Primary prevention of acute coronary events with lovastatin in men and women with average cholesterol levels (AFCAPS/TexCAPS)
(JAMA 1998; 279:1615)

Study Type: POEM, Primary prevention
Purpose: Does lowering cholesterol in generally healthy middle-aged and older men and women with average cholesterol and LDL levels, below average HDL prevent first acute major coronary events?
Study Duration: mean 5 year follow-up
Trial Design: randomized placebo-controlled trial; primary prevention trial; 2 centers in Texas (Lackland Air Force Base and University of North Texas)
Drug: Lovastatin 20 mg QD, titrated to 40 mg if LDL was > 110 vs matching placebo
Patients: 6605 patients, 85% men mean age 58 yrs; 15% women mean age 63 yrs; 89% white, 3% black, BMI = 27, BP = 138/78; baseline lipids: TC 221 mg/dl, LDL 150 mg/dl, HDL 36/40 mg/dl; 22% had hypertension, ~3% diabetic, 12% smokers
Inclusion: no prior evidence of CAD, PVD, CVD; TC 180-264 mg/dl, LDL 130-190 mg/dl, HDL<45-47 mg/dl, TG<400 mg/dl
Exclusion: uncontrolled HTN, DM type I/II managed with insulin or HbA1c>10%, body weight >50% above limit
Primary Outcome: fatal or nonfatal MI, unstable angina, or sudden cardiac death
Secondary Outcomes: fatal/nonfatal revascularizations, unstable angina, fatal/nonfatal MI, fatal/nonfatal cardiovascular events, fatal/nonfatal coronary events, fatal cardiovascular events, fatal CHD events

Are the results valid?
Randomized? yes
Blinded? yes
Study/control groups similar at start? yes
Equal treatment of groups? yes
Proper accounting at end? not sure

What are the results?

<table>
<thead>
<tr>
<th></th>
<th>placebo</th>
<th>Lovastatin</th>
<th>p-value</th>
<th>RRR</th>
<th>ARR</th>
<th>NNT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatal or nonfatal MI, unstable angina, or sudden cardiac death</td>
<td>10.9%</td>
<td>6.8%</td>
<td>&lt;.001</td>
<td>37%</td>
<td>4.1%</td>
<td>24</td>
</tr>
<tr>
<td>Secondary</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Fatal/nonfatal MI</td>
<td>5.6%</td>
<td>3.3%</td>
<td>.002</td>
<td>40%</td>
<td>2.3%</td>
<td>43</td>
</tr>
<tr>
<td>Unstable angina</td>
<td>5.1%</td>
<td>3.5%</td>
<td>.02</td>
<td>32%</td>
<td>1.6%</td>
<td>63</td>
</tr>
<tr>
<td>Fatal/nonfatal cardiovascular events</td>
<td>15.3%</td>
<td>11.5%</td>
<td>.003</td>
<td>25%</td>
<td>3.8%</td>
<td>26</td>
</tr>
<tr>
<td>Fatal/nonfatal coronary events</td>
<td>12.8%</td>
<td>9.6%</td>
<td>.006</td>
<td>25%</td>
<td>3.2%</td>
<td>31</td>
</tr>
<tr>
<td>Revascularizations</td>
<td>9.3%</td>
<td>6.2%</td>
<td>.001</td>
<td>33%</td>
<td>3.1%</td>
<td>32</td>
</tr>
<tr>
<td>Fatal cardiovascular events</td>
<td>1.4%</td>
<td>1.0%</td>
<td>NS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatal CHD events</td>
<td>0.9%</td>
<td>0.6%</td>
<td>NS</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

This study was not powered to assess death. There were very few deaths as expected. Therefore there was no statistical difference in fatal cardiovascular, CHD deaths, non-cardiovascular death and all-cause mortality.

Will the results help me?
1. Primarily involved white men.
2. Groups most likely to benefit are men, smokers, hypertensives. Age and FHx are not factors.
3. Change in lipids from baseline with treatment: TC 228 to 184 mg/dl, LDL 156 to 115 mg/dl, HDL 38 to 39 mg/dl.
4. Slightly more likely to die of any cause or a noncardiovascular cause with lovastatin treatment.
5. Fifty percent of patients treated with 40 mg of lovastatin.
6. Significant percent of patients had hypertension (22%) and smoked (12%).
7. No increased incidence of cancer, violent death, or LFTs.

Conclusion: For every 1000 middle-aged healthy men with average cholesterol levels, average LDL’s, but below average HDL’s, 23 fatal/nonfatal MI’s would be prevented, 31 revascularization procedures and 32 fatal/nonfatal coronary events would be prevented at a cost of 2 to 4 million depending on the dose of lovastatin (20 mg or 40 mg generic). No deaths for any reason would be spared in this patient population (low study power).