Benefits of switch from saturated fat to corn oil for longer life challenged

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Long-ignored and surprising randomized trial failed to find that unsaturated fats are healthier

Replacing saturated fats in the diet with unsaturated corn oil fails to reduce the risk of death, according to a finding from a large randomized trial in the U.S. that went mysteriously unpublished for decades despite its implications for nutrition recommendations.

The "diet-heart hypothesis" predicts that replacing saturated fat with vegetable oil rich in linoleic acid will lower cholesterol levels in the blood and reduce cardiovascular events and deaths. Despite years of claims that unsaturated fats like corn oil are healthier, at the time the findings of a gold-standard randomized controlled trial weren't fully published.

Now Christopher Ramsden at the U.S. National Institutes of Health in Bethesda, Md., and his team have analyzed data from the Minnesota coronary experiment. It was a blinded randomized trial that occurred 45 years ago on 9,423 men and women from state mental hospitals and a nursing home in Minnesota.

The participants were followed for up to 4½ years and fed either corn oil rich in unsaturated omega-6 fatty acid or a diet high in saturated fat from meat, butter and shortening as a control.

Higher risk of death

First study author Dr. Robert Frantz of the Mayo Clinic in Rochester, Minn., son of the study's original principal investigator Dr. Ivan Frantz Jr., had to dig through the original files in the basement of his family home. The data had to be converted from magnetic tapes into usable data.

The "diet-heart hypothesis" predicts that replacing saturated fat with vegetable oil rich in linoleic acid will lower cholesterol levels in the blood and reduce cardiovascular events and deaths. The hypothesis has been dealt a serious blow by the Minnesota study. (Jeff Gentner/Associated Press)

"We were able to find that actually those that lowered their cholesterol more actually had increased rather than reduced risk of death," Ramsden said in an interview. "It was surprising."

The original investigators measured participants' blood cholesterol for at least a year and performed 295 autopsies to look at the degree of atherosclerosis and number of stroke and heart attacks. Ramsden's team was able to recover all of the cholesterol data and half of the autopsies.

"If he were alive today, I know my father would have been delighted that the data he had devoted his career to making possible had been painstakingly revisited in order to shed additional light on the frustratingly paradoxical results," Frantz wrote in a supplementary tribute to his father.

The re-evaluation, published in Tuesday's online issue of BMJ, also includes a review of four smaller randomized controlled trials on providing vegetable oils rich in linoleic acid in place of saturated fat, including the Sydney heart study that Ramsden also dusted off to analyze.

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- Heart-healthy oil claims reconsidered
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Richard Bazinet, a professor of nutrition at the University of Toronto, studies fatty acids and was not involved in the research.

"This is the first time we're debating where there is no effect or there's harm, and yet we have policies saying we should go ahead and consume these products," Bazinet said.

With the new findings, the recommendation to consume less than 10 per cent of calories per day from saturated fats will be scrutinized, J. Lennert Veerman, a senior lecturer at the University of Queensland's School of Public Health, said in a journal editorial.

'If they had actually published a study that said, "Boy, we remove saturated fat and replace vegetable oil and we actually kill people," that would've inhibited the [diet-heart hypothesis] movement.' - Gary Taubes

Ideally, dietary recommendations should be based on clinical outcomes such as survival, not surrogates such as cholesterol concentrations, Veerman said.

Bazinet said the saga shows the importance of publishing neutral or negative findings, which has implications for how we're advised to eat.

"I think what was lost was a major contributor to the debate with the publication of this," Bazinet said. "I think it really shifts the weight of that debate."

The nutritional take-home message, Bazinet said, is don't make corn oil the staple of your diet. Rather, regular cooking oils should contain a balance of omega-3 and omega-6.

When journalist Gary Taubes interviewed Frantz Jr. by email before his death, he was told they were "disappointed" with how the study came out and that's why it wasn't published for 16 years.

"If they had actually published a study that said, 'Boy, we remove saturated fat and replace vegetable oil and we actually kill people, that would've inhibited the [diet-heart hypothesis] movement, and I'm sure they knew that."

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The idea that saturated fats were associated with high cholesterol and heart disease was sparked by Frantz Jr.'s colleague, Ancel Keys. Keys's seven countries study of middle-aged men in Europe, South Africa, Japan and the U.S. found an association between total fat intake and cardiovascular health.

Taubes compares the failure to publish the original findings to investigators not acknowledging evidence to exonerate the accused in a criminal trial, but he recognizes it's human nature for the researchers to have decided they must not have done the clinical trial correctly.

"What they didn't take into account was that they happened to do a better job than anyone else," Taubes said.