

## We've been bamboozled

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'We've been bamboozled' about cholesterol risks

Roni Rabin

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If you're a woman like me who worries about your blood cholesterol level, there's something you should know.

Buried in the back pages of a leading medical journal recently was a study that raised serious questions about whether cholesterol-lowering drugs are useful for women who are otherwise healthy.

The study didn't get a lot of media attention. But its results were surprising – especially considering how many millions of women are taking drugs known as statins to lower their cholesterol. Women like me, who've had it drummed into us that heart disease is the leading cause of death we face. And who've been told repeatedly cholesterol is a major risk factor.

The paper, published in the Journal of the American Medical Association, examined the results of 13 carefully selected clinical trials and teased out the effects on women. It wasn't easy: At least 80 percent of the participants were men.

The researchers found that for women who are taking statins as a preventative measure – they've never had cardiovascular disease but may be at risk – it wasn't clear the pills bestowed any benefit. That's because so few women in this group have heart attacks to begin with.

For women who have cardiovascular disease, the drugs reduced the risk of another heart incident – but did not reduce overall deaths.

"The risk for total mortality was not lower in women treated with lipid-lowering drugs, regardless of whether they had prior cardiovascular disease or not," Dr. Judith M.E. Walsh and Dr. Michael Pignone wrote.

Last year, scientists at the University of British Columbia's Therapeutics Initiative came to a similar conclusion about the use of statins in men who didn't have prior heart disease. Sure, they had fewer heart attacks – but they still died at the same rate. "What we're hypothesizing is that there was some other harm" associated with the medication, said Dr. Jim Wright, the clinical pharmacologist who did the study, funded entirely by a grant from British Columbia's health department. "That really should concern people."

"Before we prescribe this to millions of people who are basically healthy, we should be proving that the overall benefits outweigh the harms," he said. "And we don't think that's the case."

Health consumer advocates, such as Maryann Napoli of the Center for Medical Consumers, have expressed concerns about statins, which have been linked to muscle problems, including a rare condition that can be fatal. The FDA banned Baycol in 2001; last week, Public Citizen's Health Research Group called for banning Crestor.

The drugs do reduce blood cholesterol levels. But the relationship between high cholesterol and heart disease is not so simple, especially for women. The landmark Framingham heart study found that in the vast majority of people, there was no difference in blood cholesterol levels between those who developed heart disease and those who did not. The only strong association between heart disease and elevated cholesterol was found in young and middle-aged men – not women – and it receded with age.

Still, the American Heart Association recommends aggressive treatment to lower cholesterol in women, especially if other risk factors are present, according to Dr. Nieca Goldberg, chief of the Women's Heart Program at Lenox Hill Hospital in New York and a spokeswoman for the AHA.

And when doctors talk about heart disease risks for women, they mention high cholesterol in the same breath as high blood pressure, diabetes, obesity, smoking and family history.

Wright, the Canadian researcher, suggests a distinction should be made. "The weakest risk factor is cholesterol," he said. "The correlation is extremely weak and even becomes negative as you get older." He said the message about cholesterol has been distorted.

"We've been bamboozled," he said.

Dr. Beatrice Golomb, an assistant professor of medicine at the University of California at San Diego who has done research on cholesterol and statins, says no study has ever demonstrated that statins extend life for women. "The people who benefit are middle-aged men who are at high risk or have heart disease ..." she said. "The mortality benefits don't extend to the elderly or to women."

Yes, heart disease is the leading cause of death in women – but only when women 75 and older are included in the figures. Take those women out and the picture changes.

Younger women know that, intuitively. It's misleading to scold them for worrying too much about cancer and not enough about heart disease. For women ages 35–74, cancer is the No. 1 threat, killing almost twice as many women as heart disease, according to national statistics.

So if your doctor recommends a statin, ask about the side effects. Find out if you have other risk factors for heart disease that justify the medication. Male or female, "assume any new symptom you develop after starting any new drug is caused by the drug," says Dr. Sidney Wolfe, of Public Citizen. Report muscle aches, pain, tenderness or weakness, and cognitive changes, and the sooner the better, Wolfe says.

And make sure to tell the doctor what drugs you take.  
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