
The Disputed Science on Saturated Fats



EXECUTIVE SUMMARY

In order to continue the limits on saturated fat, health officials must show ample and *consistent* evidence that these fats damage health. The principal allegation against them has been that they cause heart disease, according to the **diet-heart hypothesis** which was first proposed in the 1950s.[1]

However, rigorous evidence for this hypothesis on saturated fats has, from the start, been lacking.

The scientific evidence: The most rigorous kind of data, which can demonstrate *cause and effect* from randomized, controlled clinical trials. Some 75,000 people have been tested in such trials. The question tested: whether saturated fats cause heart disease. The results

from all these trials?

—>**Conclusion:** Saturated fats of any kind have **no effect on cardiovascular or total mortality.**

There have now been more than a dozen systematic analysis of this more rigorous trial data, summarized in a “review of reviews” paper (cited below), which concludes:

“To summarise, the results of most meta-analyses do not support the diet-heart hypothesis or the recommendation to replace saturated fat with polyunsaturated fat.”

REVIEWS OF DATA FROM RANDOMIZED CONTROLLED TRIALS:

REVIEW OF REVIEWS:

“Fat or fiction: the diet-heart hypothesis,”(review of 17 systematic analysis of clinical-trial data)

BMJ Evidence-Based Medicine (2019)

Robert DuBroff, Department of Internal Medicine/Cardiology at the University of New Mexico; Michel de Lorgeril, Department of Equipe Coeur & Nutrition, University of Grenoble

Conclusion: Diets that replace saturated fat with polyunsaturated fat do not convincingly reduce cardiovascular events or mortality...[We] must consider that the diet-heart hypothesis is invalid or requires modification.

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INDIVIDUAL META-ANALYSES AND SYSTEMATIC REVIEWS OF RANDOMIZED, CONTROLLED CLINICAL TRIALS (RCTS), which are the more rigorous evidence (presented in chronological order):

1. “Effects of Nutritional Supplements and Dietary Interventions on Cardiovascular Outcomes: An Umbrella Review and Evidence Map” (2019)

Annals of Internal Medicine

Safi U. Khan, MD; Muhammad U. Khan, MD; Haris Riaz, MD; Shahul Valavoor, MD; Di Zhao, PhD; Lauren Vaughan, MD; Victor Okunrintemi, MD, MPH; Irbaz Bin Riaz, MD, MS; Muhammad Shahzeb Khan, MD; Edo Kaluski, MD; M. Hassan Murad, MD; Michael J. Blaha, MD, MPH; Eliseo Guallar, MD, DrPH; Erin D. Michos, MD, MHS, representing ten health institutions and universities in the U.S.

Conclusions (on fats): "In our analysis, the Mediterranean diet, modified dietary fat, reduced dietary fat, reduced saturated fat intake, omega-6 PUFA, or omega-3 ALA PUFA did not reduce the risk for mortality or cardiovascular outcomes."

2. "Dietary Fats and Cardiovascular Disease: A Presidential Advisory From the American Heart Association" (2017)

Circulation (the journal of the American Heart Association, original authors of the policy advocating for reduction in saturated fats, starting in 1961)

Sacks FM, Lichtenstein AH, Wu JHY et al., for the American Heart Association.

Conclusions: In summary, randomized controlled trials that lowered intake of dietary saturated fat and replaced it with polyunsaturated vegetable oil reduced CVD by $\approx 30\%$Prospective observational studies in many populations showed that lower intake of saturated fat coupled with higher intake of polyunsaturated and monounsaturated fat is associated with lower rates of CVD and of other major causes of death and all-cause mortality....Replacement of saturated with unsaturated fats lowers low-density lipoprotein cholesterol, a cause of atherosclerosis, linking biological evidence with incidence of CVD in populations and in clinical trials....[W]e conclude strongly that lowering intake of saturated fat and replacing it with unsaturated fats, especially polyunsaturated fats, will lower the incidence of CVD.

3. "The effect of replacing saturated fat with mostly n-6 polyunsaturated fat on coronary heart disease: a meta-analysis of randomized, controlled trials."

Nutrition Journal (2017)

Steve Hamley

Results: When pooling results from only the adequately controlled trials there was no effect for major CHD events (RR = 1.06, CI = 0.86–1.31), total CHD events (RR = 1.02, CI = 0.84–1.23), CHD mortality (RR = 1.13, CI = 0.91–1.40) and total mortality (RR = 1.07, CI = 0.90–1.26). Whereas, the pooled results from all trials, including the inadequately controlled trials, suggested that replacing SFA with mostly n-6 PUFA would significantly reduce the risk of total CHD events (RR = 0.80, CI = 0.65–0.98, $P = 0.03$), but not major CHD events (RR = 0.87, CI = 0.70–1.07), CHD mortality (RR = 0.90, CI = 0.70–1.17) and total mortality (RR = 1.00, CI = 0.90–1.10).

Conclusion: "Available evidence from adequately controlled randomised controlled trials suggest **replacing SFA with mostly n-6 PUFA is unlikely to reduce CHD events, CHD mortality or total mortality**. The suggestion of benefits reported in earlier meta-analyses

is due to the inclusion of inadequately controlled trials. These findings have implications for current dietary recommendations.”

4 “Evidence from prospective cohort studies does not support current dietary fat guidelines: a systematic review and meta-analysis”

British Journal of Sports Medicine (2016)

Harcombe, Z., Baker, JS, Davies B.

Results: Across 7 studies, involving 89 801 participants (94% male), there were 2024 deaths from CHD during the mean follow-up of 11.9±5.6 years. The death rate from CHD was 2.25%. Eight data sets were suitable for inclusion in meta-analysis; all excluded participants with previous heart disease. Risk ratios (RRs) from meta-analysis were not statistically significant for CHD deaths and total or saturated fat consumption. The RR from meta-analysis for total fat intake and CHD deaths was 1.04 (95% CI 0.98 to 1.10). The RR from meta-analysis for saturated fat intake and CHD deaths was 1.08 (95% CI 0.94 to 1.25).

Conclusions: Epidemiological evidence to date found no significant difference in CHD mortality and total fat or saturated fat intake and thus does not support the present dietary fat guidelines. The evidence per se lacks generalisability for population-wide guidelines.

5. “Re-evaluation of the traditional diet-heart hypothesis: analysis of recovered data from Minnesota Coronary Experiment (1968-73)”

The BMJ (2016) starting p. 7. (on RCT data)

Ramsden, C., National Institutes of Health,. et al.

Details: This paper contains, as a separate piece of research, a systematic review and meta-analysis of clinical trials in which saturated fats were replaced by “oils rich in linoleic acid (such as corn oil, sunflower oil, safflower oil, cottonseed oil, or soybean oil).” (5 trials, 10,808 participants)

Results: “There was no evidence of benefit on mortality from coronary heart disease (hazard ratio 1.13, 95% confidence interval 0.83 to 1.54).”

Conclusion: “Although limited, available evidence from randomized controlled trials provides no indication of benefit on coronary heart disease or all cause mortality from replacing saturated fat with linoleic acid rich vegetable oils.”

6. “Reduction in saturated fat intake for cardiovascular disease,” (systematic review and meta-analysis of randomized, controlled clinical trials)

Cochrane Database Systematic Review, 2015

Hooper, L. et al.

Details: This is a systematic review and meta-analysis of randomized controlled trials, performed by the Cochrane collaboration – an independent organization of scientists. The trials reviewed include more than 59,000 participants.

Findings: The study found no statistically significant effects of reducing saturated fat on the following outcomes: all-cause mortality, cardiovascular mortality, fatal MIs (myocardial infarctions), non-fatal MIs, stroke, coronary heart disease mortality, coronary heart disease events. The one significant finding was an effect for saturated fats on cardiovascular events. However this finding lost significance when subjected to a sensitivity analysis (Table 8, page 137).

Conclusion: People who reduced their saturated fat intake were just as likely to die, or get heart attacks or strokes, compared to those who ate more saturated fat.

7. "Dietary fatty acids in the secondary prevention of coronary heart disease: a systematic review, meta-analysis and meta-regression," (on clinical trials)

BMJ Open (2014)

Lukas Schwingshackl and Georg Hoffman, Faculty of Life Sciences, Department of Nutritional Sciences, University of Vienna, Vienna, Austria

Details: This paper compares low-fat trials to high-fat trials and only includes those with detailed reporting on cholesterol risk factors. A total of 32 trials on nearly 9,000 participants analyzed.

Conclusion: (looking only at subjects with existing CVD) The present systematic review provides no evidence (moderate quality evidence) for the beneficial effects of reduced/modified fat diets in the secondary prevention of coronary heart disease. Recommending higher intakes of polyunsaturated fatty acids in replacement of saturated fatty acids was not associated with risk reduction.

8. "Association of Dietary, Circulating, and Supplement Fatty Acids with Coronary Risk: A Systematic Review and Meta-analysis" (on observational data on all fatty acids and RCTs on supplementation with polyunsaturated fats, o3s or o6s)

Annals of Internal Medicine (2014)

Rajiv Chowdhury, MD, PhD, University of Cambridge, Samantha Warnakula, University of Cambridge, et al.

Details: RCT data reviewed is on 105,085 participants; observational data is on roughly 550,000 participants. The RCT analysis combined trials that increased either omega 3s or omega 6s.

Conclusion: "Current evidence does not clearly support cardiovascular guidelines that encourage high consumption of polyunsaturated fatty acids and low consumption of total saturated fats."

9. "Reduced or Modified Dietary Fat For Preventing Cardiovascular Disease" (Systematic Review and Meta-analysis) (Analysis of clinical trials)

Cochrane Database Syst Review (2012), An independent organization of scientists who specialize in systematic reviews. This review is an update on one conducted in 2011.

Hooper L, Norwich Medical School, University of East Anglia, Summerbell CD, Thompson R, et al.

Conclusions: There were no clear effects of dietary fat changes on total mortality, cardiovascular mortality, stroke, total MIs or non-fatal MIs. Reducing saturated fat by reducing and/or modifying dietary fat reduced the risk of cardiovascular events by 14%," This finding was for men only and disappeared upon the authors "Removing studies with systematic differences in care between intervention and control groups, or other dietary differences."

10. "Effects on Coronary Heart Disease of Increasing Polyunsaturated Fat in Place of Saturated Fat: A Systematic Review and Meta-analysis of Randomized Controlled Trials"

PLOS Medicine (2010)

Mozaffarian D, Department of Epidemiology, Harvard School of Public Health, Micha R, Department of Epidemiology, Harvard School of Public Health, and Wallace S, Department of Epidemiology, Harvard School of Public Health.

Conclusions: "These findings provide evidence that consuming PUFA in place of SFA reduces CHD events in RCTs. This suggests that rather than trying to lower PUFA consumption, a shift toward greater population PUFA consumption in place of SFA would significantly reduce rates of CHD"

11. "Dietary Fat and Coronary Heart Disease: Summary of Evidence From Prospective Cohort and Randomised Controlled Trials" (review of observational data and clinical trials)
Annals of Nutrition and Metabolism (2009)

Skeaff CM, PhD, Professor, Dept. of Human Nutrition, the University of Otago, Miller J.

Conclusions: “Intake of SFA was not significantly associated with CHD mortality, with a RR of 1.14 (95% CI 0.82–1.60, $p = 0.431$) for those in the highest compared with the lowest category of SFA intake (fig. 6). Similarly SFA intake was not significantly associated with CHD events (RR 0.93, 95% CI 0.83–1.05, $p = 0.269$ for high vs. low categories). Moreover, there was no significant association with CHD death (RR 1.11, 95% CI 0.75–1.65, $p = 0.593$) per 5% TE increment in SFA intake.”

NON-SYSTEMATIC REVIEWS ON CLINICAL TRIALS

“Saturated Fat, Carbohydrate, and Cardiovascular Disease” (Review of clinical trials)

American Journal of Clinical Nutrition (2010)

Siri-Tarino PW, Children’s Hospital, Oakland Research Institute Oakland, Sun Q, MD, Departments of Nutrition and Epidemiology, Harvard School of Public Health, Hu FB, MD, Departments of Nutrition and Epidemiology, Harvard School of Public Health, et al.

Conclusions: “Although substitution of dietary polyunsaturated fat for saturated fat has been shown to lower CVD risk, there are few epidemiologic or clinical trial data to support a benefit of replacing saturated fat with carbohydrate.”

REVIEWS OF OBSERVATIONAL STUDIES:

Meta-analyses and systematic reviews (in reverse chronological order):

1. “Dietary total fat, fatty acids intake, and risk of cardiovascular disease: a dose-response meta-analysis of cohort studies”

Lipids in Health and Disease (2019)

Yongjian Zhu, Yacong Bo & Yanhua Liu, Department of Nutrition, The first affiliated hospital of Zhengzhou University

Conclusion: “This current meta-analysis of cohort studies suggested that total fat, SFA, MUFA, and PUFA intake were not associated with the risk of cardiovascular disease. However, we found that higher TFA intake is associated with greater risk of CVDs in a dose-response fashion. Furthermore, the subgroup analysis found a cardio-protective effect of PUFA in studies followed up for more than 10 years. **Dietary guidelines taking these findings into consideration might be more credible.**”

2. “Intake of Saturated and Trans Unsaturated Fatty Acids and Risk of All Cause Mortality, Cardiovascular Disease, and Type 2 Diabetes: Systematic Review and Meta-Analysis of Observational Studies.” (on observational data)

The BMJ (Clinical Research ed.) (2015)

R.J. de Souza, Department of Clinical Epidemiology and Biostatistics, McMaster University, Chanchlani Research Centre, McMaster University, A. Mente, Population Health Research Institute, McMaster University, et al.

Conclusion: "Saturated fats are not associated with all cause mortality, CVD, CHD, ischemic stroke, or type 2 diabetes, but the evidence is heterogeneous with methodological limitations."

3. "Evidence from prospective cohort studies does not support current dietary fat guidelines: a systematic review and meta-analysis"

British Journal of Sports Medicine (2016)

Harcombe, Z., Baker, JS, Davies B.

Results: Across 7 studies, involving 89 801 participants (94% male), there were 2024 deaths from CHD during the mean follow-up of 11.9±5.6 years. The death rate from CHD was 2.25%. Eight data sets were suitable for inclusion in meta-analysis; all excluded participants with previous heart disease. Risk ratios (RRs) from meta-analysis were not statistically significant for CHD deaths and total or saturated fat consumption. The RR from meta-analysis for total fat intake and CHD deaths was 1.04 (95% CI 0.98 to 1.10). The RR from meta-analysis for saturated fat intake and CHD deaths was 1.08 (95% CI 0.94 to 1.25).

Conclusions: Epidemiological evidence to date found no significant difference in CHD mortality and total fat or saturated fat intake and thus does not support the present dietary fat guidelines. The evidence per se lacks generalisability for population-wide guidelines.

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Conclusion: "Current evidence does not clearly support cardiovascular guidelines that encourage high consumption of polyunsaturated fatty acids and low consumption of total saturated fats."

5. "Meta-analysis of Prospective Cohort Studies Evaluating the Association of Saturated Fat with Cardiovascular Disease"

American Journal of Clinical Nutrition (2010)

Siri-Tarino PW, Children's Hospital, Oakland Research Institute Oakland, Sun Q, MD, Departments of Nutrition and Epidemiology, Harvard School of Public Health, Hu FB, MD, Departments of Nutrition and Epidemiology, Harvard School of Public Health, et al.

Conclusions: "A meta-analysis of prospective epidemiologic studies showed that there is no significant evidence for concluding that dietary saturated fat is associated with an increased risk of CHD or CVD. More data are needed to elucidate whether CVD risks are likely to be influenced by the specific nutrients used to replace saturated fat."

6. "A Systematic Review of the Evidence Supporting a Causal Link Between Dietary Factors and Coronary Heart Disease" (review of observational data and clinical trials)

Archives of Internal Medicine (2009)

Andrew Mente, MA, PhD, Associate Professor, Department of Clinical Epidemiology & Biostatistics, McMaster University, Lawrence de Koning, Clinical Assistant Professor, Department of Pathology and Laboratory Medicine, Pediatrics, University of Calgary, et al.

Conclusions: "The evidence supports a valid association of a limited number of dietary factors and dietary patterns with CHD.... Insufficient evidence (< or =2 criteria) of association is present for intake of supplementary vitamin E and ascorbic acid (vitamin C); saturated and polyunsaturated fatty acids;..."

7. "Dietary Fat and Coronary Heart Disease: Summary of Evidence From Prospective Cohort and Randomised Controlled Trials" (review of observational data and clinical trials)

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Skeaff CM, PhD, Professor, Dept. of Human Nutrition, the University of Otago, Miller J.

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NON-SYSTEMATIC REVIEWS OF OBSERVATIONAL STUDIES:

"Saturated Fats Versus Polyunsaturated Fats Versus Carbohydrates for Cardiovascular Disease Prevention and Treatment"

Annual Review of Nutrition (2015)

Patty W. Siri-Tarino, PhD, Sally Chiu, PhD, Nathalie Bergeron, PhD, and Ronald M. Krauss, PhD, Atherosclerosis Research Program, Children's Hospital Oakland Research Institute, Oakland, California

Conclusions: "Replacement of SFAs with polyunsaturated fatty acids has been associated with reduced CVD risk, although there is heterogeneity in both fatty acid categories. In contrast, replacement of SFAs with carbohydrates, particularly sugar, has been associated with no improvement or even a worsening of CVD risk..."

Replacement of SFAs with CHOs [carbohydrates] has not been associated with benefit and may be associated with increased CVD risk....The effects of various SFA replacement scenarios on CVD risk factors other than lipids and lipoproteins are ambiguous...

LARGEST-EVER SINGLE OBSERVATIONAL STUDY:

The PURE Study: largest-ever epidemiological study, *contradicts* diet-heart hypothesis

"Associations of fats and carbohydrate intake with cardiovascular disease and mortality in 18 countries from five continents (PURE): a prospective cohort study"

The Lancet (2017)

*Mahshid Dehghan, Andrew Mente, Xiaohe Zhang, et al., on behalf of the Prospective Urban Rural Epidemiology (PURE) study investigators**

Interpretation of findings: "High carbohydrate intake was associated with higher risk of total mortality, whereas total fat and individual types of fat were related to lower total mortality. Total fat and types of fat were not associated with cardiovascular disease, myocardial infarction, or cardiovascular disease mortality, whereas saturated fat had an inverse association with stroke. Global dietary guidelines should be reconsidered in light of these findings."

LONGEST-EVER SINGLE OBSERVATIONAL STUDY:

The Boyd Orr Cohort study: longest-ever epidemiological study, *contradicts* the diet-heart hypothesis "Diet in childhood and adult cardiovascular and all cause mortality: the Boyd Orr cohort"

Heart (2005)

Ness AR, Maynard M, Frankel S, Smith GD, Frobisher C, Leary SD, Emmett PM, Gunnell D.

Methods: 4028 people (from 1234 families) took part in Boyd Orr's survey of family diet and health in Britain between 1937 and 1939 and were followed up through the National Health

Service central register to 2000.

Conclusions: No significant associations for childhood saturated fat intake and cardiovascular mortality or any cause of death. For all-cause mortality the rate ratio between the highest and lowest quartiles of saturated fat intake was 0.91 (95% CI 0.70 to 1.17, p for trend 0.2) after adjustment for age, sex, and energy intake.

For press reports and expert analyses challenging the hypothesis that saturated fats cause heart disease, [click here](#).

This summary is by Nina Teicholz.

[1] The “diet-heart hypothesis,” proposed principally by Ancel Benjamin Keys, holds that saturated fats and dietary cholesterol cause heart disease. Authorities in the U.S., including the American Heart Association and the U.S. Dietary Guidelines for Americans, have recently dropped their caps on dietary cholesterol, exonerating it from Keys’ original claim. However these authorities continue their caps on saturated fats.