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THE FAT LIES

PRADIP JAMNADAS, MD, MBBS, FACC, FSCAI, FCCP, FACP

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Please join us at the next talk on

Wednesday April 17th, 2019

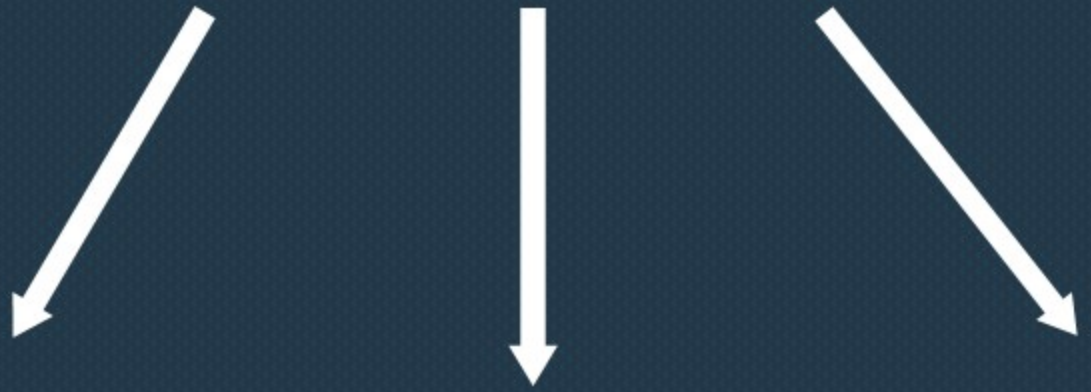
THE BITTERSWEET TRUTH

PRADIP JAMNADAS, MD
MBBS, FACC, FSCAI, FCCP, FACP

THE FOUNDER AND CHAIRMAN OF THE GALEN FOUNDATION IS A MEDICAL GRADUATE OF THE UNIVERSITY COLLEGE OF LONDON, ENGLAND WITH POST-GRADUATE TRAINING AT YALE UNIVERSITY IN CARDIOLOGY. HE HAS A SUCCESSFUL SPECIALTY PRACTICE IN ORLANDO, FLORIDA SINCE 1990 AND PERFORMS INTERVENTIONAL PROCEDURES AND IS A CONSULTANT CARDIOLOGIST WITH A LARGE DIVERSIFIED INPATIENT AND OUTPATIENT PRACTICE. HE HAS BEEN RECOGNIZED IN ORLANDO MAGAZINE AS TOP DOCTOR IN CARDIOLOGY FOR MULTIPLE YEARS OVER THE PAST DECADE. HE IS ALSO A CLINICAL ASSISTANT PROFESSOR OF MEDICINE AT THE FLORIDA STATE UNIVERSITY AND UNIVERSITY OF CENTRAL FLORIDA. HE IS A RENOWNED LECTURER AND TEACHER, WITH A PASSION FOR HIGH TECH INTERVENTIONS WHEN CALLED FOR, YET PLACES GREATER EMPHASIS ON PREVENTION MEASURES.

LIPID HYPOTHESIS

Cholesterol Causes Atherosclerosis



Coronary Artery Disease

Cerebrovascular Disease

Peripheral Vascular Disease

DATA

- 1957 – Dr. George Thorpe stated that in order for patients to lose weight they must be on a high-protein, high-fat, and low-carbohydrate diet.
- 1961 – Multiple studies showed that eating a high-carbohydrate diet caused Lipemia within one hour.

ANCEL KEYS

"THE ONLY SURE WAY TO CONTROL CHOLESTEROL IS TO REDUCE FAT IN THE US DIET FROM 40% TO 15% OF TOTAL CALORIES AND CUT SATURATED FATS FROM 17% TO 4% OF TOTAL CALORIES

AMERICANS EAT TOO MUCH FAT AND MOST OF THAT IS SATURATED WHICH DAMAGES ARTERIES AND LEADS TO CORONARY ARTERY DISEASE"

- B.A in Economics
- PhD in Fish Physiology

- Ancel's theory (Diet-Heart Hypothesis) stated that dietary saturated fat increases cholesterol in the blood, in turn increasing risk of CAD.

SIX-COUNTRY STUDY

- Correlated increased dietary fat and death rates from CHD.

Left: Ancel Key's Countries picked in his study

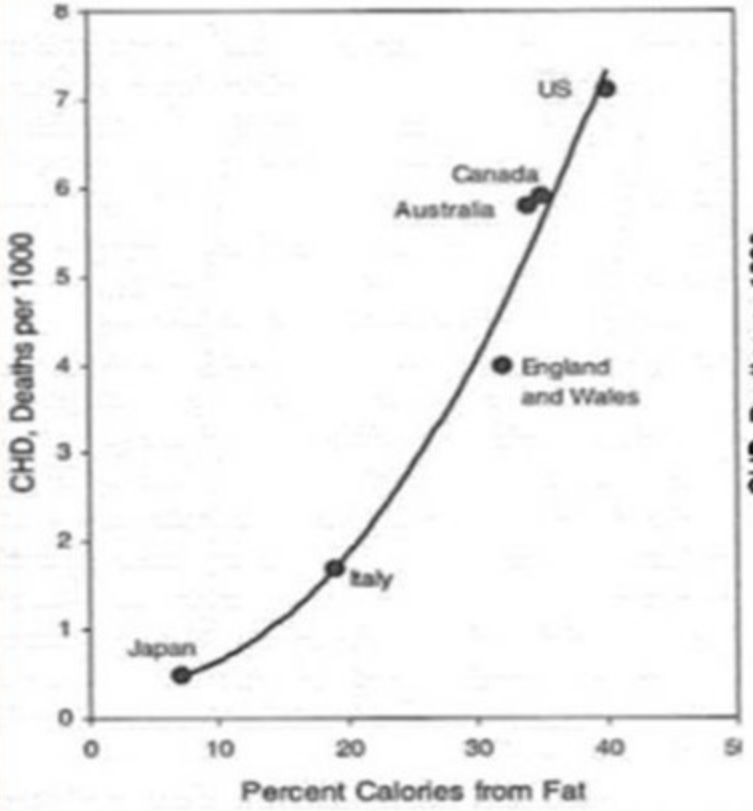


Figure 1A. Correlation between the total fat consumption as a percent of total calorie consumption, and mortality from coronary heart disease in six countries. Data from Keys.[1]

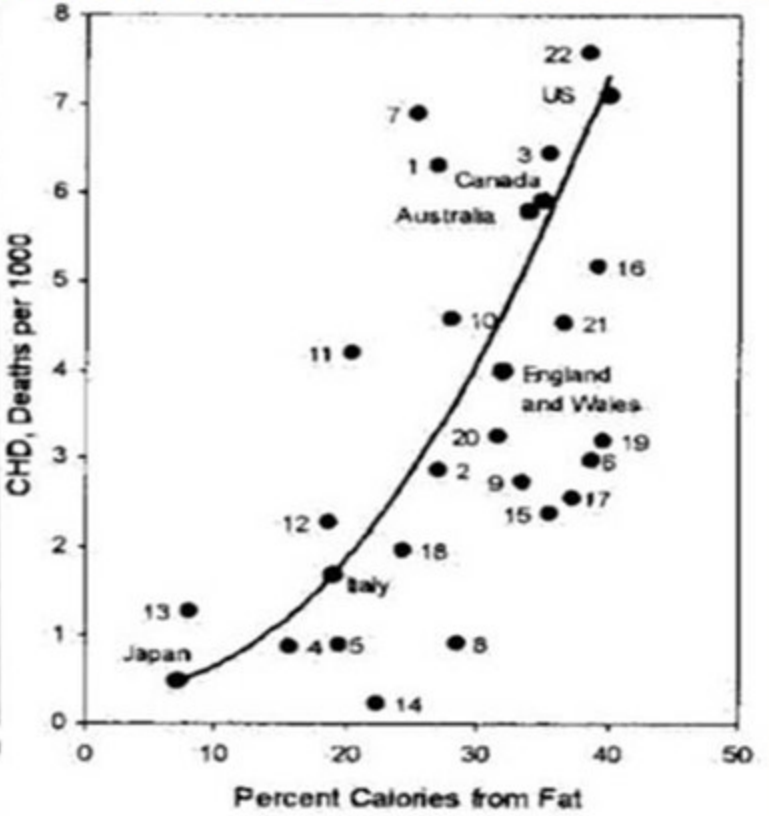


Figure 1B - as 1A but with all countries where data were available when Keys published. 1 Australia 2 Italy 3 Canada 4 Ceylon 5 Chile 6 Denmark 7 Finland 8 France 9 W Germany 10 Ireland 11 Israel 12 Italy 13 Japan 14 Mexico 15 Holland 16 New Zealand 17 Norway 18 Portugal 19 Sweden 20 Switzerland 21 Great Britain 22 USA
Data from Yerushalamy and Hilleboe

Right: Other 16 countries data available to Ancel

- J. Yerushalmy and H. E. Hilleboe, "Fat in the Diet and Mortality from Heart Disease: A Methodologic Note," *New York State Journal of Medicine* 57, no. 14 (1957): 2343-54.

SEVEN-COUNTRY STUDY AND THE PURE STUDY

- Again, correlated dietary fat to increased risk of CHD however more artfully. So people started to believe him.
- Still hand-picked countries, only included men (12,700), and only showed a small percentage of their diet.

- PURE STUDY – 2017
  - Looked at 135,335 men AND women and across Eighteen countries.
  - Conclusion: There was no associated between CHD or mortality with intake of saturated fat or overall fat.
    - In fact, higher saturated fat was associated with lower stroke rates.
    - Higher carbohydrate intake was associated with an increase in mortality.

M. Dehghan et al., "Association of Fats and Carbohydrate Intake with Cardiovascular Disease and Mortality in 18 Countries from Five Continents (PURE): A Prospective Cohort Study," *Lancet* 390, no. 10107 (2017): 2050-62.

JAMA. 2006 Feb 8;295(6):655-66.

Low-fat dietary pattern and risk of cardiovascular disease: the Women's Health Initiative Randomized Controlled Dietary Modification Trial.

Howard BV[1], Van Horn L, Hsia J, Manson JE, Stefanick ML, Wassertheil-Smoller S, Kuller LH, LaCroix AZ, Langer RD, Lasser NL, Lewis CE, Limacher MC, Margolis KL, Mysiw WJ, Ockene JK, Parker LM, Perri MG, Phillips L, Prentice RL, Robbins J, Rossouw JE, Sarto GE, Schatz IJ, Snetselaar LG, Stevens VJ, Tinker LF, Trevisan M, Vitolins MZ, Anderson GL, Assaf AR, Bassford T, Beresford SA, Black HR, Brunner RL, Brzyski RG, Caan B, Chlebowski RT, Gass M, Granek I, Greenland P, Hays J, Heber D, Heiss G, Hendrix SL, Hubbell FA, Johnson KC, Kotchen JM.

- Several RCTs in the 1960s were done disproving Ancel Key's hypothesis, showing that dietary fat was not actually linked to heart disease.

- But people didn't like these results because they were different than what everyone else believed.

- Most notable trial was this one that ran for 10 years.
  - Reduced total fat intake to about 20% and saturated fat down to 7%.
- Results – No improvement in heart disease rates
- Considered a major failure by many people because it did not align with the public's opinion.

- After the same results for so long, scientists began to give up trying to prove that a low-fat diet had any significance. However, the public still insisted that a low-fat diet did indeed have significance.

TYPES OF FAT

- Saturated Fat - Meat, Poultry, Coconut, Tropical plant oils (Palm Oil), Lard, Tallow, Pork Fat, Butter
- Monounsaturated Fats - Olive oil, Nuts
- Polyunsaturated Fats (Omega-3 and Omega-6) - Manufactured Vegetable Oils
  - Examples: Soybean oil, Peanut oil, Safflower seed oil, Sunflower seed oil, Cottonseed oil
- Trans Fats - Margarine, Baked products, Chips, Reheated Vegetable Oil

WHAT CHANGED IN THE PAST 100 YEARS?

Coronary Artery Disease and Diabetes Mellitus were both unknown at the turn of the century.

Over Time:

- Smoking increased and so did Coronary Artery Disease.
- Vegetable Oils entered the market and were marketed as safer without any evidence.
- Introduced in 1911 by Proctor & Gamble, CRISCO is a brand of shortening and was the first to be made entirely of vegetable oil (specifically cottonseed oil) which was usually used for candles, wax, and lubrication

NIKOLAI ANITSCHKOW - 1913

- Fed animal fats to rabbits and caused atherosclerosis
- Cholesterol got the blame
- Rabbits are vegetarian

THE JOURNEY TO INCREASED CARBOHYDRATE INTAKE

- 1948: Framingham Heart Study
  - Found that patients with increased cholesterol had coronary heart disease.
- 1953: AHA Promoted Corn Oil, Margarine, Chicken, and cold cereals to replace saturated fats.
- 1953: Six-Country Study
  - Ancel Keys – observed a correlation between % of dietary fat in the diets of 6 *hand-picked* countries and their death rates from CHD.
- 1970: Seven-Country study
  - Results were % Dietary Fat correlating to CHD death

THE JOURNEY TO INCREASED CARBOHYDRATE INTAKE

- 1977: McGovern Report
  - Dietary Goals of US Government
- 1984: Center for Science in Public Interest
  - Coerced everyone to change from animal fat to vegetable oils (Omega-6).
- 1992: USDA Food Pyramid
  - Encouraged the propagation that fat = BAD and Carbohydrates = GOOD
- 2010: Dietary Guidelines for Americans USDA and USHHS recommendation was saturated fat should be <7% of daily calorie intake
- **Therefore, a MASSIVE increase in carbohydrate intake occurred. Through all of this, coronary heart disease continued to increase.**

% OF POPULATION WITH A BMI >30

USA	31%	Portugal	13%
Mexico	24%	Finland	13%
United Kingdom	23%	Turkey	12%
Slovak	22%	Belgium	12%
Greece	22%	Poland	11%
Australia	22%	Netherlands	10%
New Zealand	21%	Sweden	10%
Hungary	19%	Denmark	10%
Czech	15%	France	9%
Canada	14%	Austria	9%
Spain	13%	Italy	9%
Ireland	13%	Norway	8%
Germany	13%	Japan	3%
		Korea	3%

ANCEL KEYS & THE MEDITERRANEAN DIET - 1959 -

- Found that 40% of the Cretan diet was from fat yet the mortality was low
- Postulated that this was due to Olive Oil & Fish
- Pushed the idea of Polyunsaturated fats being healthy
- This is all made up!

- “There is no correlation between heart disease and % of calories from saturated fat”
  - - British Journal of Nutrition 2012

- % of saturated fats in the French is greater than 40% saturated fat and yet have a much lower incidence of heart disease.

- The French have a greater than 40% calories from fat of which 15% of it are saturated fats.

FLAWED DATA

POOR EPIDEMIOLOGICAL DATA

- Meat Intake and Mortality paper stated that "… Modest increase in total mortality and cardiovascular disease nationally…" (Sinha R., 2009)
  - Poor case selection because the participants were able to eat processed meats such as hot dogs, a high-carbohydrate diet, had a very sedentary lifestyle, and ate few vegetables.
  - Too many variables which you must control for.

- Dean Ornish Diet
  - Patients were asked to become vegetarians, asked to quit tobacco, decrease sugar, and increase exercise levels.
  - How do you know which variable actually made a difference?

PROSPECTIVE STUDIES

- 1948: Framingham Study: Dr. William Castelli stated there is “No correlation between fat intake and coronary heart disease”.
- 1957: Chicago Western Electric Company Study – No correlation between dietary fat and blood cholesterol levels
- 1971: Honolulu Heart Study - Low carb diet decreased CHD
  - No correlation between dietary fat/cholesterol intake to CHD death.
- 1999: University of California study
  - Low fat diet Pattern A → Pattern B
  - High fat diet Pattern B → Pattern A

PROSPECTIVE STUDIES

- 2001: MMJ Reviews – Type of fat intake had no effect on CHD.
- 2007: Swiss Study – In children, fructose and a low fat diet produced Pattern B Hyperlipidemia.
- 2010: Queensland Study was a 16 year study – Full fat milk consumption resulted in 60% less myocardial infarction
- 2012: US and Germany Study – Dairy fat caused a decrease in CHD and Type 2 Diabetes
- 2017 British Journal of Sports Medicine – Saturated fat does not clog arteries. CHD is a chronic inflammatory condition and the risk can be reduced by healthy lifestyle interventions

CORRECTIVE THINKING

- Rabbits are herbivores
- Dogs given saturated fats do not get CHD
- Six and Seven-Country studies deliberately omitted many countries because they did not fit Ancel's plan. If all countries were included, it would have showed there was no correlation between fats to CHD whatsoever.
- Remote tribes such as the Maasai in Tanzania, the Arctic Inuit, and the Aboriginal tribes of Australia consume more than 60% dietary fat and have the lowest CAD.
- Breast milk has 54% saturated fat.

DIET HISTORY OF MAN

- PALEOLITHIC ERA
  - 2.5 million years (Homo sapiens 200,000 years)
  - Hunter-gatherer man
  - Ate fatty animal parts, some seeds, roots, fruits, bulbs, grains, legumes, and corn.
- AGRICULTURAL ERA
  - 10,000 years ago
  - Increased carbohydrate intake
- INDUSTRIAL AGE
  - 250 years ago
  - Even more carbohydrates, sugars, vegetable oils, and trans fats

CHOLESTEROL AND MORTALITY. 30 YEARS OF FOLLOW-UP FROM THE FRAMINGHAM STUDY (ANDERSON KM, 1987).

- 11% increased mortality seen for each 1% drop in cholesterol!
- No increased mortality with high cholesterol
- JAMA. 1987 Apr 24;257(16):2176-80.

WHY WAS THE MCGOVERN REPORT PASSED?

- Because they felt compelled to do something due to increased incidence of CHD.
- Eisenhower had a heart attack (chain smoker).
- 2005 European Cardiovascular Disease statistics showed an inverse relationship between cholesterol levels and cardiovascular disease

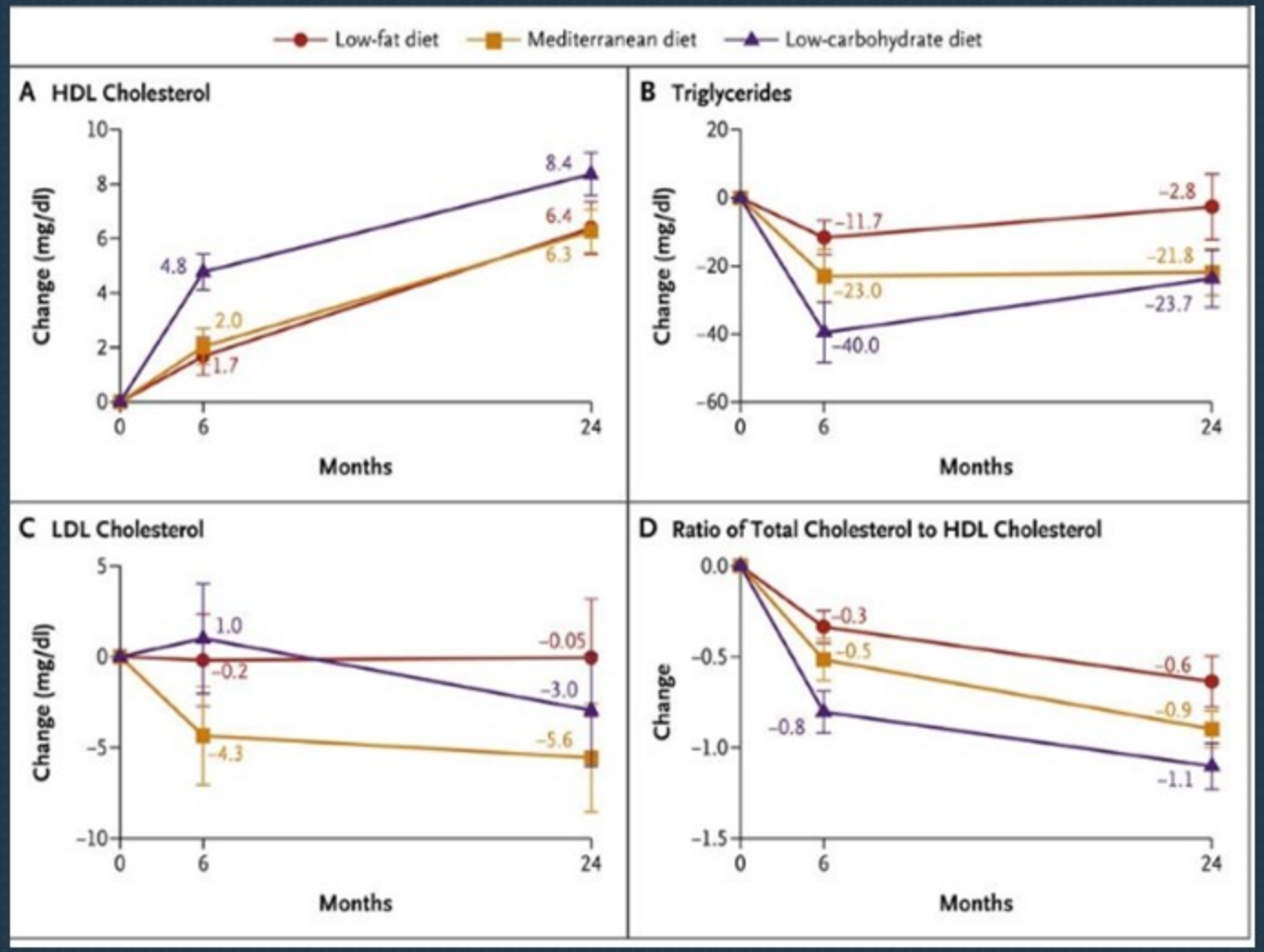
MORE STUDIES

- No significant evidence for concluding that dietary saturated fat is associated with an increased risk of CVD (Siri-Tarino PW, 2010).
- No relationship of fats to MI
- Lyon Diet Heart Study
  - Mediterranean VS low saturated fat western diet
  - Showed increased risk in low saturated fat group
  - Also, cholesterol level did not change in Mediterranean diet group
  - Higher cholesterol had better survival
  - Low fat diet did not protect against CAD

IN THE PAST 100 YEARS…

- 535% INCREASE in Vegetable Oil intake
- 1150% INCREASE in Sugar intake
- 83% DECREASE in Saturated Fat
- 200% INCREASE in Chicken intake
- 30% DECREASE IN RED MEAT

THE MAJORITY OF MYOCARDIAL INFARCTION PATIENTS DO NOT HAVE A HIGH LDL

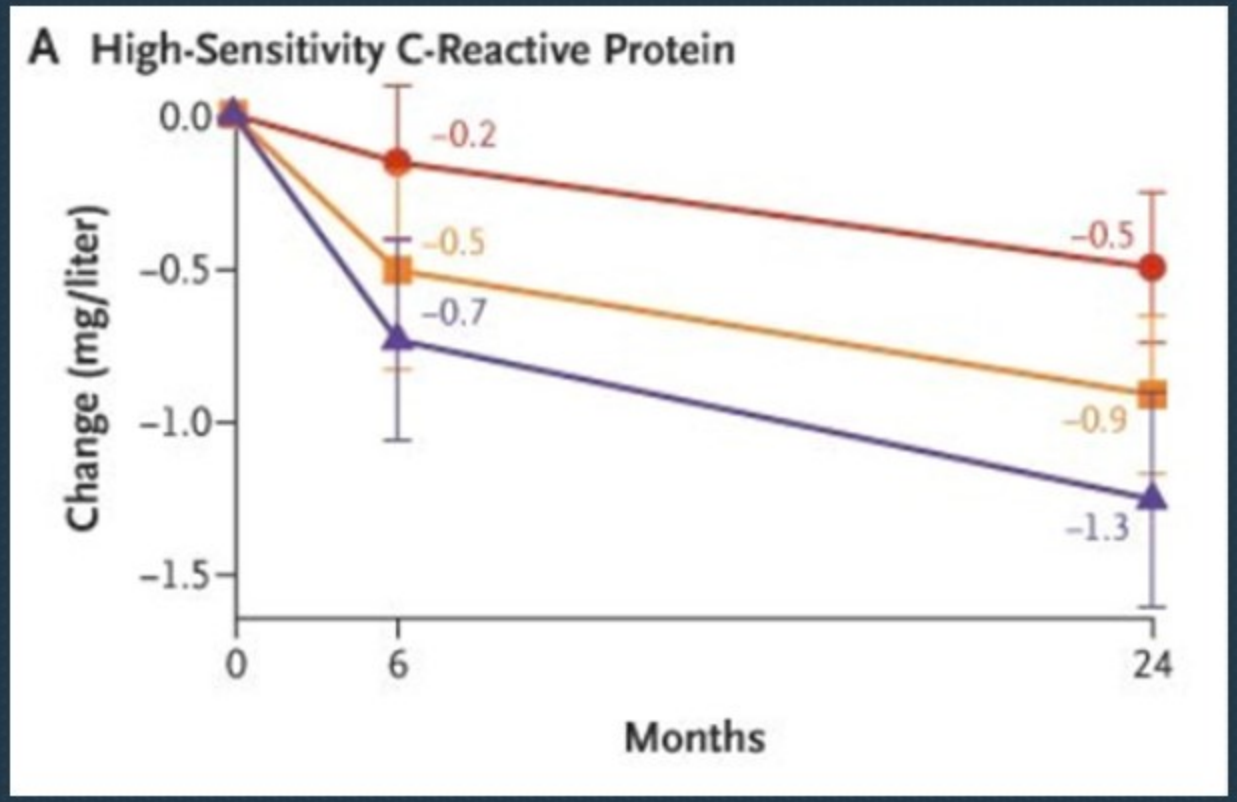


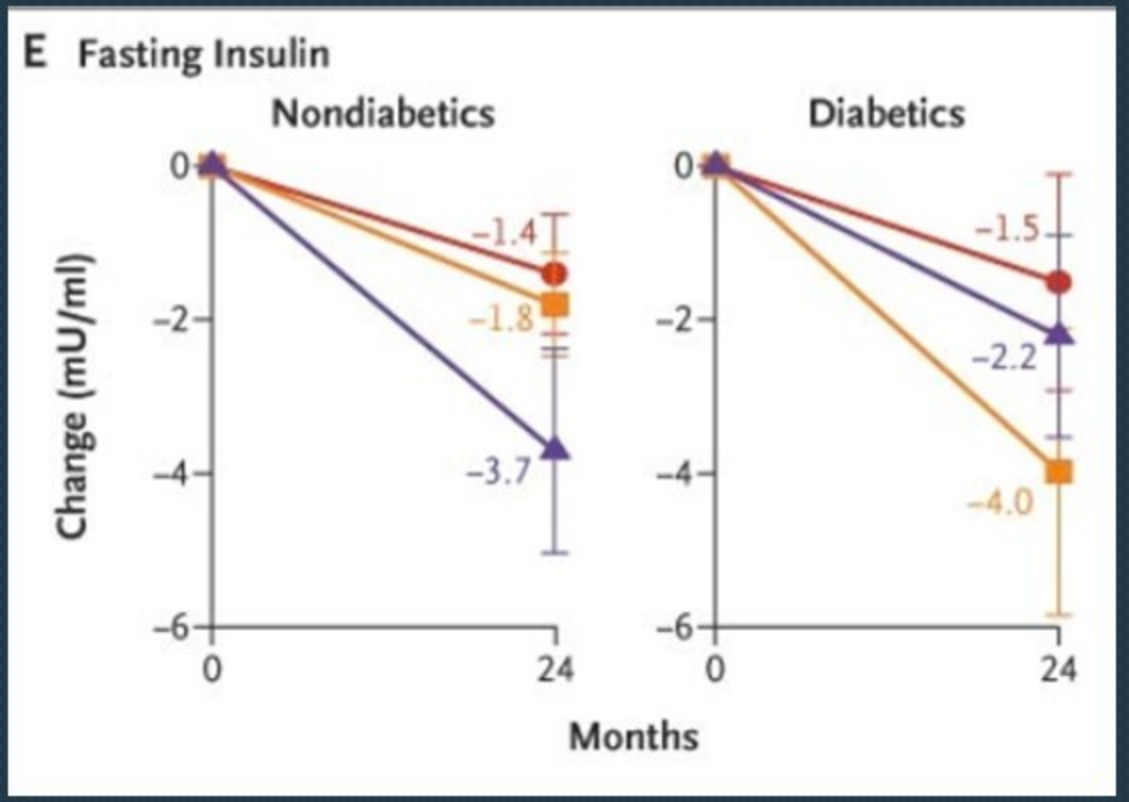
Work Place Diet Trial (Shai, 2008)

	Low Fat Diet	Mediterranean	Low-Carb Diet
CRP	- 0.6	-0.9	-1.3
Triglycerides	-2.8	-21	-23
HDL	+6.3	+6.4	+8.4
LDL	-0.5	-5.6	-3

Low-Carbohydrate diet results in BEST reduction in CRP, triglycerides, and most improvement in triglycerides/HDL ratio.

WORK PLACE DIET TRIAL (CONTINUED

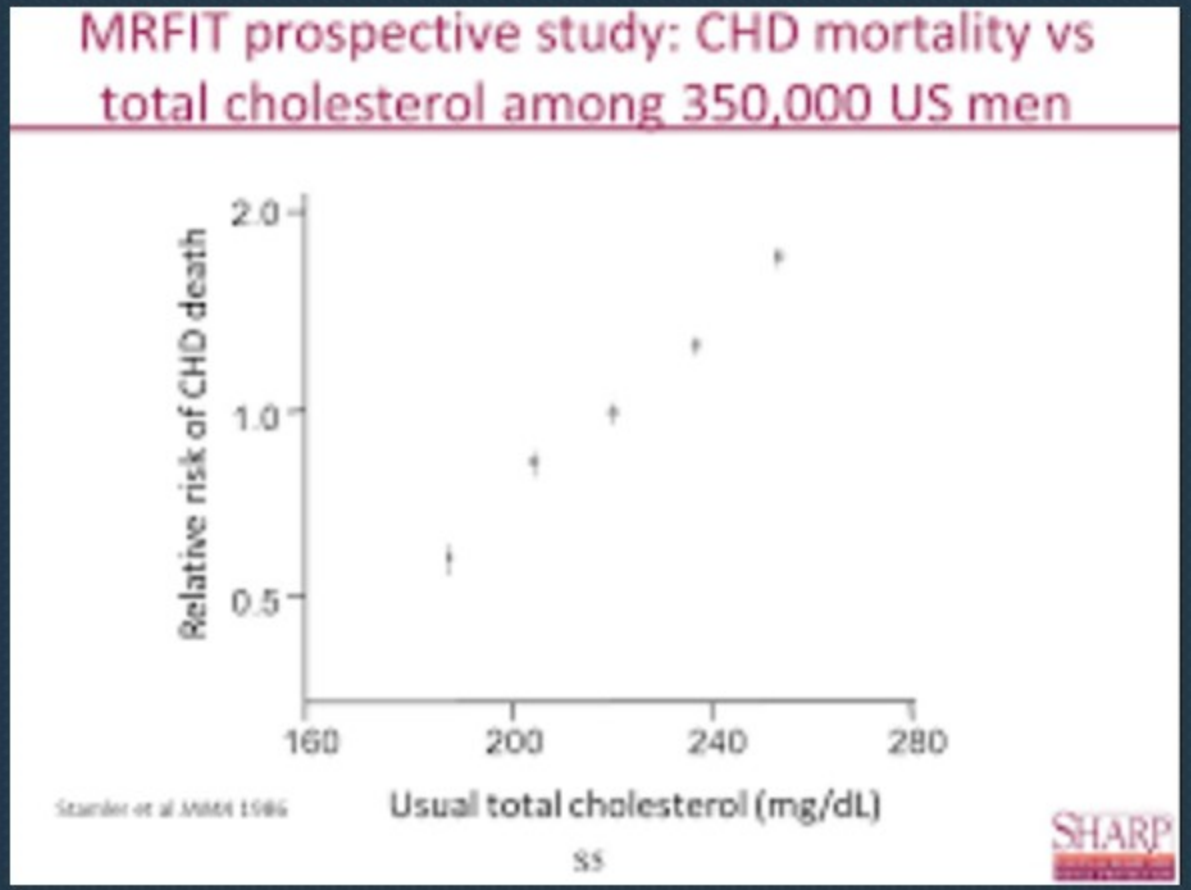




IF NOT DIET, WHAT ABOUT DRUGS FOR CHOLESTEROL?

- 1° Prevention statins
  - NNT
  - 104-300 for MI – 5 years
  - 21 for muscle pains
  - 24 for Diabetes
- 2° Prevention statins
  - NNT
  - 83 – Mortality
  - 39 for Non-fatal myocardial infarction
  - 125 – CVA prevention
  - 50 – Diabetes
  - 10 – Muscle Pain

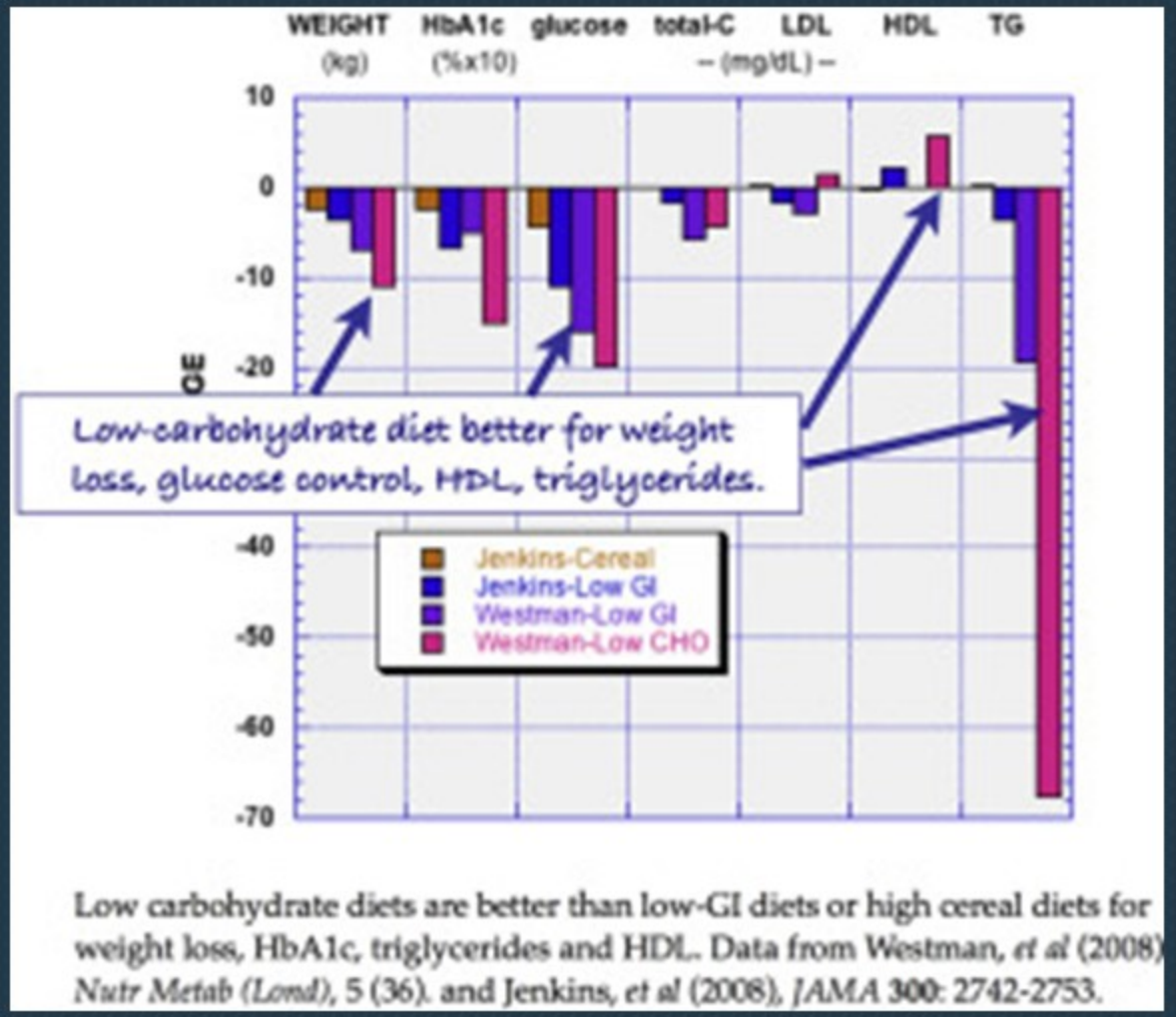
WHAT ABOUT LDL AND CHOLESTEROL LEVELS?



- A graph like this created the media frenzy and attack on cholesterol.
- However, look at the scale of the relative risk of heart disease; it is not an absolute risk.

JAMA. 1986 Nov 28; 256 (20): 2823-8.

COMPARISON OF DIETS



Low carbohydrate diets are better than low-GI diets or high cereal diets for weight loss, HbA1c, triglycerides and HDL. Data from Westman, *et al* (2008) *Nutr Metab (Lond)*, 5 (36). and Jenkins, *et al* (2008), *JAMA* 300: 2742-2753.

- A low-carbohydrate diet gave the best weight loss, glycemic control, increase in HDL, decrease in triglycerides
- However, note the tiny increase in LDL.

Nutrition. 2015 Jan;31(1):1-13.

WHAT IS THE ACTUAL RISK OF CVD DEATH?

- LDL < 150
  - 0.3% death rate from CHD (99.7% Survival)
- LDL > 290
  - 1.3% death rate from CHD (98.7% Survival)
- Difference is 1% difference [Absolute Risk]
  - Highest cholesterol level causes
  - $\frac{1.3}{0.3}$ = 4.13 = >400% increased risk of CHD Death! [Relative Risk]

Lancet. 2001 Aug 4;358(9279):351-5.

Cholesterol and all-cause mortality in elderly people from the Honolulu Heart Program: a cohort study.

Schatz IJ[1], Masaki K, Yano K, Chen R, Rodriguez BL, Curb JD.

Abstract

BACKGROUND: A generally held belief is that cholesterol concentrations should be kept low to lessen the risk of cardiovascular disease. However, studies of the relation between serum cholesterol and all-cause mortality in elderly people have shown contrasting results. To investigate these discrepancies, we did a longitudinal assessment of changes in both lipid and serum cholesterol concentrations over 20 years, and compared them with mortality.

METHODS: Lipid and serum cholesterol concentrations were measured in 3572 Japanese/American men (aged 71-93 years) as part of the Honolulu Heart Program. We compared changes in these concentrations over 20 years with all-cause mortality using three different Cox proportional hazards models.

FINDINGS: Mean cholesterol fell significantly with increasing age. Age-adjusted mortality rates were 68.3, 48.9, 41.1, and 43.3 for the first to fourth quartiles of cholesterol concentrations, respectively. Relative risks for mortality were 0.72 (95% CI 0.60-0.87), 0.60 (0.49-0.74), and 0.65 (0.53-0.80), in the second, third, and fourth quartiles, respectively, with quartile 1 as reference. A Cox proportional hazard model assessed changes in cholesterol concentrations between examinations three and four. Only the group with low cholesterol concentration at both examinations had a significant association with mortality (risk ratio 1.64, 95% CI 1.13-2.36).

INTERPRETATION: We have been unable to explain our results. These data cast doubt on the scientific justification for lowering cholesterol to very low concentrations (<4.65 mmol/L) in elderly people.

- 3572 Men studied for 20 years
- Low cholesterol increased risk of death

Cardiovascular medicine
Research

Lack of an association or an inverse association between low-density-lipoprotein cholesterol and mortality in the elderly: a systematic review

Uffe Ravnskov[1], David M Diamond[2], Rokura Hama[3], Tomohito Hamazaki[4], Björn Hammarskjöld[5], Niamh Hynes[6], Malcolm Kendrick[7], Peter H Langsjoen[8], Aseem Malhotra[9], Luca Mascitelli[10], Kilmer S McCully[11], Yoichi Ogushi[12], Harumi Okuyama[13], Paul J Rosch[14], Tore Schersten[15], Sherif Sultan[6], Ralf Sundberg[16]

Conclusions High LDL-C is inversely associated with mortality in most people over 60 years. This finding is inconsistent with the cholesterol hypothesis (ie, that cholesterol, particularly LDL-C, is inherently atherogenic). Since elderly people with high LDL-C live as long or longer than those with low LDL-C, our analysis provides reason to question the validity of the cholesterol hypothesis. Moreover, our study provides the rationale for a re-evaluation of guidelines recommending pharmacological reduction of LDL-C in the elderly as a component of cardiovascular disease prevention strategies.

BMJ Open. 2016 Jun 12;6(6):e010401.

WHAT ABOUT LOWERING LDL WITH DRUGS?

- Where did this come from?
  - Ancel Keys
- Hypothesis: The lower the cholesterol, and lower risk
- 1965 – Corn Oil Rx for CAD
  - Corn Oil – 80g per day (2 tsbp) and low saturated fat diet VS placebo (usual diet)
  - Results
    - Usual diet: cholesterol went from 250 → 252
    - Corn Oil Diet – 260 → 225
    - Therefore, there was a definite drop in cholesterol levels.
    - HOWEVER, at 3 years survival or MI free state was vastly different. Corn oil group 50% survival, and usual diet 75% survival

January 20, 1984

The Lipid Research Clinics Coronary Primary Prevention Trial Results

I. Reduction in Incidence of Coronary Heart Disease

JAMA. 1984;251(3):351-364. doi:10.1001/jama.1984.03340270029025

The Lipid Research Clinics Coronary Primary Prevention Trial (LRC-CPPT), a multicenter, randomized, double-blind study, tested the efficacy of cholesterol lowering in reducing risk of coronary heart disease (CHD) in 3,806 asymptomatic middle-aged men with primary hypercholesterolemia (type II hyperlipoproteinemia). The treatment group received the bile acid sequestrant cholestyramine resin and the control group received a placebo for an average of 7.4 years. Both groups followed a moderate cholesterol-lowering diet. The cholestyramine group experienced average plasma total and low-density lipoprotein cholesterol (LDL-C) reductions of 13.4% and 20.3%, respectively, which were 8.5% and 12.6% greater reductions than those obtained in the placebo group. The cholestyramine group experienced a 19% reduction in risk ($P<.05$) of the primary end point—definite CHD death and/or definite nonfatal myocardial infarction—reflecting a 24% reduction in definite CHD death and a 19% reduction in nonfatal myocardial infarction. The cumulative seven-year incidence of the primary end point was 7% in the cholestyramine group v8.6% in the placebo group. In addition, the incidence rates for new positive exercise tests, angina, and coronary bypass surgery were reduced by 25%, 20%, and 21%, respectively, in the cholestyramine group. The risk of death from all causes was only slightly and not significantly reduced in the cholestyramine group. The magnitude of this decrease (7%) was less than for CHD end points because of a greater number of violent and accidental deaths in the cholestyramine group. The LRC-CPPT findings show that reducing total cholesterol by lowering LDL-C levels can diminish the incidence of CHD morbidity and mortality in men at high risk for CHD because of raised LDL-C levels. This clinical trial provides strong evidence for a causal role for these lipids in the pathogenesis of CHD.

- Cholestyramine group had 24% reduction in CHD death.
- But, no change in all cause mortality
- So, where was the 24% reduced CHD death?
- This study urged pharmaceutical companies to search for a drug like a statin

Lancet. 2003 Apr 5;361(9364):1149-58.

Prevention of coronary and stroke events with atorvastatin in hypertensive patients who have average or lower-than-average cholesterol concentrations, in the Anglo-Scandinavian Cardiac Outcomes Trial--Lipid Lowering Arm (ASCOT-LLA): a multicentre randomised controlled trial.

Sever PS[1], Dahlöf B, Poulter NR, Wedel H, Beevers G, Caulfield M, Collins R, Kjeldsen SE, Kristinsson A, McInnes GT, Mehlsen J, Nieminen M, O'Brien E, Ostergren J; ASCOT investigators.

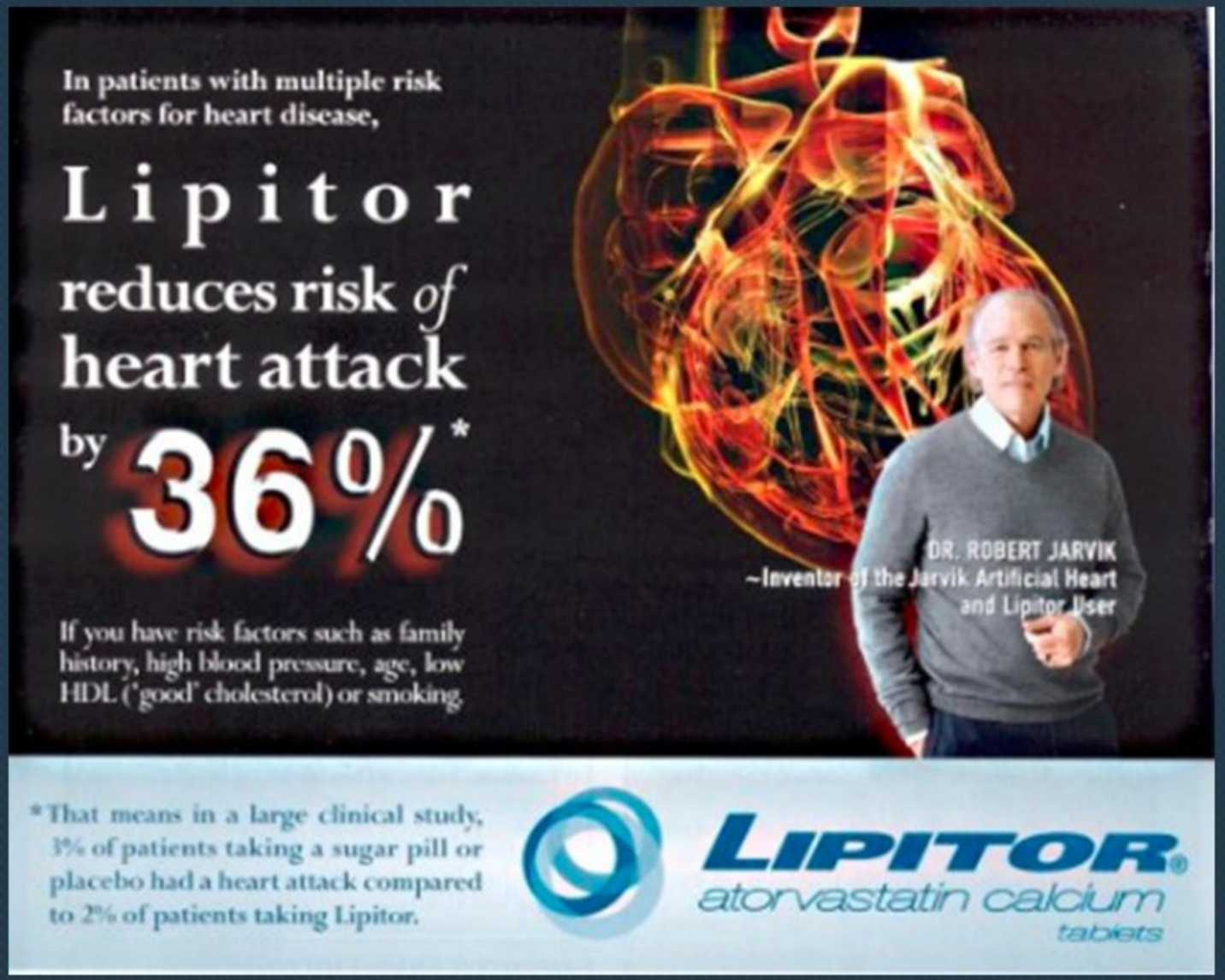
Abstract

BACKGROUND: The lowering of cholesterol concentrations in individuals at high risk of cardiovascular disease improves outcome. No study, however, has assessed benefits of cholesterol lowering in the primary prevention of coronary heart disease (CHD) in hypertensive patients who are not conventionally deemed dyslipidaemic.

METHODS: Of 19342 hypertensive patients (aged 40-79 years with at least three other cardiovascular risk factors) randomised to one of two antihypertensive regimens in the Anglo-Scandinavian Cardiac Outcomes Trial, 10305 with non-fasting total cholesterol concentrations 6.5 mmol/L or less were randomly assigned additional atorvastatin 10 mg or placebo. These patients formed the lipid-lowering arm of the study. We planned follow-up for an average of 5 years, the primary endpoint being non-fatal myocardial infarction and fatal CHD. Data were analysed by intention to treat.

FINDINGS: Treatment was stopped after a median follow-up of 3.3 years. By that time, 100 primary events had occurred in the atorvastatin group compared with 154 events in the placebo group (hazard ratio 0.64 [95% CI 0.50-0.83], p=0.0005). This benefit emerged in the first year of follow-up. There was no significant heterogeneity among prespecified subgroups. Fatal and non-fatal stroke (89 atorvastatin vs 121 placebo, 0.73 [0.56-0.96], p=0.024), total cardiovascular events (389 vs 486, 0.79 [0.69-0.90], p=0.0005), and total coronary events (178 vs 247, 0.71 [0.59-0.86], p=0.0005) were also significantly lowered. There were 185 deaths in the atorvastatin group and 212 in the placebo group (0.87 [0.71-1.06], p=0.16). Atorvastatin lowered total serum cholesterol by about 1.3 mmol/L compared with placebo at 12 months, and by 1.1 mmol/L after 3 years of follow-up.

INTERPRETATION: The reductions in major cardiovascular events with atorvastatin are large, given the short follow-up time. These findings may have implications for future lipid-lowering guidelines.



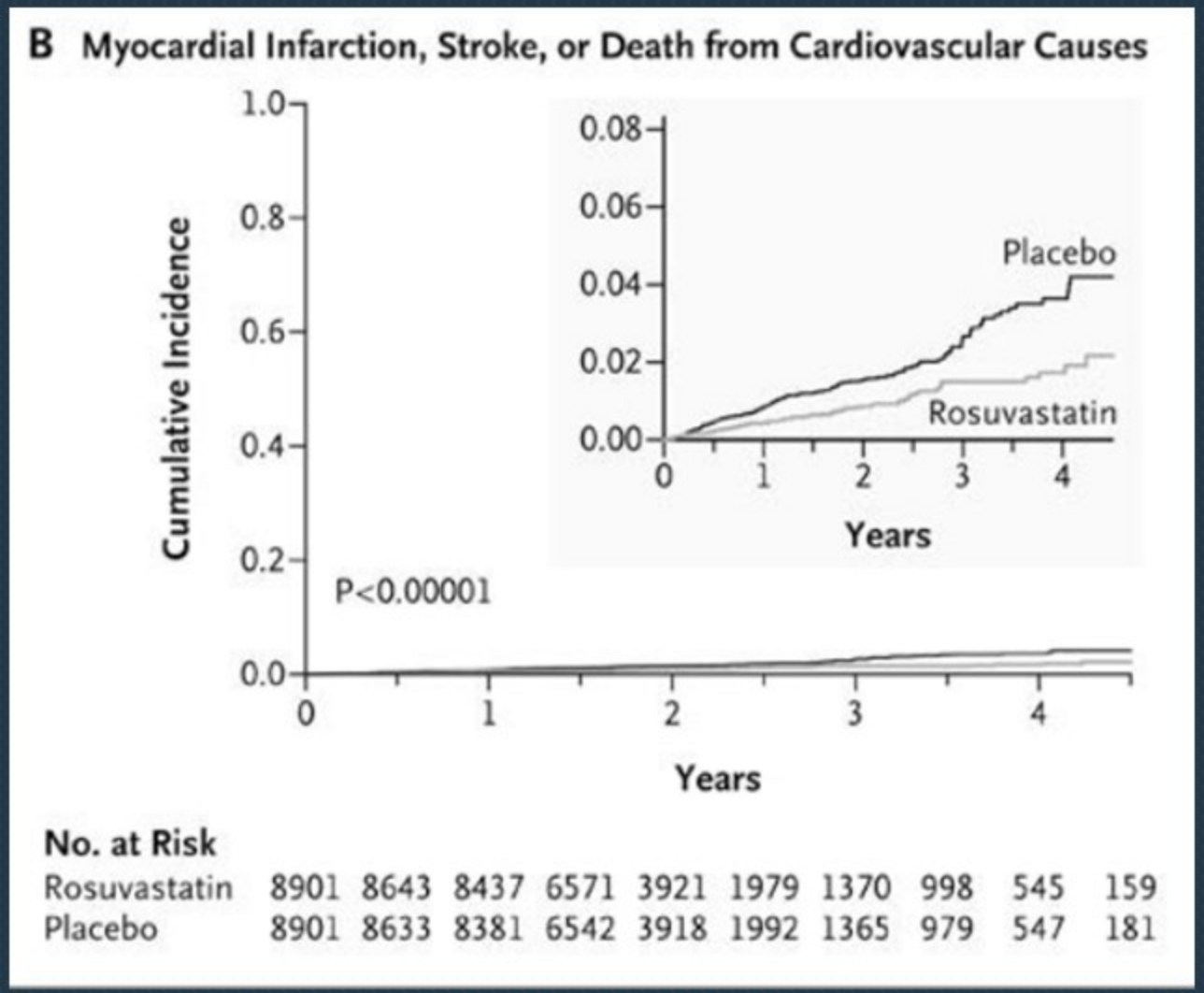
- How did they come up with 36%?

- Event-free survival
- 98.1% Atorvastatin
- 97% Placebo
- Difference = 1.1%

- $\frac{1.1\%}{3.0\%}$ = 36%!

- This is relative risk reduction, not absolute risk reduction.
- Absolute risk reduction was 1.1%
- NNT = $\frac{1}{ARR}$ = 91!

JUPITER STUDY – ROSUVASTATIN TO PREVENT VASCULAR EVENTS IN MEN AND WOMEN WITH ELEVATED C-REACTIVE PROTEIN



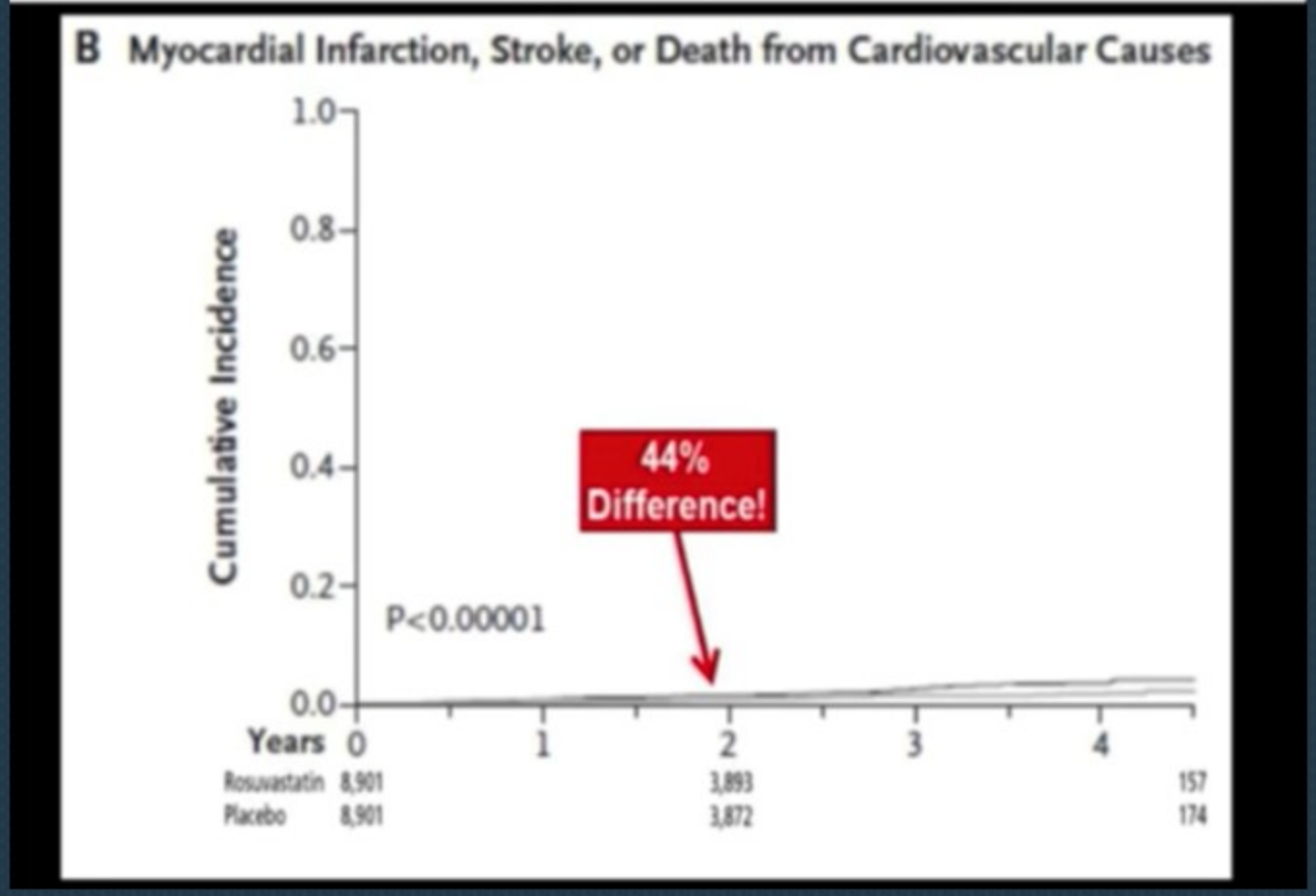
N Engl J Med. 2008 Nov 20; 359(21): 2195-207.

- Event Free
  - 98.4% Rosuvastatin
  - 97.2% Placebo
  - =1.2% difference
- Placebo group has a 100-97.2 risk = 2.8%
- Relative Reduction is $\frac{1.2\%}{2.8\%} = 44\%$
- Absolute Risk is 1.2%
- NNT = $\frac{1}{ARR} = \frac{1}{0.012} = 83$

JUPITER STUDY – ROSUVASTATIN TO PREVENT VASCULAR EVENTS IN MEN AND WOMEN WITH ELEVATED C-REACTIVE PROTEIN

Rosuvastatin to Prevent Vascular Events in Men and Women with Elevated C-Reactive Protein

N Engl J Med 2008;359:2195-207.



SIDE EFFECTS OF STATIN THERAPY

- Testosterone levels in males fall; September 2012 Federal Practitioner
- Statins and MSK conditions JAMA 2013
- Statin use and risk of kidney disease: A follow up 8.4 years AJC 2015
- Erectile dysfunction – JCPT 1996
- Statin therapy and risk of Type II Diabetes – A Meta-analysis Diabetes Care 2009
- Effects of the magnitude of lipid lowering and risk of liver dysfunction, rhabdomyolysis and cancer – JACC Vol 50 2007
- Statins and all cause mortality in high-risk primary prevention
- 11 Randomized controlled trials with 65,229 participants showed no evidence of survival/all-cause mortality in high-risk primary prevention
  - Arch Int. MED. 2010 170(12) 1024-1031.

DIABETES RISK WITH STATINS

46% Increased Risk of Diabetes in People on Statins

Increased risk of diabetes with statin treatment is associated with impaired insulin sensitivity and insulin secretion: a 6 year follow-up study of the METSIM cohort

Henna Cederberg · Alena Stančáková · Nagendra Yaluri · Shalem Modi · Johanna Kuusisto · Markku Laakso

Diabetologia 10 March 2015

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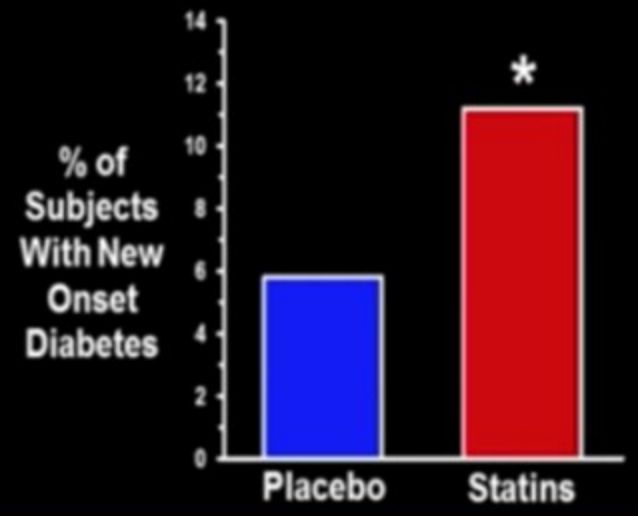

NNT for Diabetes $\frac{1}{0.065}$ = 15

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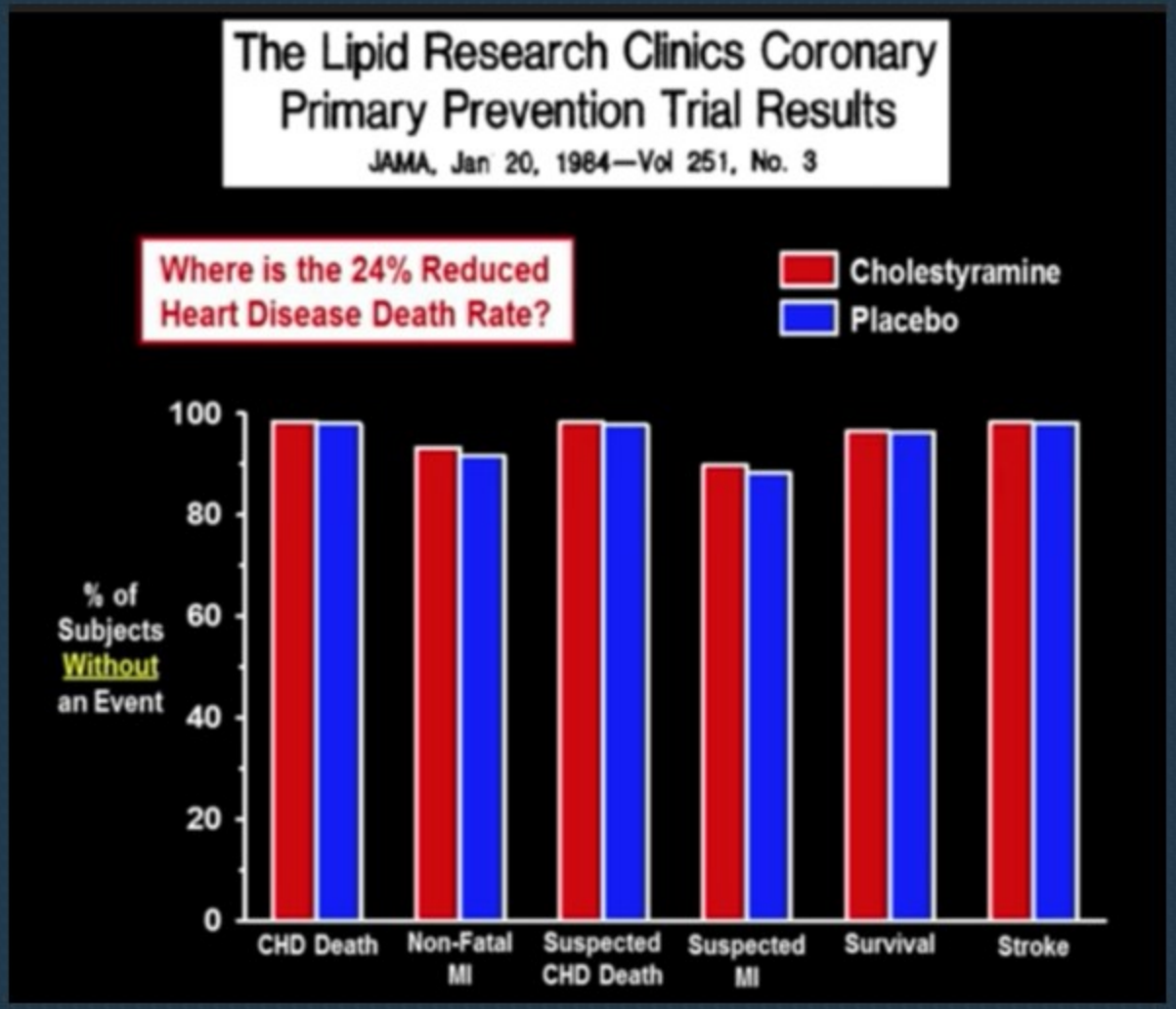
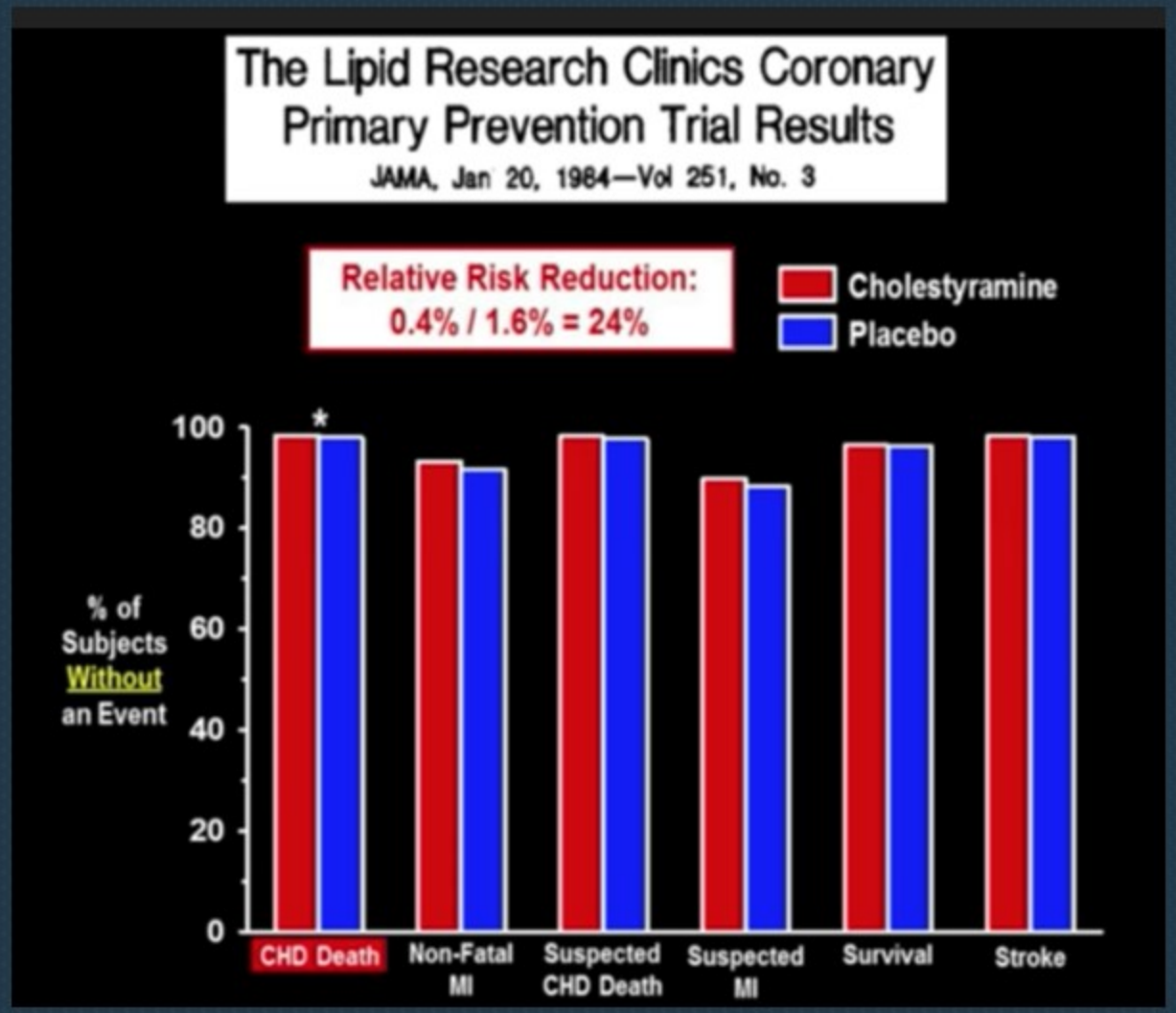
Cash or Check to one of our volunteers just outside of the auditorium

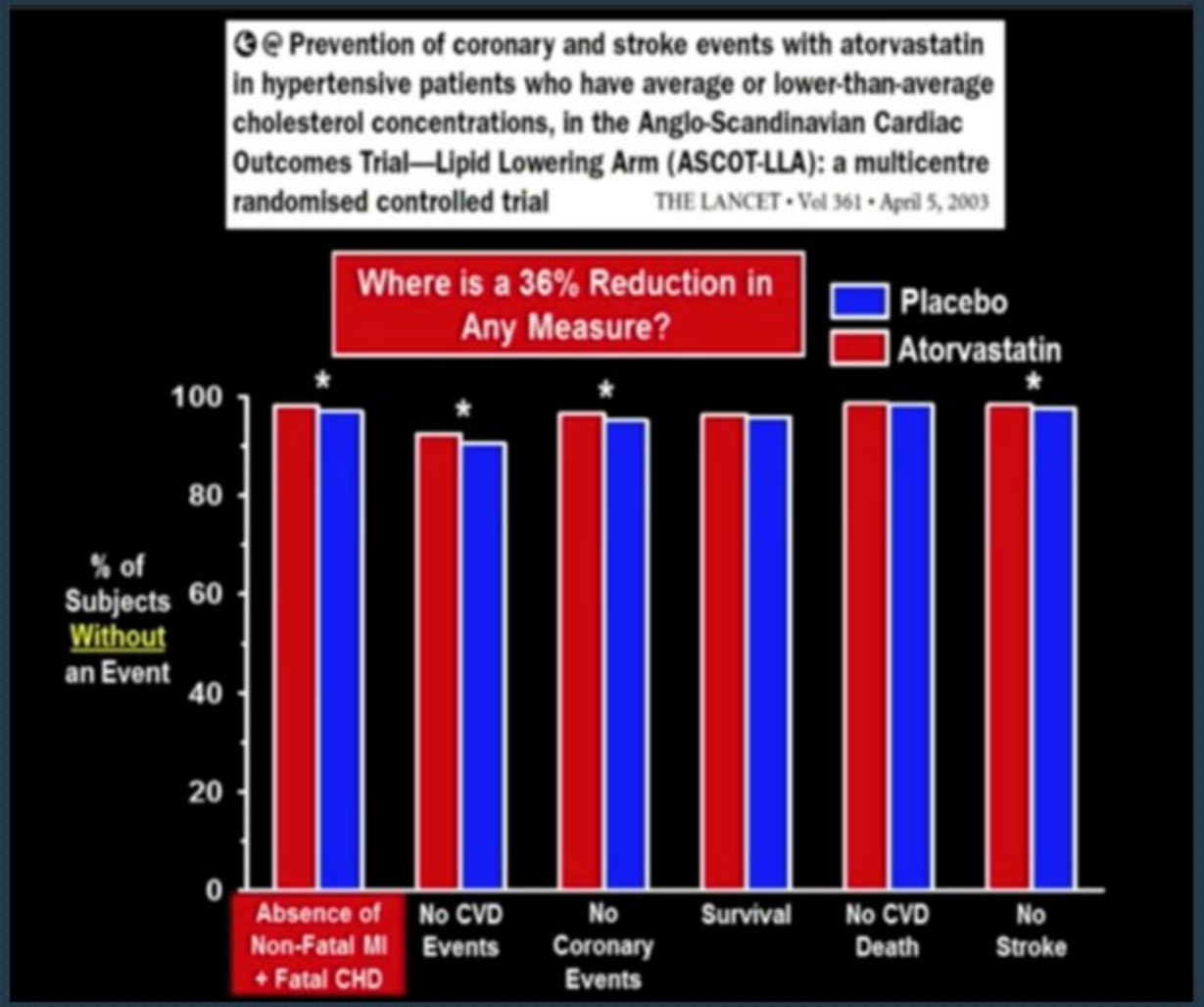
Please join us at the next talk on

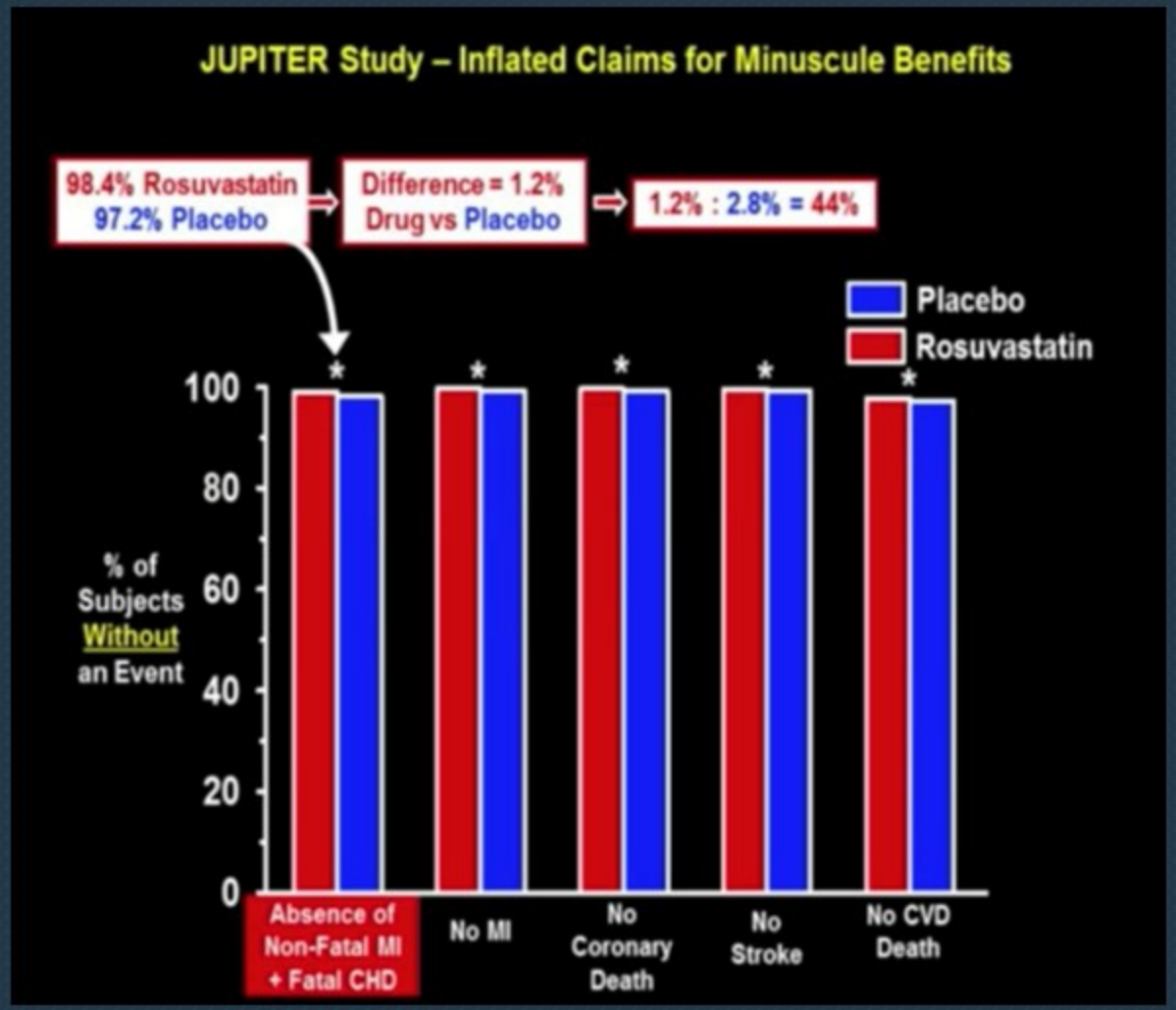
Wednesday April 17th, 2019

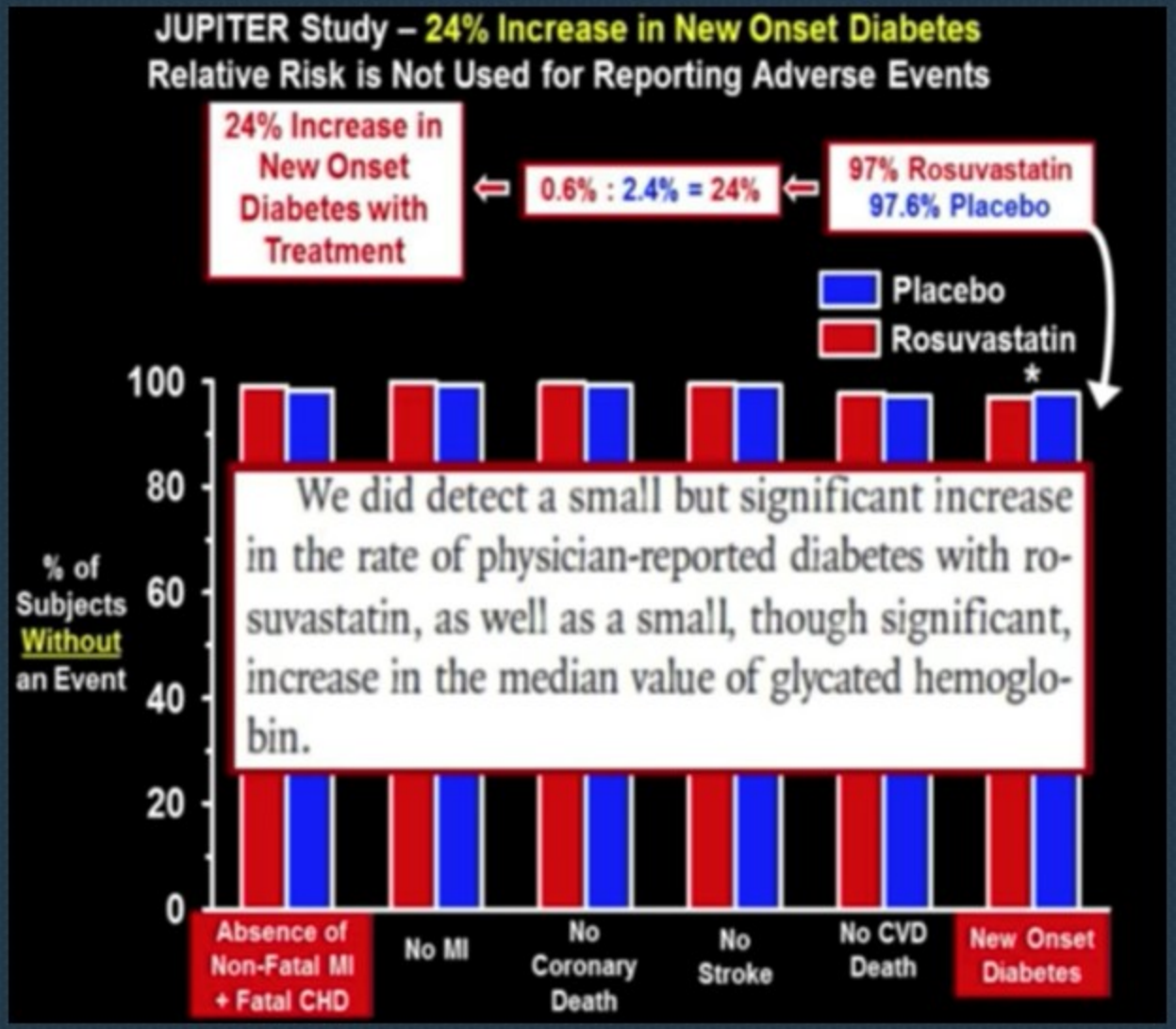
THE BITTERSWEET TRUTH


The Lipid Research Clinics Coronary Primary Prevention Trial Results
JAMA, Jan 20, 1984—Vol 251, No. 3
Where is the 24% Reduced Heart Disease Death Rate?
Cholestyramine
Placebo
% of Subjects Without an Event
100
80
60
40
20
0
CHD Death
Non-Fatal MI
Suspected CHD Death
Suspected MI
Survival
Stroke


The Lipid Research Clinics Coronary Primary Prevention Trial Results
JAMA, Jan 20, 1984—Vol 251, No. 3
Relative Risk Reduction:
0.4% / 1.6% = 24%
Cholestyramine
Placebo
*
100
80
60
40
20
0
% of Subjects Without an Event
CHD Death
Non-Fatal MI
Suspected CHD Death
Suspected MI
Survival
Stroke


Prevention of coronary and stroke events with atorvastatin in hypertensive patients who have average or lower-than-average cholesterol concentrations, in the Anglo-Scandinavian Cardiac Outcomes Trial—Lipid Lowering Arm (ASCOT-LLA): a multicentre randomised controlled trial
THE LANCET • Vol 361 • April 5, 2003
Where is a 36% Reduction in Any Measure?
Placebo
Atorvastatin
% of Subjects Without an Event
100
80
60
40
20
0
Absence of Non-Fatal MI + Fatal CHD
No CVD Events
No Coronary Events
Survival
No CVD Death
No Stroke


JUPITER Study – Inflated Claims for Minuscule Benefits
98.4% Rosuvastatin
97.2% Placebo
Difference = 1.2%
Drug vs Placebo
1.2% : 2.8% = 44%
Placebo
Rosuvastatin
100
80
60
40
20
0
% of Subjects Without an Event
Absence of Non-Fatal MI + Fatal CHD
No MI
No Coronary Death
No Stroke
No CVD Death


JUPITER Study – 24% Increase in New Onset Diabetes
Relative Risk is Not Used for Reporting Adverse Events
24% Increase in New Onset Diabetes with Treatment
0.6% : 2.4% = 24%
97% Rosuvastatin
97.6% Placebo
Placebo
Rosuvastatin
*
We did detect a small but significant increase in the rate of physician-reported diabetes with rosuvastatin, as well as a small, though significant, increase in the median value of glycated hemoglobin.
% of Subjects Without an Event
100
80
60
40
20
0
Absence of Non-Fatal MI + Fatal CHD
No MI
No Coronary Death
No Stroke
No CVD Death
New Onset Diabetes

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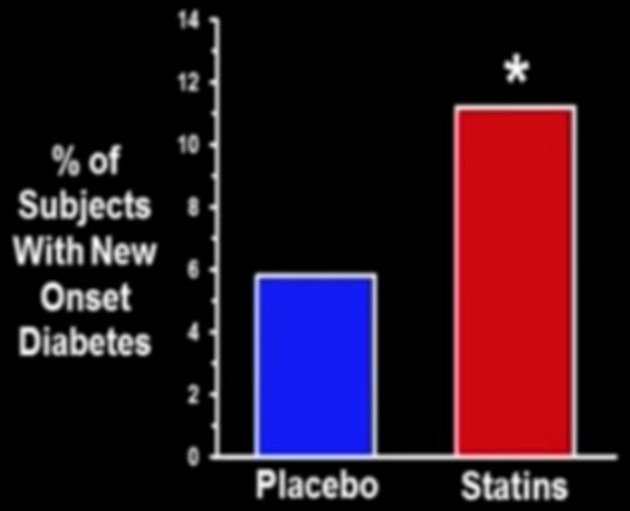

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