</tr>
</tbody>
</table>

†combined end-point of cardiovascular death, stroke and myocardial infarction

1. CRESTOR, Summary of Product Characteristics.
A New Perspective on LDL–C and/or Non-HDL–C Treatment Goals

Lack of RCT evidence to support continued use of specific LDL–C and/or non-HDL–C treatment targets

No recommendations for or against specific LDL-C and non-HDL-C goals for primary or secondary prevention

Summary: 2013 Guideline Recommendations for Statin Therapy

ASCVD Statin Benefit Groups
Heart healthy lifestyle habits are the foundation of ASCVD prevention

<table>
<thead>
<tr>
<th>Clinical ASCVD</th>
<th>LDL-C ( \geq 190 ) mg/dL</th>
<th>Diabetes; age 40-75 years*</th>
<th>Estimated 10-yr ASCVD risk ( \geq 7.5% ); age 40-75 years*</th>
</tr>
</thead>
<tbody>
<tr>
<td>• High-Intensity statin (age ( \leq 75 ) years)</td>
<td>• High-intensity statin</td>
<td>• Moderate-intensity statin</td>
<td>• Moderate-to high-intensity statin</td>
</tr>
<tr>
<td>• Moderate-intensity statin if ( &gt;75 ) years or not a candidate for high-intensity statin</td>
<td>• Moderate-intensity statin if not a candidate for high-intensity statin</td>
<td>• High-intensity statin if estimated 10 year ASCVD risk ( \geq 7.5% )</td>
<td></td>
</tr>
</tbody>
</table>

ASCVD prevention benefit of statin therapy may be less clear in other groups. Consider additional factors influencing ASCVD risk, potential ASCVD risk benefits and adverse effects, drug-drug interactions, and patient preferences for statin treatment.

* With LDL-C of 70-189 mg/dL
† Estimated using the Pooled Cohort Risk Assessment Equations
Recommendations for Non-statin Therapies

• No data supporting the routine use of non-statin drugs combined with statin therapy to further decrease ASCVD events

• In high-risk patients who have an insufficient response to statin therapy, or who are unable to tolerate either a statin or the recommended statin intensity, addition of a non-statin cholesterol-lowering therapy can be considered


Role of Biomarkers and Non-invasive Tests in Assessing ASCVD Risk

Factors include:
- Primary LDL–C ≥160 mg/dL or other evidence of genetic hyperlipidemias
- Family history of premature ASCVD with onset <55 years of age in a first degree male relative or <65 years of age in a first degree female relative
- High-sensitivity C-reactive protein ≥2 mg/L
- Coronary Artery Calcium score ≥300 Agatston units or ≥75 percentile for age, sex, and ethnicity
- Ankle-brachial index <0.9
- Elevated lifetime risk of ASCVD

Safety Considerations

**Selection of appropriate statin**

- Select the appropriate statin and dose based on patient characteristics, level of ASCVD* risk, and potential for adverse effects.

- Moderate-intensity statin therapy should be used in individuals in whom high-intensity statin therapy would otherwise be recommended when characteristics predisposing them to statin-associated adverse effects are present.

- Characteristics predisposing individuals to statin adverse effects include, but are not limited to:
  - Multiple or serious comorbidities, including impaired renal or hepatic function
  - History of previous statin intolerance or muscle disorders
  - Unexplained ALT elevations >3 times ULN
  - Patient characteristics or concomitant use of drugs affecting statin metabolism
  - >75 years of age

- Additional characteristics that may modify the decision to use higher statin intensities may include, but are not limited to:
  - History of hemorrhagic stroke
  - Asian ancestry

- Statins used in combination with other cholesterol-lowering drug therapies might require more intensive monitoring.

*Based on the presence of clinical ASCVD, diabetes mellitus, LDL-C ≥190 mg/dL, or level of estimated 10-year ASCVD risk.


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**Safety Considerations**

**Creatinine Kinase (CK)**

- Routine monitoring of CK not recommended
- Measurement may be useful at baseline in those at increased risk of muscle events and in patients with muscle symptoms
- Guideline provides recommendations for management of muscle symptoms

**Alanine Transaminase (ALT)**

- Baseline measurement recommended
- Routine hepatic monitoring not recommended unless symptoms suggesting hepatotoxicity are present

**Type-2 Diabetes**

- Statins modestly increase risk of type-II diabetes in patients with risk factors for diabetes
- Potential for ASCVD risk reduction benefit outweighs risk of diabetes in all but lowest risk individuals
- Evaluate for new onset diabetes according to current diabetes screening guidelines

What is new in the 2013 Guideline?

- Identification of 4 major statin benefit groups
- Shift away from treat to target approach
- Definitions of statin intensity provided
- New global risk assessment tool for primary prevention
- Addition of non-statin drug therapy to statins to further decrease ASCVD risk addressed


Statin treatment: can genetics sharpen the focus?

![Graph showing event rates in the primary prevention setting, based on participants of the JUPITER and ASCOT trials as reported by Mega and colleagues].

Figure: Hypothetical event rates in the primary prevention setting, based on participants of the JUPITER and ASCOT trials as reported by Mega and colleagues. The combination of individuals in the highest quintile of the genetic risk score from both trials resulted in average annual event rates of close to 0.9% that was almost halved by statin treatment. The same annual numbers in the lowest quintile of the genetic risk score were 0.49% without a statin and 0.32% with a statin. The shaded areas represent the benefit related to statin treatment in individuals with a high or low genetic risk score. The event rates in JUPITER were extrapolated to 6.3 years—i.e., the duration of the ASCOT trial.
Age- and Sex-Specific Criteria Could Sharpen Statin Treatment Guidelines: Analysis

- Study population included 3685 adults, average age 57.2 years, from the Framingham Offspring Study, with no CVD at baseline.
- Researchers calculated patients' 10-year estimated CV event risk based on the pooled cohort equations and followed the cohort for events over 10 years, stratifying results by age.
- The events included:
  Nonfatal MI, coronary heart disease death, fatal or nonfatal stroke, peripheral arterial disease, and heart failure.

Navar-Boggan AM, Peterson ED, D’Agostino RB Sr, Pencina MJ, Sniderman AD.

RESULTS:

- Basing statin therapy recommendations on a 10-year fixed risk threshold of 7.5% Results in:
  - Lower statin consideration among women than men (63% vs. 33% <0.0001),
  - The majority of those aged 66–75 years were recommended for treatment (90.3%).
  - The fixed 7.5% threshold also had relatively low sensitivity for capturing 10-year events in younger women and men (aged 40-55 years).
  - The sensitivity of the recommendations were substantially improved when the treatment threshold was reduced to 5% in those aged 40-55 years (changing sensitivity from 36% to 61% in women, and 49% to 71% in men).
  - Among older adults (aged 66–75) specificity was poor (18% in women, 3% in men), but when the treatment threshold was raised to 10% in women and 15% in men, specificity significantly improved (to 34% in women,14% in men), with only small to no loss in sensitivity (95% to 87% in women, and 96% at both thresholds in men).
Conclusion

Cholesterol treatment recommendations could be improved by utilizing individualized age- and sex-specific CVD risk thresholds.

Navar-Boggan AM, Peterson ED, D’Agostino RB Sr, Pencina MJ, Sniderman AD.

Summary

• 4 major statin benefit groups identified for whom ASCVD risk reduction outweighs the risk of adverse events

• Shift away from a treat to target LDL-C approach

• No longer recommend non-statin drug therapy in combination with statins to further decrease ASCVD events

Thank You