
UNPUBLISHED STUDIES DISPROVED SATURATED FAT—HEART DISEASE CONNECTION LONG AGO

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An unpublished study conducted four decades ago, but recently discovered in a dusty basement, raises new questions about the longstanding dietary advice regarding saturated fats. The research, known as the Minnesota Coronary Experiment, was a major double blind randomized controlled clinical trial conducted from 1968 to 1973. It studied the diets of more than 9,400 people at state mental hospitals and a nursing home. Although the study was conducted over 40 years ago it was not published until just recently. This study is a good example of what happens when the results of an investigation do not coincide with the prevailing scientific dogma of the time—it doesn't get published. Numerous studies were conducted from the 1960s through the 1990s that were designed to demonstrate the dangers of eating cholesterol and saturated fat, but proved otherwise and consequently were never published.

In his book, *Heart Fraruds*, Charles T. McGee, MD talks about this problem and shares the experience of a patient of his who participated in a feeding study.¹ "John worked in a regional primate center, one of several research centers funded by the federal government. One old baboon, named George, was selected to participate in the study because he had a mean disposition and none of the animal keepers liked him. "The staff dreamed up an experiment in which George was given the opportunity to give his life for science and not be around to bother them anymore. They fed the old baboon nothing but hardboiled eggs for one year, then put him down and performed an autopsy. "Because of the propaganda about the cholesterol theory, the staff confidently expected to find massive

obstructions in the old baboon's arteries. They dreamed of seeing their names in large print on the top of a published scientific paper supporting the widely accepted and popular cholesterol theory." However, "...no evidence of atherosclerosis was found in George's arteries, no paper was written. The feeding study demonstrated once again ... that studies that do not support an accepted theory usually don't get published."

In 2013, Dr. Ramsden and his colleagues published another controversial paper involving a large clinical trial that had been carried out in Australia in the 1960s which also had never been fully analyzed or published. Like the Minnesota study, the researchers never had their study published because the results were not what they had expected. The trial found that men who replaced saturated fat with omega-6-rich polyunsaturated fats lowered their cholesterol. But they were also more likely to die from a heart attack than a control group of men who ate more saturated fat.

Today, saturated fat is not considered the evil demon it was a few years ago. The medical community is now acknowledging that saturated fat may not be so bad after all. Fortunately the data from the Minnesota study has been found, analyzed, and published. The Minnesota Coronary Experiment, was paid for by the National Heart, Lung and Blood Institute and led by Dr. Ivan Frantz, Jr. of the University of Minnesota Medical School. Many diet studies have relied on the participants' memory in recalling what they ate over previous days or weeks. Such studies are lim-

ited by the accuracy of the subjects' memories, and therefore, are not totally reliable. This study was significant because the researchers were able to tightly regulate the diets of the institutionalized study subjects so that they knew exactly what the subjects ate. Half of those subjects were fed meals rich in saturated fats from milk, cheese, and beef.

The remaining group ate a diet in which much of the saturated fat was removed and replaced with corn oil, a polyunsaturated fat that is common in many processed foods. The study also had the benefit of detailed autopsies on 149 patients who had died during the study. The study was intended to show that removing saturated fat from people's diets and replacing it with polyunsaturated vegetable oil would protect them against heart disease and lower their risk of mortality.

So what was the result? Despite being one of the largest tightly controlled clinical dietary trials of its kind ever conducted, the data were never fully analyzed, and consequently never published. Why put so much effort and expense into a study and not publish it?

Several years ago, Christopher E. Ramsden, a medical investigator at the National Institutes of Health, learned about the long-overlooked study. Intrigued, he contacted the University of Minnesota in hopes of reviewing the unpublished data. Dr. Ivan Frantz, Jr who died in 2009, had been a prominent scientist at the university, where he studied the link between saturated fat and heart disease. One of his closest colleagues was Ancel Keys, an influential scientist whose flawed research in the 1960s helped establish the belief that saturated fat was a dietary monster, prompting

the federal government to recommend low-fat diets to the entire nation. "My father definitely believed in reducing saturated fats, and I grew up that way," said Dr. Robert Frantz, the lead researcher's son and a cardiologist at the Mayo Clinic. "We followed a relatively low-fat diet at home, and on Sundays or special occasions, we'd have bacon and eggs." The younger Dr. Frantz made three trips to the family home, finally discovering the dusty box marked "Minnesota Coronary Survey," in his father's basement. He turned it over to Dr. Ramsden for analysis.

The results were a surprise. Participants who ate a diet low in saturated fat and enriched with corn oil reduced their cholesterol by an average of 14 percent. But the low-saturated fat diet did not reduce mortality. In fact, the study found that the greater the drop in cholesterol, the higher the risk of death during the trial. The fact that blood cholesterol levels decreased when corn oil replaced the saturated fat was expected, as this had been observed before. What wasn't expected was the drop in cholesterol was correlated with an increase in the number of deaths. The findings ran counter to the prevailing belief at the time that diets low in saturated fat reduces the risk of heart disease. This study indicated just the opposite.

Preliminary analysis of the data uncovered the apparent discrepancy with the prevailing belief at the time. While it is unclear exactly why the researchers did not complete the analysis and seek publication, but one possibility is that Dr. Frantz and his colleagues had a hard time getting it published. If they had sought publication they would have faced stiff resistance from medical journal editors who might have refused to publish the study because it questioned a popular and generally accepted belief that saturated fat promoted heart disease. Any study that did not support this

position was simply out of step with established scientific belief and considered unreliable, and therefore, not worthy of publication. Many leading edge studies are not published simply because they suggest ideas that go contrary to accepted medical belief.

Another possibility, and the one that is most likely, is that Dr. Frantz and his colleagues were so convinced that saturated fat was the problem, that they couldn't believe their own data and decided not to seek publication. Maybe they thought the results were just a fluke or perhaps an undetected error had crept in that influenced the results. This reason is most likely because Dr. Frantz continued to strongly believe in the saturated fat heart disease connection even after this study was completed. The younger Dr. Frantz said his father was probably startled by what seemed to be no benefit in replacing saturated fat with vegetable oil. "When it turned out that it didn't reduce risk, it was quite puzzling," he said. "And since it was effective in lowering cholesterol, it was weird."

The new analysis of the Minnesota Coronary data was published, in the April 2016 edition of the *British Medical Journal*.² Based on the analysis, the authors concluded that although the replacement of polyunsaturated vegetable oils for saturated fat in the diet can lower blood cholesterol, it does not lower the risk of death from coronary heart disease or any other cause. Also, the prejudice against saturated fats over the years has contributed to the over estimation of the perceived benefits of replacing saturated fat with vegetable oils rich in omega-6 fatty acids (primarily linoleic acid). To investigate whether the new findings were a fluke, Dr. Daisy Zamora, a research scientist at the University of North Carolina at Chapel Hill and one of the main authors of the new study, and her colleagues analyzed four similar, rigorous

trials that tested the effects of replacing saturated fat with vegetable oils rich in linoleic acid. Those, too, failed to show any reduction in mortality from heart disease. "One would expect that the more you lowered cholesterol, the better the outcome," Dr. Ramsden said. "But in this case the opposite association was found. The greater degree of cholesterol-lowering was associated with a higher, rather than a lower, risk of death." We have been looking at cholesterol levels the wrong way. Higher cholesterol reduces the risk of death in comparison to low cholesterol.

One explanation for the surprise finding may be omega-6 fatty acids, which are found in high levels in corn, soybean, cottonseed, and sunflower oils. While cooking with these vegetable oils instead of butter lowers cholesterol, the high levels of omega-6 can simultaneously promote inflammation—a major contributing factor to heart disease. In 2013, Dr. Ramsden and his colleagues published another controversial paper involving a large clinical trial that had been carried out in Australia in the 1960s which also had never been fully analyzed or published.³ Like the Minnesota study, the researchers never had their study published because the results were not what they had expected. The trial found that men who replaced saturated fat with omega-6-rich polyunsaturated fats lowered their cholesterol. But they were also more likely to die from a heart attack than a control group of men who ate more saturated fat.

The Australian study was conducted from 1966 to 1973. One group of men with heart disease increased omega-6-rich polyunsaturated fat intake to 15 percent of calories, while reducing saturated fat intake to less than 10 percent. Another group of men with heart disease continued their normal diets. The men were followed for an average of 39 months, and those on the polyun-

saturated-rich diet lowered their cholesterol levels by an average of 13 percent. But they also were more likely to die, and in particular to die of a heart attack, than those who stuck with their usual diet, which consisted of about 15 percent saturated fat. This study — the results of which weren't fully analyzed when it was conducted in the early days of enthusiasm for polyunsaturated oils — adds to a growing body of data suggesting that consuming polyunsaturated oils, even though they reliably lower cholesterol, may nevertheless increase the risk of heart disease.

The science behind dietary fat may be more complex than nutrition recommendations suggest. Apparently we can get 15 percent or more of our daily calories from saturated fat without problem. However, we need to limit our omega-6 or polyunsaturated fat intake. Our bodies do require omega-6 fatty acids (linoleic acid) in small amounts, about 2 percent of calories. But emerging research suggests that excess linoleic acid may play a role in a variety of disorders including liver disease, chronic pain, diabetes, and heart disease. A century ago, it was common for Americans to get

ries from omega-6 fatty acids by eating whole, natural foods. Today, Americans on average consume more than triple that amount, much of it from processed foods like lunch meats, salad dressings, desserts, pizza, French fries, and packaged snacks like potato chips. Natural sources of fat such as olive oil, butter, and egg yolks contain omega-6 fatty acids as well, but in much smaller quantities. Eating whole, unprocessed foods is the best way to get all the omega-6 fatty acids your body needs, without getting too much.

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