

The Cholesterol Scandal and the Truth About Statin Drugs

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In 1953 Ancel Keys, an American professor in physiology thought that he had found the cause of the increasing heart mortality in the United States. It was fat food, of course. As a member of several influential committees in World Health Organization (WHO) and Food and Agriculture Organization (FAO), Keys had easy access to all kinds of population statistics. In his paper he presented a diagram that showed a strong association between fat consumption and heart mortality in six countries. In countries with a high fat consumption, heart mortality was high, and vice versa.

Keys also claimed that blood cholesterol went up if he gave test individuals a food rich in saturated fat. As cholesterol was a dominating molecule in atherosclerotic tissue, the case was settled: Atherosclerosis and myocardial infarction was caused by fat food and high cholesterol.

But Keys cheated. In his experiments, Keys didn't use natural saturated fat. He used vegetable oils saturated by chemical procedures — the same process that creates transfat. Worse was that he had used only the data from six countries that supported his hypothesis and ignored the others. At that time data from 22 countries were available, and by using all of them the association disappeared. This was revealed by the biostatistician Jacob Yerushalmy and the epidemiologist Herman Hilleboe four years later, but nobody reacted, because in 1961 William Kannell, head of the Framingham project, together with his co-workers, published a paper which, unfortunately, has had an enormous influence.

They had measured blood cholesterol in a few thousand healthy Framingham, Massachusetts's inhabitants six years previously. They found that cholesterol had been a little higher in those who had suffered from a heart attack. Now, everybody was convinced.

Their observation was not proof, of course. A statistical association does not mean causation. Yellow fingers do not cause lung cancer. The cause is smoking which also can make fingers yellow. There are also many contradictory facts.

High cholesterol, for instance, is not a risk factor for women or healthy people, and more than twenty studies have shown that old people with high cholesterol live the longest. Many studies have also shown that people with low cholesterol become just as atherosclerotic as people with high cholesterol.

There are many more contradictions. Some of the strongest ones came up three years ago. In a study from UCLA Medical Center, Ashwin Sachdeva and his co-workers found that the mean LDL-cholesterol in 136,905 patients referred to hospital because of an acute heart attack was lower than normal, not higher. This

surprising finding was confirmed a few months later, in a similar, although smaller, study by Mouaz Al-Mallah and his co-workers at Henry Ford Heart and Vascular Institute in Detroit. In addition, these authors noted that at follow-up three years later, twice as many had died among those with the lowest compared with those with the highest LDL.

The authors of these papers did not question the cholesterol hypothesis, however. Instead they concluded that cholesterol had to be lowered even more.

The Framingham researchers were just as inane. They didn't change their minds after the 30-year follow-up in 1987 when they realized that more had died among those whose cholesterol had dropped compared with the others. To cite the report: *For each 1 mg/dl drop of cholesterol there was an 11 percent increase in coronary and total mortality.*

Did the Framingham researchers tell people that high cholesterol wasn't anything of which to be afraid? Not at all: instead you can read the following in a joint statement from the American Heart Association and the National Heart, Lung, and Blood Institute entitled *The Cholesterol facts* published in the medical journal *Circulation* three years later: *The results of the Framingham study indicate that a 1% reduction...of cholesterol corresponds to a 2% reduction in CHD risk.*

I have often been asked how it can be that the pioneers of the anti-cholesterol campaign continue undisturbed with their bad advice ignoring and even lying about the many contradictory findings. Lars Werkö, a Swedish professor in internal medicine, gave me the answer. As a young researcher he participated in a conference in the U.S., where one of the speakers argued eagerly for an anti-cholesterol campaign. Werkö asked him, if it wouldn't be more effective to concentrate on the influence of smoking, because the bad influence from tobacco smoking was beyond any doubt, whereas the role of cholesterol was questionable.

"Oh, you see," he was told, "tobacco research isn't profitable."

But research on cholesterol is very profitable. The pharmaceutical drug industry and those who produce margarine and vegetable oils pay researchers who praise the cholesterol hypothesis. Those companies are generous because they can afford to be generous.

The medical journals profit as well. The problem is that if they accept a paper questioning the anti-cholesterol campaign the flow of money stops.

Last year the drug industry alone sold statins for almost 30 billion dollars and their income from statins increases year by year, because it is much more profitable to sell drugs to healthy people than to patients because there are more healthy people than sick people.

Their sales argument is that the statins lower the risk of dying from a heart attack or a stroke by at least 20 per cent. Their claim is a wild exaggeration. Statin treatment

is able to lower mortality by two percentage points at most, and only for men who already have had cardiovascular disease. No trial has ever succeeded in prolonging the life for women or healthy people of both sexes.

The industry doesn't lie, however. If mortality for those who take a statin pill every day for five years is eight per cent and it is ten per cent for those taking a sugar pill, then the difference is two percentage points. But because two is twenty per cent of ten, they say instead that mortality has been lowered by twenty per cent.

Is it, nevertheless, useful to lower cholesterol? No. Statins have other beneficial effects, and they aren't due to cholesterol lowering, because the benefit is the same whether the cholesterol is reduced maximally or just a little. Statins might be more useful if they didn't block the synthesis of cholesterol, because blocking cholesterol is not harmless. Cholesterol is a vital molecule without which human life is impossible.

According to the drug trial directors, adverse reactions are rare and innocent, but independent researchers have come up with something completely different. Two years ago Julia Hippisley-Cox and Carol Coupland published a study in the British Medical Journal (BMJ) including nearly a quarter million statin-treated patients. Compared to 1½ million patients, who were not on statin treatment, more than four percent had severe liver damage, acute renal (kidney) failure, muscle problems or cataracts after 6-7 years of treatment.

Furthermore, Hippisley-Cox and Coupland underestimated adverse events. Muscle problems, estimated at 1 percent, for example, were only recorded if the substance that reflects muscle damage (CPK) was at least four times higher than the highest normal value. Independent researchers can tell you that 20-25 percent is much nearer the truth. In a recent paper in Archives of Internal Medicine Beatrice Golomb and her coworkers from the University of California at San Diego, those who have studied the effects longest and most thoroughly, told us that up to 40 percent of female patients have muscle problems, and in ten per cent they are serious.

Some side effects were not included at all by Hippisley-Cox and Coupland. Hemat Solomon and his staff at St. Thomas' Hospital in London, for example, have shown that about 20 per cent of men treated with statins become more or less impotent after a few months. The study was funded by Pfizer, but nothing is mentioned about that problem on the Lipitor website. Pfizer has, of course, a solution to the problem named Viagra.

Diabetes wasn't included either. In Women's Health Initiative, the world's largest food experiment, almost ten per cent of the women who were on statins had acquired diabetes after 7-8 years treatment, but this was seen in only a little more than six per cent of the untreated women.

Other adverse effects are poor memory, irritability, depression, insomnia and suicide. Nothing is mentioned about those problems in the statin trials, but recently, the Food and Drug Administration has published a warning.

Cholesterol lowering in rats and mice may result in cancer, and this may be the case in human beings as well. Three statin trials have resulted in cancer with statistical significance. Furthermore, in the first two simvastatin trials non-melanoma skin cancer increased in the treatment group. The differences were not statistically significant in either of them, by themselves, but when put together, they are significant. Since then, no drug trial director has recorded the number of skin cancer cases. This is a most curious decision, because skin cancer is the type of cancer that we should discover earliest if the statins are carcinogenic.

Another reason adverse effects are underestimated is that many patients stop taking the pills during the trials. A more correct figure is achieved by relating the number of cancer cases to the degree of cholesterol lowering. This is what the Japanese researcher Masunori Matzusaki and his co-workers from Yamaguchi University in Ube, Japan have done. They gave more than 47,000 patients a small dose of simvastatin (Zocor). Six years later, three times more had died of cancer among those who had lowered their cholesterol the most compared with those whose cholesterol was still normal.

But the “official” cholesterol experts (those who are paid for their opinions) remain unaffected by these facts and the campaign continues. In Denmark for instance, Professor Børge Nordestgaard, whose research is paid for by six pharmaceutical companies, recently claimed that 900,000 more Danes need cholesterol medication and if they do not get it, 30,000 of them will die in the next ten years. The medication is safe, he wrote. He compared statin treatment with using a safety belt in the car.

A more realistic comparison would be jumping from an airplane wearing a parachute without a ripcord.

What I have written here may seem unbelievable, but if you doubt, go to my books.
<http://www.ravnskov.nu/my%20books.htm>
Here you will find references to the scientific literature for every one of my apparently incredible statements.