

AFCAPS/TexCAPS
The Air Force Texas Coronary Atherosclerosis Prevention Study

Title

- a. Design and rationale of the Airforce/ Texas Coronary Atherosclerosis Prevention Study (AFCAPS/TexCAPS)
 - b. Primary prevention of acute coronary events with lovastatin in men and women with average cholesterol levels.
- Results of AFCAPS/TexCAPS .

Purpose

To investigate whether lovastatin therapy, in addition to a lipid lowering diet, will be associated with reduction in major coronary events in patients with normal to mildly elevated cholesterol levels and no evidence of atherosclerotic cardiovascular disease .

Design

Randomized, double blind, placebo controlled, 2 centers .

Patients

5608 men (age 45-73 years) and 997 women (age 55-73 years), with serum total cholesterol 180-264 mg/dL, LDL cholesterol 130-190 mg/dL, HDL cholesterol < 45 mg/dL for men and < 47 mg/dL for women and triglycerides < 400 mg/dL were included. Patients with prior history of cardiovascular disease, secondary forms of hyperlipidemia, nephrotic syndrome, insulin dependent or uncontrolled diabetes mellitus, or uncontrolled hypertension were excluded.

Follow-up

An average of 5.2 years (0.1-7.2 years)

Treatment regimen

Placebo or lovastatin 20 mg/d, titrated to 40 mg/d in patients who had LDL cholesterol > 110 mg/dL.

Additional therapy

AHA step 1 diet for all patients

Results

- The study was terminated early after the second interim analysis due to a finding of statistically significant benefits for lovastatin therapy.
- Study drug regimens were maintained until the termination of the study by 71% of the patients assigned to lovastatin and by 63% of the patients assigned to placebo.
- Lovastatin therapy was associated with 25% decrease in LDL cholesterol levels ($p < 0.001$), 18% decrease in triglyceride levels ($p < 0.001$), and 6% increase in HDL levels ($p < 0.001$).
- Lovastatin was equally effective in men and women.
- The primary end point (myocardial infarction, unstable angina, or sudden cardiac death) was reached by 10.9% of the placebo group vs 6.8% of the lovastatin group (relative risk 0.67; 95% CI 0.52-0.85; $p=0.001$). 5.6% of the placebo vs only 33% of the lovastatin group had myocardial infarction (relative risk 0.60; 95% CI 0.43-0.83; $p=0.02$).
- Life table plots demonstrated that treatment benefit began in the first year of treatment and continued throughout the study period.
- The effect of lovastatin therapy on the relative risk of first acute major coronary events was 46% in women vs 37% in men ($p=NS$).
- The overall mortality (4.4 vs 4.6 per 1000 patient years) was comparable in the placebo and lovastatin groups.
- Lovastatin was well tolerated. Adverse events leading to discontinuation of the study medication occurred in 13.6% of the lovastatin group vs 13.8% in the placebo group.

Conclusion

Lovastatin therapy for an average of 5.2 years reduced the risk for the first acute major coronary event in men and women without prior history of coronary artery disease and with average triglyceride and LDL cholesterol levels and low HDL cholesterol levels.