

Abbott's TriCor Fails To Beat A Sugar Pill

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ATLANTA -- A popular triglyceride-lowering drug that has been taken by millions of Americans failed to prevent heart disease in a big federal study being presented today.

The drug, TriCor from Abbott Laboratories, has been used for over a quarter of a century to lower levels of fatty particles in the blood called triglycerides. The presumption has been that doing so would prevent heart attacks or heart-related deaths. TriCor has annual sales of more than \$1 billion.

But the new study being presented at the American College of Cardiology meeting casts doubt on this. In the study, funded by the National Heart, Lung and Blood Institute, 5,500 patients with diabetes got either TriCor or a placebo. After five years, there was no difference in the rate of heart attacks, strokes and deaths in the patients who got Tricor versus those who took a sugar pill.

This is not the first time TriCor fell short. An even bigger 2003 study of diabetics also found that the drug had no overall impact in preventing heart attacks and cardiovascular deaths. Abbott says neither study accurately reflected which patients do benefit from TriCor and that the drug is not overprescribed.

Some top cardiologists said doctors should sharply curtail their use of the drug in the wake of the new findings. "Here is a situation where we can do less and spend less without harming the patient," says Harlan Krumholz, a Yale University cardiologist and epidemiologist. "In fact, it seems avoiding this medication might benefit patients."

The doubts about TriCor emphasize the increasing uncertainty over how much drugs vetted mainly by blood test results can be trusted to actually prevent disease, especially in an age when safe cholesterol-lowering and blood pressure drugs are already available. TriCor came to prominence before medicines like Lipitor and Zocor became mainstays, revolutionizing cardiology. The results are worse than in the 2003 study, in which TriCor came closer to having a statistically significant benefit, though it still missed.

"I think it's going to be the end of [TriCor]," says William Boden, chief of cardiology at the University of Buffalo. "I really do."

Temple University's Alfred Bove, the current president of the American College of Cardiology, counters: "It's not as good as we thought it was, but we don't want to lose the drug either."

Controversies over whether good results on lab tests really translate into benefits for patients have turned out badly for some blockbuster drugs. Merck's cholesterol drug Vytorin, for instance, has gone from growth driver to decliner. Amgen's Aranesp raises hemoglobin levels in anemic patients, but may cause heart attacks in some. GlaxoSmithKline's Avandia improves blood sugar levels, but also increases heart-related chest pain in some studies.

TriCor has defenders. The new results “100% support” the use of the drug in a “targeted” population, says Frank Sacks of Harvard Medical School. Some patients did benefit, he argues: those with high triglycerides and low levels of protective high-density lipoprotein. (Triglycerides had to be more than 200 milligrams per deciLiter, and HDL below 30 mg/dL). Henry Ginsberg of Columbia Medical Center, who led the study, also makes this point.

The average TriCor patient has triglycerides of 300 mg/dL, according to Abbott. That indicates the drug is already being used only in very sick patients. The drug, which can cost \$140 a month, is certainly popular. It was prescribed 12 million times a year, according to drug data tracker IMS Health.

Abbott has reformulated it as a way to outmaneuver generics, and recently received FDA clearance for a slightly modified version, called TriLipix, which it is advertising on television and in magazines. It recently bought TriCor's European maker, Solvay, for more than \$6 billion.

But it has never started a big study – known as an 'outcome trial' - to prove TriCor prevents heart attacks, strokes, or deaths. “The company selling this product has had many opportunities to perform outcome trials,” says Steven Nissen, chair of cardiovascular medicine at the Cleveland Clinic. “Instead they have focused expenditures on marketing.” Now might be a good time to change.

Wall Street has been anxiously awaited TriCor result, and analysts have argued that a bad result was unlikely to hurt TriCor sales. But Abbott shares fell 1.8% Friday after a CitiGroup analyst told investors to sell because Abbott was “masking underlying profitability trouble” with the Solvay deal.

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