

Doctors say Vytorin-cancer link can't be ruled out

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Results so far from three studies of the cholesterol-lowering drug Vytorin are not enough to prove or rule out a possible link to a higher risk of cancer, so the drug should be used with caution until more is known, editors of a leading medical journal urged Tuesday.

The New England Journal of Medicine published results online from one study and an analysis of partial results from two others. They also were presented at a cardiology conference in Munich.

Vytorin is a combination of Merck's Zocor, a long-sold statin drug, and Schering-Plough's Zetia, a newer type of medicine that lowers cholesterol in a different way.

The possible cancer risk unexpectedly arose in July, when Dr. Terje Pedersen of Oslo, Norway, announced preliminary results from a study testing whether Vytorin could prevent damage to the heart's aortic valve from worsening.

The drug made no difference in heart attacks, strokes or surgeries related to the valve problem. But doctors saw a greater number of cancer cases in those taking it compared to others given dummy pills.

That prompted an interim analysis of results of two other ongoing studies of Vytorin by scientists at Oxford University in England. Their review found higher rates of cancer deaths among Vytorin users, but the number of cancer cases did not significantly differ.

"I don't think there is any evidence of hazard here," concluded Sir Richard Peto, a cancer epidemiologist who is helping lead one of the drug company-sponsored studies.

But editors of the medical journal noted that participants in these two studies have been followed for less than three years — a short time for risks like cancer to emerge — and concluded that a link could not be ruled out. Patients and doctors "are unfortunately left for now with uncertainty" about the safety and effectiveness of the drug, they wrote.

Other doctors also were not convinced that Vytorin is safe.

"The jury is still out as to whether there's a cancer signal," said Dr. Gordon Tomaselli, cardiology chief at Johns Hopkins Hospital and a spokesman for the American Heart Association. He was not connected to the research.

Pedersen's study involved 1,873 people in Europe and the United States who were starting to have problems with their aortic valves. They were either given Vytorin or a placebo in hopes that lowering cholesterol would ward off future heart problems.

Of those given Vytorin, 105 developed cancer, compared with 70 among those on placebo. That is higher than the 93 cases among Vytorin users and 65 in the others that scientists reported on a conference call in July when the issue first became known.

Cancer-related deaths were higher in all three studies. Editors of the medical journal, who combined the results and found 134 among Vytorin users and 92 in the others, said the increase cannot simply be chalked up to chance.

Some doctors said that although Vytorin may not have helped heart valve problems, it still might be useful for people who need their cholesterol lowered — if other drugs do not work.

"If I was on this medication and it was the only way to get my cholesterol down, I would not change my therapy based on this," said Dr. Douglas Weaver, president of the American College of Cardiology. The group has been asked by the U.S. Senate to account for the money it accepts from pharmaceutical companies, including Merck. The American Heart Association also accepts funding from Merck and other drug companies to finance ongoing operations.

The federal Food and Drug Administration is looking into the cancer concerns but has said that patients should not stop taking Vytorin because the evidence of any link is unclear.

With other options available for heart patients, some doctors said there was no obvious reason to take Vytorin. "There's no proof that this combination is working," said Dr. Christer Hoglund, a cardiologist at Sweden's Karolinska Institute.

"We don't know that this drug is bad, but we don't know that it's any good either."

AP Business Writer Linda A. Johnson in Trenton, N.J. and AP Medical Writer Marilyn Marchione in Milwaukee, Wis. contributed to this report.