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Study Questions Treatment Used in Heart Disease

By GARDINER HARRIS
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WASHINGTON — Lowering bad [cholesterol](#) levels reduces [heart attack](#) risks, and researchers have long hoped that raising good cholesterol would help, too. Surprising results from a large government study announced on Thursday suggest that this hope may be misplaced.

[The study](#) could change the way doctors treat millions of patients with heart disease. Common wisdom has been that such patients should take a statin drug like [Lipitor](#) or [Zocor](#) to lower bad cholesterol and, in many cases, the vitamin [niacin](#) to raise their good cholesterol. But in the trial, niacin provided no benefit over simple statin therapy.

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The results are part of a string of studies that suggest that what doctors thought they knew about cholesterol may be wrong. Studies that track patients over time have for decades shown that patients with higher levels of high-density lipoproteins ([H.D.L.](#), or good cholesterol) tend to live longer and have fewer heart problems than those with lower levels of this cholesterol.

Not surprisingly, doctors thought that if they could raise H.D.L. levels, their patients would benefit. So far, that assumption is not panning out. Nobody knows why.

In 2006, Pfizer halted development of a drug that raised good cholesterol levels after studies showed that the medicine increased the risks of death. And on Thursday, government scientists announced that Niaspan, an extended release form of niacin, not only did not provide any protection against heart attacks when taken with Zocor in patients with heart disease but also slightly increased their risk of stroke.

“We were stunned, to say the least,” said Dr. William E. Boden, a professor of medicine and [preventive medicine](#) at the University at Buffalo who was a trial investigator.

What is remarkable about the study is that niacin seemed to be working. Patients taking the medicine along with Zocor had higher levels of H.D.L. and lower levels of [triglycerides](#), a fat in the blood. Despite these seeming improvements, the patients fared no better and may have done slightly worse than those taking Zocor alone. That is why the entire theory behind trying to increase H.D.L. levels in patients with heart disease may need rethinking.

The study results may be greeted as a mixed blessing by some patients. A drug many had hoped would help is now thought to be at best useless. But for many people, niacin is hard to take because it can cause flushing and headaches. Doctors have for years wheedled

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patients into tolerating these side effects in hopes that the medicine would save their lives. Now, they will not have to.

Dr. William M. Schreiber, a Louisville, Ky., internist, said he had stopped prescribing niacin because so many patients told him they could not abide its effects. "I'm delighted to hear that statins alone are just as good as statins and niacin," he said.

The study is bad news for the maker of Niaspan, Abbott Laboratories, for the drug industry as a whole and even for the Food and Drug Administration. Abbott last year had \$927 million in Niaspan sales, and the company spent \$32 million on the study (the government spent \$21 million) in the hope that it would increase sales. Instead, the results are bound to lower use of the drug.

[In a statement](#), Dr. Eugene Sun, a vice president at Abbott, said, "Based on its long history of clinical evidence, Niaspan remains an important agent for patients with" blood lipid problems.

The study gives no comfort to other drug makers, many of which have been trying to come up with new drugs to raise levels of good cholesterol or otherwise lower heart attack risks. [Statins](#) and other drugs have proven so effective in treating heart disease that improvements are proving very tough to find.

The study is also bad news for the F.D.A., which heavily relies on laboratory results to decide whether to approve drugs.

"This study shows that approving drugs and allowing them to stay on the market on the basis of how they affect [lipids](#) and other biomarkers is not good policy," said Dr. Steven Nissen, chairman of cardiovascular medicine at the [Cleveland Clinic](#). "It's time to have a new regulatory approach."

In the trial, 3,414 participants with heart and vascular disease were given either Zocor and a placebo or Zocor and Niaspan and followed for 32 months. The trial ended 18 months early because it was found that there was almost no chance taking Niaspan would prove beneficial. Zocor and other medications did a good job of keeping patients' bad cholesterol levels relatively low.

Researchers said patients should not stop taking Niaspan without talking to their doctors first.

"We have great evidence that lowering L.D.L. is beneficial," said Dr. Bruce Psaty, a professor of medicine and epidemiology at the University of Washington. "We lack good evidence that changing H.D.L. or triglycerides does much."

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