Achieving Aggressive Lipid Goals: 2008 Update

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Chair of the Department of Pharmacy Practice

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Speaker: Dr. Stolte joined the faculty of the Bernard J. Dunn School of Pharmacy at Shenandoah University in 1998. Dr. Stolte has been fortunate to work with wonderful faculty and staff members and students during his time at Shenandoah University.

Speaker Disclosure: Dr. Stolte has no actual or potential conflicts of interest in relation to this program.

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Pharmacy Technicians 798-000-08-025-L01-T

Target Audience: Pharmacists & Technicians

CE Credits: 1.0 Continuing Education Hour or 0.1 CEU for pharmacists/technicians

Expiration Date: 03/11/2011

Program Overview: Come join us as Scott Stolte, Pharm.D. presents the good, bad, and ugly of Achieving Aggressive Lipid Goals this year

Objectives:
1. Explain the rationale for combination therapy in lipid management.
2. Define the value of a co-administration approach in achieving NCEP goals.

This program has been supported by an educational grant from MERCK Pharmaceuticals
Outline

• Discuss relationship between lipid values and coronary events
• Evaluate clinical data for aggressive lipid management
• Describe rationale for combination therapy
• Explain how to achieve aggressive goals with combination therapy
MR. FISHHAWK, THERE'S GOOD CHOLESTEROL AND THERE'S BAD CHOLESTEROL...

BUT ACCORDING TO THESE TEST RESULTS...

YOUR BAD CHOLESTEROL HAS ENGINEERED A HOSTILE TAKEOVER OF YOUR GOOD CHOLESTEROL.
Hyperlipidemias

- 17% of US adults have total cholesterol of 240 mg/dl or higher
- Average total cholesterol in adults is 203 mg/dl
- > 30% of adults have LDL that exceeds goal
- 16% of adults over 20 need lifestyle changes
- 13-46% meet criteria for drug treatment

National Center for Health Statistic. Health, United States, 2006
Am Heart J 2005;150:595-601.
Benefits of Cholesterol Reduction

- Reduction of CHD risk
- Reduction of cardiovascular morbidity and mortality
- Improved survival in pts. with or without CHD
- Reduced need for procedures (PTCA, CABG)
- Reduced progression of atherosclerosis
- Reduction in stroke risk
L-TAP: Patients Achieving NCEP Goals

Category | No CHD | CHD Patients | All Subjects
--- | --- | --- | ---
Low Risk | < 2 RF | <160 mg/dl | 68% | 37% | 38%
High Risk | ≥2 RF | <130 mg/dl | 37% | 18% | 38%

Arch Intern Med 2000;160:459-467
NEPTUNE II - % High Risk Patients Who Achieved LDL-C Goal

NEPTUNE II = NCEP Evaluation Project Utilizing Novel E-Technology
Why Do So Few Patients Reach Their LDL-C Goal?

- Aggressive goals
- Many patients are never treated
- Poor adherence
- Most LDL-C reduction occurs with starting dose of statins
- Doses are not titrated
Risk Assessment

• Evaluate risk of patient
  – Established CHD/CHD risk equivalent
  – Multiple (2+) risk factors
  – Zero-one risk factor

• Evaluate lipid profile and cholesterol goals
  – Primary target: LDL

Circulation 2004;110:227-239
CHD Risk Factors

- Cigarette smoking
- Hypertension
- Low HDL-C (<40 mg/dl)
- Male ≥ 45 or Female ≥ 55
- Family history of premature heart disease (male parent or sibling before 55 or female before 65)

Circulation 2004;110:227-239
Cardiovascular Disease and Cardiovascular Risk Equivalent (CRE)

- Cardiovascular disease
  - Established coronary and other atherosclerotic vascular disease
    - Carotid artery disease
    - Peripheral arterial disease
    - Atherosclerotic aortic disease

- Cardiovascular Risk Equivalent
  - Diabetes
  - 10-year risk for CHD > 20%
Cardiovascular Risk Assessment

Risk Assessment Tool for Estimating 10-year Risk of Developing Hard CHD (Myocardial Infarction and Coronary Death)

• Uses data from the Framingham Heart Study to estimate 10-year risk for “hard” coronary heart disease outcomes (myocardial infarction and coronary death)
• Designed to estimate risk in adults aged 20 and older who do not have heart disease or diabetes.

www.nhlbi.nih.gov/health/prof/other/index.htm
What Is His Estimated Risk of CHD?

- Steve is a 48-year-old who was recently diagnosed with high cholesterol.
- History: smokes 1 ppd, no medications, construction worker, denies any family history of heart disease
- Lipid profile:
  - Total cholesterol = 215 mg/dl, LDL =160 mg/dl
  - HDL-C = 30 mg/dl, TG=150 mg/dl
- BP:138/80
## LDL Goals: Based on Cardiovascular Risk Factor Assessment

<table>
<thead>
<tr>
<th>Risk Category</th>
<th>LDL Goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHD</td>
<td>&lt; 100 mg/dl</td>
</tr>
<tr>
<td></td>
<td>(&lt;70 is reasonable)</td>
</tr>
<tr>
<td>CRE (10-year risk &gt; 20%)</td>
<td>&lt; 100 mg/dl</td>
</tr>
<tr>
<td>2+ Risk Factors (10 year risk &lt; 20 %)</td>
<td>&lt; 130 mg/dl</td>
</tr>
<tr>
<td></td>
<td>(&lt;100 is option)</td>
</tr>
<tr>
<td>0 – 1 Risk Factor</td>
<td>&lt; 160 mg/dl</td>
</tr>
</tbody>
</table>

CRE = CHD Risk Equivalent

J Am Coll Cardiol 2006;47:2130-9
Circulation 2004;110:227-239
# HDL and TG Goals

<table>
<thead>
<tr>
<th>Category</th>
<th>Goals</th>
</tr>
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<tbody>
<tr>
<td>HDL</td>
<td>&gt; 40 mg/dl (men)</td>
</tr>
<tr>
<td></td>
<td>&gt; 50 mg/dl (women)</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>&lt; 150 mg/dl</td>
</tr>
</tbody>
</table>

NCEP ATP III – HDL > 40 for both genders  
AHA – HDL > 40 for men, > 45 for women  
ADA – HDL > 50 for women
Protective Effects of HDL-C

- Reverse cholesterol transport
- Reduction of oxidative modification of LDL-C
- Inhibition of expression of adhesion molecules by cytokine-activated endothelial cells (anti-inflammatory)
Treatment Gap

- Reducing LDL from 120-180 mg/dl baseline to 100-140 mg/dl with statins reduces CV events 25%
  - 3 out of 4 events occurred despite statin therapy
- Only 1 in 3 CHD patients is at or below the more liberal current LDL goal of 100 mg/dl.

*NEJM* 2004;350:1495-502
How Low Should LDL Go?
Atherosclerosis Progression Trials

\[ y = 0.0004x - 0.0267 \]
\[ R^2 = 0.6116 \]
\[ p = 0.001 \]

*J Am Coll Cardiol 2004;43:2142-2146*
Primary Prevention Trials

\[ y = 0.0599x - 3.3952 \]
\[ R^2 = 0.9305 \]
\[ p = 0.0019 \]
Secondary Prevention Trials

\[ y = 0.1629x - 4.6776 \]

\[ R^2 = 0.9029 \]

\[ p < 0.0001 \]

CHD Events (%) vs. LDL Cholesterol (mg/dL)

J Am Coll Cardiol 2004;43:2142-2146
How Low is TOO Low?

• Cholesterol is an essential component of cell membrane and precursor for bile acid, steroid hormone, and vitamin D synthesis.

• People with naturally low LDL → longevity

• No relationship between on-treatment LDL level and medication adverse effects
For every 30 mg/dl change in LDL, relative risk for CHD is changed by about 30%
Other Benefits of Physiologically Normal (50-70 mg/dl) LDL

- Decreased inflammation (↓ CRP)
- Improvement in endothelial dysfunction
- Decreased incidence of PVD, stroke, dementia, macular degeneration, aortic stenosis, and osteoporosis-related hip and vertebral fractures
Cholesterol Metabolism

Dietary C (300-700 mg/day)

Biliary C (~1000 mg/day)

Absorption

VLDL $\rightarrow$ IDL $\rightarrow$ LDL

Excretion

Saturated/Trans Fats

Liver

Intestine
Getting Patients to Goal

What does it take to achieve an LDL-C of 70 or 100mg/dl?
How do we get Steve to goal?

• Lipid profile:
  – Total cholesterol = 215 mg/dl, LDL = 160 mg/dl
  – HDL-C = 30 mg/dl, TG = 150 mg/dl
• Started on TLC (low fat diet and exercise 3 x/wk) and scheduled for follow-up in 3 months.
## Therapeutic Lifestyle Changes

<table>
<thead>
<tr>
<th>TLC Component</th>
<th>LDL-C</th>
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<tbody>
<tr>
<td>Low saturated fat/dietary cholesterol</td>
<td>↓ 12-15%</td>
</tr>
<tr>
<td>Viscous fiber (10–25 g/d)</td>
<td>↓ 10-15%</td>
</tr>
<tr>
<td>Plant stanols/sterols (1.5-4 g/d)</td>
<td>↓ 10-20%</td>
</tr>
<tr>
<td>Soy protein (20-30 g/d)</td>
<td>↓ 5-7%</td>
</tr>
<tr>
<td>Policosanol (sugar cane)</td>
<td>↓ &lt;10 - 20%</td>
</tr>
<tr>
<td>Fish oils (Lovaza®, 4-9 g/day)</td>
<td>↓ TG 25-35%, ↑ HDL 9%</td>
</tr>
<tr>
<td>Weight loss (5-10%)</td>
<td>Variable</td>
</tr>
<tr>
<td>120 min/wk exercise</td>
<td>↑ HDL 2.5 mg/dl</td>
</tr>
</tbody>
</table>
BIZARRO By Dan Piraro

Welcome to TEXAS
“Come for the BBQ—stay for the angioplasty”
The Follow-up

• Steve has been carefully following the low fat diet and walking or going to gym 3 days per week.

• Lipid profile
  – LDL = 136 mg/dl
  – HDL-C = 34 mg/dl
  – TG=140 mg/dl
### Lipid Effects of Various Agents

<table>
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<th>Agent</th>
<th>LDL</th>
<th>TG</th>
<th>HDL-C</th>
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<td>Colestipol/Cholestyramine Colesevelam (Welchol)</td>
<td>↓ 10-25%</td>
<td>↑ 0-12%</td>
<td>↑ 3-10%</td>
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<td>↓ 10-25%</td>
<td>↓ 20-50%</td>
<td>↑ 15-35%</td>
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<td>Fenofibrate (Tricor) Gemfibrozil (Lopid)</td>
<td>↓ 10-15%</td>
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<td>Ezetimibe (Zetia)</td>
<td>↓ 15-23%</td>
<td>↓ 7-9%</td>
<td>↑ 4-9%</td>
</tr>
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<td>Atorvastatin (Lipitor) Fluvastatin (Lescol)</td>
<td>↓ 21-60%</td>
<td>↓ 7-30%</td>
<td>↑ 5-15%</td>
</tr>
</tbody>
</table>
Therapy to Attain Goals

- Intensity of initial statin therapy should be sufficient to reach a 30-40% reduction in LDL-C levels

**TABLE 1. Doses of Currently Available Statins Required to Attain an Approximate 30% to 40% Reduction of LDL-C Levels (Standard Doses)*

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose, mg/d</th>
<th>LDL Reduction, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atorvastatin</td>
<td>10†</td>
<td>39</td>
</tr>
<tr>
<td>Lovastatin</td>
<td>40†</td>
<td>31</td>
</tr>
<tr>
<td>Pravastatin</td>
<td>40†</td>
<td>34</td>
</tr>
<tr>
<td>Simvastatin</td>
<td>20–40†</td>
<td>35–41</td>
</tr>
<tr>
<td>Fluvastatin</td>
<td>40–80</td>
<td>25–35</td>
</tr>
<tr>
<td>Rosuvastatin</td>
<td>5–10‡</td>
<td>39–45</td>
</tr>
</tbody>
</table>

*Estimated LDL reductions were obtained from US Food and Drug Administration package inserts for each drug.

Circulation 2004;110:227-239
What if Steve also had diabetes?

- What would his LDL goal be?
- How would you achieve this goal?
Options for Aggressive Lipid Lowering

- High dose statin (+ diet and exercise)
- Combination therapy (+ diet and exercise)
Issues with High Dose Statins

- Rule of 6’s
- Still may not reach goal

Issues with High Dose Statins

• Dose related adverse effects
  – Elevations of LFTs – potential for liver toxicity
    • Overall – 0.5-2% of patients
    • Appears to be higher rate with higher doses
  – Myopathy
    • Overall – 0.1– 0.5 %
    • <0.1% progress to rhabdomyolysis
    • Rate does appear to be higher with higher doses

Pharmacotherapy 2005;25:345-351
Curr Med Res Opin 2001;17:43-50
J Am Coll Cardiol 2002;40:567-72
Situations for Close Monitoring or Avoidance of High Dose Statins

- Chronic use of medications known to interact with statins
- Patients > 80
- Thin or frail women
- Multisystem disease, especially chronic renal failure from diabetes
- Perioperative
- Asian Americans (Rosuvastatin)

*J Am Coll Cardiol* 2002;40:567-572
Conclusions of the NLA Safety Task Force for Muscle Safety

- Myopathy and rhabdomyolysis are associated with statin therapy (class effect)
- Elevated creatine kinase (CK) levels may indicate statin-induced muscle damage
- Muscle weakness or pain without CK elevation may indicate statin-induced muscle damage
- Myopathy and rhabdomyolysis risk increases with increased statin dose and serum levels
- Myopathy and rhabdomyolysis risk increases with drug-drug interactions that retard statin metabolism
- Drugs that can interact to amplify statin related myopathy include gemfibrozil and CYP-3A4 inhibitors

*Am J Cardiol*. 2006;97:69C-76C
Recommendations Regarding Patient Monitoring

- Monitoring CK levels is recommended only for symptomatic patients.
- Patients on statin therapy do not require routine monitoring of liver function*, renal function, or cognitive function.

*Note: Liver function monitoring is currently recommended by the regulatory authorities and manufacturers.

*Am J Cardiol. 2006;97:69C-76C*
Messages for Patients

- Statins can produce muscle pain and weakness, which can very rarely become an important medical problem
- Serious liver damage due to statins is extremely rare
- Marketed doses of statins do not have any direct adverse effects on the kidney
- Statins do not cause peripheral neuropathy and do not impair memory or cognition

*Am J Cardiol. 2006;97:69C-76C*
Combination Therapy

- Statin + Niacin
- Statin + Fibrate
- Statin + BAS
- Statin + Stanol/sterol
- Statin + Ezetimibe
- Fibrate + Ezetimibe
- Triple therapy
Statin + Niacin

• **Efficacy**
  - HATS: 160 pts with CHD, low HDL, normal LDL
    - Simvastatin (10 mg titrated) + Slo-Niacin 1000 mg BID
    - 90% reduction in CV events over 3 yrs, 0.4% regression of lesions, LDL ↓42%, HDL ↑26%
  - Lovastain 40 mg/d-niacin ER 2000 mg/d
    - LDL ↓47%, TG ↓41%, HDL ↑41%

• **Adverse effects**
  - 4 of 871 cases of statin-induced rhabdomyolysis were attributed to statin/niacin combo
  - 0.5% with elevated LFTs

*Am J Cardiol* 2002;89:672-678
Statin + Fibrate

• **Efficacy**
  - Fenofibrate 300 mg/d + pravastatin 20 mg/d or simvastatin 10 mg/d
    - LDL ↓28%, TG ↓41%, HDL ↑22%
  - Fenofibrate 200 mg/d + atorvastatin 20 mg/d
    - LDL ↓46%, TG ↓50%, HDL ↑22%

• **Safety**
  - 0.12 – 0.22 % overall frequency of muscle damage
  - 9% of rhabdomyolysis cases (statin + gemfibrozil)

*Pharmacotherapy* 2005;25:345-351
*Diabetes Care* 2002;25:1198-1202
*Ann Pharmacother* 2001;35:908-917
**Dietary C** (300-700 mg/day)

**Biliary C** (≈1000 mg/day)

**Liver**

**Intestine**

**Blood**

**Saturated/Trans Fats**

**Doubt Inhibition Therapy**

Statins

CAI/ BAS/ Stanol

CAI=cholesterol absorption inhibitor
**Statin + BAS**

- **Efficacy**
  - Colesevelam 3.6 g/d + simvastatin 10 mg/d
    - ↓ LDL by 42%
  - Colesevelam 3.8 g/d + atorvastatin 10 mg/d
    - ↓ LDL by 48%

- **Issues**
  - Side effects with older BAS – rarely get full effect
  - Colesevelam – 6 tablets/day
  - Increases in TG

*Atherosclerosis* 2001;158:407-16
Statin + Plant Stanol/Sterol

• **Efficacy**
  – Meta analysis of 41 studies of stanol/sterol alone
    • Lowers LDL 10%
  – 2.24 g/d of stanol esters (80% rapeseed oil spread) added to simvastatin 20-40 mg
    • Lowered LDL an additional 20%

• **Safety**
  – No known adverse effects

• ↑’d caloric intake from stanol/sterol spreads (9-27 gm fat)

Arterioscler Thromb Vasc Biol 2000;20:500-506
Statin + Cholesterol Absorption Inhibitor

• As two separate products
  – statin + ezetimibe (Zetia®)
• Combination product
  – simvastatin/ezetimibe (Vytorin®)
*atorvastatin 80 mg, lovastatin 40mg, pravastatin 40 mg, rosuvastatin 10 mg, simvastatin 80 mg

Eur Hear J 2002;4:J9-J18
### Safety of Ezetimibe + Statin

- **EASE**: 3030 patients on stable statin dose not at goal, ezetimibe 10 mg/d or placebo

<table>
<thead>
<tr>
<th>Parameter</th>
<th>P + Statin</th>
<th>E + Statin</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALT $\geq$ 3X ULN</td>
<td>0.2</td>
<td>0.4</td>
<td>NS</td>
</tr>
<tr>
<td>AST $\geq$ 3X ULN</td>
<td>0.1</td>
<td>0.2</td>
<td>NS</td>
</tr>
<tr>
<td>CK $\geq$ 10X ULN w/or w/out symptoms</td>
<td>0.0</td>
<td>0.0</td>
<td>NS</td>
</tr>
</tbody>
</table>

ALT, alanine transaminase; AST, aspartate transaminase; CK, creatine kinase; ULN, upper limit of normal

ACC 53rd Annual Scientific Session; March 2004; New Orleans, LA
Efficacy of Combination Product

• 12 wk trial in 887 patients
• Drug regimens studied:
  – Placebo
  – Ezetimibe 10 mg qd
  – Simvastatin 10 mg, 20 mg, 40 mg, or 80 mg
  – Ezetimibe/simvastatin (Vytorin) 10/10 mg, 10/20 mg, 10/40 mg, or 10/80 mg
• Results:
  – Ezetimibe/simvastatin 10/10 mg ≈ simvastatin 80 mg (↓ LDL 46% )
  – Ezetimibe/simvastatin 10/80 mg ↓ LDL 60%

*Mayo Clinic Proc 2004;79:620-629*
Efficacy of Combination Product – Comparison with Atorvastatin

10/10mg 10mg 20mg 10/40mg 40mg 10/80mg 80mg

*Statistically significant

Am J Cardiol 2004;93:1487-1494
Combination Therapy

- Statin 10 mg
- 20 mg, 40 mg, 80 mg
- 5–6% 5–6% 5–6%
- 3-Step titration

- Statin 10 mg + Ezetimibe 10 mg
- 15–18%
- 1-Step coadministration

Reduction in LDL (%)

Goal Achievement in Patients with CHD or CHD Risk Equivalent

Patients reaching LDL-C goal < 70 mg/dl

Drugs Affecting Lipid Metabolism Meeting 10/2004; Abstract 114.

* p<0.01
ENHANCE

- Multinational, randomized, double-blind, trial 10 mg ezetimibe + 80 mg simvastatin vs. simvastatin 80 mg in 720 patients with Heterozygous Familial Hypercholesterolemia (HeFH).
- Combo 58% drop in LDL vs. 41% for simvastatin
- Change in carotid artery intima thickness was no different
# Combination Therapy Comparison

<table>
<thead>
<tr>
<th>Combo</th>
<th>Additional LDL ↓</th>
<th>Costs / day*</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statin + fenofibrate 145 mg</td>
<td>10%</td>
<td>$3.33</td>
<td>↓ TG &amp; Lp(a), ↑ HDL</td>
</tr>
<tr>
<td>Statin + niacin 1.5g (Niaspan)</td>
<td>10-15%</td>
<td>$8.17</td>
<td>Same as above, $3.29 for lovastatin/niacin (Advicor® 1000/20)</td>
</tr>
<tr>
<td>Statin + colesevelam 3.75 g</td>
<td>10-16%</td>
<td>$8.60</td>
<td>Potential to ↑ TG, 6 tabs</td>
</tr>
<tr>
<td>Statin + sterol 3 tabs/day (CholestaPro)</td>
<td>10-20%</td>
<td>$4.02</td>
<td>Calories w/spread, no effect on HDL, TG, or Lp(a)</td>
</tr>
<tr>
<td>Statin + ezetimibe 10 mg (Zetia)</td>
<td>23-26%</td>
<td>$5.37</td>
<td>Single pill option (Vytorin® $3.03)</td>
</tr>
</tbody>
</table>

* simvastatin 10 mg + dose given of other agent
Combination Treatment

- Additive effects for reducing LDL-C
  - Statin + ezetimibe
  - Statin + ezetimibe or BAS + niacin
- Additional benefit for reducing very high TG
  - Fibrate + niacin
  - Fibrate or niacin + fish oil
  - Fibrate + niacin + fish oil

*Am Heart J 2004;148:S9-13*
Combination Treatment

• Complimentary benefit for mixed dyslipidemias (low HDL-C, high TG, high LDL-C)
  – Statin + niacin or fenofibrate
  – Ezetimibe + fenofibrate or niacin
    • fenofibrate 160 mg + ezetimibe 10 mg
      – ↓ LDL 22%, ↑ HDL 20%, ↓ TG 46%

Am Heart J 2004;148:S9-13
J Am Coll Cardiol. 2006;47:1584-1587
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<td>Pravastatin (Pravacol)</td>
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<td>Rosuvastatin (Crestor)</td>
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<td>Simvastatin (Zocor, generic)</td>
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<tr>
<td>Ezetimibe/simvastatin (Vytorin)</td>
<td>↓ 46-60%</td>
<td>↓ 14-35%</td>
<td>↑ 6-12%</td>
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</table>
What Else Does It Take to Achieve and Maintain Lipid Goals?

• Maintaining dietary and exercise changes
• Losing weight and keeping it off
• Adherence and persistence
  – Opportunity for Pharmacist Involvement