New Guidelines for Cholesterol

Overview

- Current cholesterol guidelines (ATP III) used at the VA
- New cholesterol guidelines presented in 2013 by the American College of Cardiology and the American Heart Association
- Focus Groups of new guidelines
- Pooled Cohort Equation
  - New Risk Calculator
- Controversy/Support of Calculator
- Summary of new guidelines

ATP III

- Expert panel created guidelines on the detection, evaluation, and treatment of high blood cholesterol in adults (Adult Treatment Panel III).
  - ATP III added a more intensive LDL-lowering therapy in certain groups of people.
  - Used a risk assessment to determine treatment.

ATP III Guidelines

1. Determine lipoprotein levels: based on LDL, total cholesterol, HDL
2. Determine presence of clinical atherosclerotic disease (high risk for CHD events or CHD risk equivalent)
3. Determine presence of major risk factors other than LDL (smoking, HTN, low HDL, family hx, age)
ATP III Guidelines

4. If 2+ risk factors (other than LDL) w/out CHD/CHD risk equivalent, assess 10-yr CHD risk (Framingham tables) http://www.medcalc.com/heartrisk.html

5. Determine risk category- then establish LDL goal for therapy, determine need for TLC and the level of drug consideration

6. Initiate TLC if LDL above goal:
   - TLC: sat. fat <7% of kcal, cholesterol<200 mg/d; increase soluble fiber (10-25 g/d) and plant sterols (2g/d)
   - wt mgmt
   - increase PA

7. Consider adding drug therapy if LDL exceeds specified levels

8. Identify metabolic syndrome and treat if present after 3 months of TLC
   - Abdominal obesity, TG level, HDL, BP, fasting glucose

9. Treat Elevated TG

Current VA/DOD Guidelines

<table>
<thead>
<tr>
<th>ADA</th>
<th>VA/DOD</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>LDL-C</strong></td>
<td><strong>LDL-C</strong></td>
</tr>
<tr>
<td>Without event CVD: &lt;100 (Add statin regardless of baseline LDL if age &gt;40 and 1 additional RF)</td>
<td>Without event CVD: &lt;100 (statin therapy may be considered regardless of LDL if 1 additional RF)</td>
</tr>
<tr>
<td>Without event CVD: &lt;70 with high dose statin</td>
<td>Non high risk: &lt;70 (statin therapy may be considered regardless of LDL if overt CVD)</td>
</tr>
<tr>
<td>Alternative goal: reduction of LDL ~30-40% from baseline</td>
<td>Use at least moderate dose statin</td>
</tr>
<tr>
<td><strong>Blood Pressure</strong></td>
<td><strong>Blood Pressure</strong></td>
</tr>
<tr>
<td>&lt;140/90</td>
<td>&lt;140/90</td>
</tr>
<tr>
<td><strong>Anti-platelet Therapy</strong></td>
<td><strong>Anti-platelet Therapy</strong></td>
</tr>
<tr>
<td>Aspirin if event CVD</td>
<td>Aspirin if event CVD</td>
</tr>
<tr>
<td>Aspirin if 10-yr CVD risk &gt;15%</td>
<td>Aspirin if event CVD</td>
</tr>
<tr>
<td>Aspirin if TGT recommended if 10-yr ASCVD risk &gt;5%</td>
<td>Aspirin if age &gt;40 and 1 or more other CVD risk factors</td>
</tr>
<tr>
<td>Use clinical judgment for 5-10% risk</td>
<td>Consider aspirin if younger and other CVD risk factors</td>
</tr>
<tr>
<td>Use clopidogrel if overt CVD and aspirin allergy</td>
<td>Consider in type 1 DM for duration of disease &gt;2yrs</td>
</tr>
</tbody>
</table>

Tobacco Use: Encourage Cessation

New Cholesterol Guidelines

• Established by American College of Cardiology (ACC) and the American Heart Association (AHA) in 2013

• Provides guidelines on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk (ASCVD) in adults

• Focus - appropriate statin medication use and the intensity of therapy rather than LDL-C targets to reduce atherosclerotic cardiovascular disease risk
  • Also addresses safety of statins
New Cholesterol Guidelines

Identified 4 major groups to benefit from statin
1. Overt ASCVD (Atherosclerotic cardiovascular disease)
2. Baseline LDL>190
3. Diabetes, ages 40-75 with LDL >70
4. Estimated 10-year ASCVD risk >7.5%

New Groups

**Group 1**
- Patients with established disease
  - History of myocardial infarction, acute coronary syndrome, angina, coronary or other arterial revascularization, stroke, transient ischemic attack and PAD) without New York Heart Association class II – IV heart failure or on hemodialysis

**Group 2**
- Patients with LDL-C ≥ 190 mg/dL

**Group 3**
- Patients 40–75 yrs with diabetes and LDL-C 70 to 189 mg/dL without clinical ASCVD

**Group 4**
- Patients w/out ASCVD or diabetes who are 40-75 yrs with LDL-C 70-189 mg/dL
- Estimated 10-yr ASCVD risk of 7.5% or higher using the new Pooled Cohort equation

Four Statin Benefit Group

- Used data from RCTs, systemic reviews, and meta-analyses of RCTs to develop recommendations in the four primary groups of patients
- Groups 1-3 are already routinely treated
- Inclusion of group 4 is the greatest change from previous guidelines and is the most controversial aspect of the new guidelines
- Prescribed statin to group 4 patients is strictly for primary prevention
Pooled Cohort Equation

- Developed to help determine which patients in group 4 should receive statin therapy
- Developed by Risk Assessment Work Group to help identify patient’s 10-yr risk for developing their first ASCVD event
- The new guidelines recommend using the predicted 10-yr ASCVD risk to guide initiation of statin therapy

New Risk Calculator

- Sex
- Age
- Ethnicity (Caucasian/non-Caucasian vs African American)
- Total cholesterol
- HDL-C
- Systolic BP
- Treatment for HTN
- Diabetes
- Smokes

New Risk Calculator

- Recommends initiation of statin treatment if the patient’s estimated 10-yr ASCVD risk is 7.5% or higher and consideration of treatment if risk is 5% to 7%.
- Risk calculator only used for primary prevention in patients (without ASCD) 40-75 yr with an LDL-C value of 70-189 mg/dL.
- Not intended for patients already treated with statin medication.
Controversy/Support - Risk calculator

• Expert panel members had many current or recent affiliations with drug manufactures while on the panel.
• Risk calculator criticized for overestimating risk by as much as 150% when applied to people in the Women’s Health Study and the Physician’s Health study.
• Risk calculator has thresholds over which the risk increased dramatically (i.e. turning 55 yrs increases patient’s risk substantially).
• Recent research of large, more diverse population has validated the ACC/AHA Pooled Cohort risk equations.
• However, threshold for starting statin therapy has been lowered.

New Cholesterol Guidelines

Focus less on target goals for LDL
• Consider intensity of statin dose

<table>
<thead>
<tr>
<th>Moderate-intensity (↓30-50%)</th>
<th>High-intensity (↓&gt;50%)</th>
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</thead>
<tbody>
<tr>
<td>Pravastatin 40 mg/d</td>
<td>Atorvastatin (40)-80 mg/d</td>
</tr>
<tr>
<td>Simvastatin 20-40 mg/d</td>
<td>Rosuvastatin 20-40 mg/d</td>
</tr>
<tr>
<td>Atorvastatin 10-20 mg/d</td>
<td></td>
</tr>
<tr>
<td>Rosuvastatin 5-10mg/d</td>
<td></td>
</tr>
<tr>
<td>Fluvastatin 80 mg/d</td>
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*From Macrovascular Complications: Lowering the Risk by Sonja Fredrickson, MD, BC-ADM

Individual Risk Factor Modification on Vascular Risk Reduction

Lipid Control (think RISK!)

• Lower is better (~25% Risk Reduction (RR) in CV events across trials)
• Even lower is even better (Cholesterol Treatment Trialists; Less vs More Statin Trials; IMPROVE-IT)
  • For every 40 mg/dL ↓LDL, ~25% RR in CV events w/ no limit.
    • ~40 mg/dL reduction leads to 25% RR in CV events
    • ~80 mg/dL reduction leads to 42% RR in CV events
    • ~120 mg/dL reduction leads to 56% RR in CV events
• ACC/AHA Recommendation (2013): Diabetes (age 40-75) with baseline LDL >70 mg/dL should receive at least moderate dose statin!

*From Macrovascular Complications: Lowering the Risk by Sonja Fredrickson, MD, BC-ADM

Don’t forget the MNT!!

• Therapeutic Lifestyle Changes (TLC) may help reduce LDL
• Limit saturated and trans fats
• Limit cholesterol (less than 200 mg/day)
• Eat more omega-3 fats
• Limit total amount of fat to 25-35 % of total kcal/day
• Eat 20-30 g of fiber/day
• Eat more plant based meals
• Get physical activity and work to maintain a healthy weight
• Don’t forget to watch alcohol and sugar intake as well!!

*From Macrovascular Complications: Lowering the Risk by Sonja Fredrickson, MD, BC-ADM
Summary

• If guidelines are followed, estimated 920 million people worldwide would be considered statin candidates when applied to a global population.

• Emphasis on using appropriate intensity of statin meds in the four groups that are most likely to benefit from therapy rather than focusing on meeting specific LDL-C goals.

• **Important to remember that lifestyle modification is one of the most critical components in ASCVD risk reduction...both before and in conjunction with cholesterol-lowering drug therapies.**