

Safety and life-saving efficacy of statins have been exaggerated, says USF scientist

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Statin advocates have created the appearance that cholesterol-lowering drugs are wonder drugs that have substantially reduced cardiovascular disease outcomes by

using 'relative risk,' a statistical tool that amplifies the miniscule beneficial effects of statins. Credit: USF

Hailed as miracle drugs when they hit the market two decades ago, statins, the cholesterol-lowering drugs prescribed to prevent heart attacks, are not as effective nor as safe as we have been led to believe, say Dr. David M. Diamond, a professor of psychology, molecular pharmacology and physiology at the University of South Florida, and Dr. Uffe Ravnskov, an independent health researcher and an expert in cholesterol and cardiovascular disease.

According to Diamond and Ravnskov, statins produce a dramatic reduction in cholesterol levels, but they have "failed to substantially improve cardiovascular outcomes." They further state that the many studies touting the efficacy of statins have not only neglected to account for the numerous serious [adverse side effects](#) of the drugs, but supporters of statins have used what the authors refer to as "statistical deception" to make inflated claims about their effectiveness.

Their critique of the exaggerated claims regarding statins' ability to prevent strokes, heart attacks and heart disease-related deaths on a large scale has been published in the medical journal *Expert Review of Clinical Pharmacology* at <http://informahealthcare.com/> .

Their paper is an analysis of the data in the statin trials which led them to conclude that "statin advocates have used statistical deception to create the illusion that statins are 'wonder drugs,' when the reality is that their modest benefits are more than offset by their adverse effects."

The paper also describes how the basis of the deception is in how authors of the statin studies present the rate of beneficial and adverse

effects. The effect of the drugs on the population is called the 'absolute risk,' which has shown that statins benefit only about 1% of the population. This means that only one out of 100 people treated with a statin will have one less heart attack. Statin researchers, however, don't present the 1% effect to the public. Instead they transform the 1% effect using another statistic, called the "relative risk," which creates the appearance that statins benefit 30-50% of the population.

The exaggeration of beneficial effects of statin treatment was illustrated in their analysis of a subset of statin studies, including the Jupiter Trial (Crestor), the Anglo-Scandinavian Cardiac Outcomes Trial Lipid Lowering Arm (ASCOT-LLA), and the British Heart Protection Study.

"In the Jupiter trial, the public and healthcare workers were informed of a 54 percent reduction in heart attacks, when the actual effect in reduction of coronary events was less than 1 percentage point," said Ravnskov and Diamond, who is also a Career Research Scientist with the Medical Research Service at the James A. Haley Veterans Hospital in Tampa, Florida. "In the ASCOT-LLA study, which was terminated early because it was considered to have such outstanding results, there were heart attacks and deaths in 3% of the placebo (no treatment) group as compared to 1.9% in the Lipitor group. The improvement in outcome with Lipitor treatment was only 1.1 percentage point, but when this study was presented to the public, the advertisements used the inflated (relative risk) statistic, which transformed the 1.1% effect into a 36% reduction in heart attack risk.

The inflated claims for statin effectiveness, and minimized portrayal of the adverse effects, has played a role in the health care providers and the public's enthusiasm for cholesterol-lowering drugs, say the authors.

"The adverse effects suffered by people taking statins are more common than reported in the media and at medical conferences" explains

Diamond and Ravnskov. According to the authors, "Increased rates of cancer, cataracts, diabetes, cognitive impairments and musculoskeletal disorders more than offset the modest cardiovascular benefits of statin treatment."

The authors emphasized that low cholesterol levels related to statin use have frequently been associated with an increased risk of cancer. They also noted that most statin trials are terminated within two to five years, a period too short to see most cancers develop. Nevertheless, studies have shown a greater incidence of cancer in people who take statins, and one long-term study demonstrated a dramatic increase in the incidence of breast cancer among women who had used statins for more than 10 years.

They emphasized that the public needs to be wary of conflicts of interest in the medical community and pharmaceutical industry when it comes to touting the benefits of statins and skewing the data in such a way as to make the drugs seem more effective at lowering [cardiovascular disease](#) and heart attack risks than they may actually be.

Diamond and Ravnskov's paper is particularly relevant at this time as reports out of Britain have revealed that leaders in health care and research, including the editor in chief of the British Medical Journal, Fiona Godlee, and the chair of Britain's Commons Health Select Committee, Sarah Wollaston, have called for drug companies to release all of their records involving undisclosed adverse effects of statins in their clinical trials.

"We welcome more medical journals to follow the new rules introduced by the British Medical Journal stating that 'clinical education articles will be authored by experts without financial ties to industry'," say Diamond and Ravnskov.

The authors advocate other health beneficial strategies that are known to reduce cardiovascular risk, such as cessation of smoking, weight control, exercise and stress reduction. They also emphasized the great value of a low carbohydrate diet for normalizing all of the biomarkers of cardiovascular risk, with excellent outcomes, especially for people with type 2 diabetes.

Diamond and Ravnskov concluded their paper with the sobering statement that "There is a great appeal to the public to take a pill that offers the promise of a longer life and to live [heart attack](#) free. The reality, however, is that [statins](#) actually produce only small beneficial effects on cardiovascular outcomes, and their [adverse effects](#) are far more substantial than is generally known."

Provided by University of South Florida

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