

## **Antibiotic Linked With Rare but Deadly Heart Risk**

*Source: Therapeutics Daily*

An antibiotic widely used for bronchitis and other common infections seems to increase chances for sudden deadly heart problems, a rare but surprising risk found in a 14-year study.

Zithromax, or azithromycin, is more expensive than other antibiotics, but it's popular because it often can be taken for fewer days. But the results suggest doctors should prescribe other options for people already prone to heart problems, the researchers and other experts said.

Vanderbilt University researchers analyzed health records and data on millions of prescriptions for several antibiotics given to about 540,000 Tennessee Medicaid patients from 1992 to 2006. There were 29 heart-related deaths among those who took Zithromax during five days of treatment. Their risk of death while taking the drug was more than double that of patients on another antibiotic, amoxicillin, or those who took none.

To compare risks, the researchers calculated that the number of deaths per 1 million courses of antibiotics would be about 85 among Zithromax patients versus 32 among amoxicillin patients and 30 among those on no antibiotics. The highest risks were in Zithromax patients with existing heart problems.

Patients in each group started out with comparable risks for heart trouble, the researchers said.

The results suggest there would be 47 extra heart-related deaths per 1 million courses of treatment with Zithromax, compared with amoxicillin. A usual treatment course for Zithromax is about five days, versus about 10 days for amoxicillin and other antibiotics. Zithromax is at least twice as expensive as generic amoxicillin; online prescription drug sellers charge a few dollars per pill for Zithromax.

"People need to recognize that the overall risk is low," said Dr. Harlan Krumholz, a Yale University health outcomes specialist who was not involved in the study. More research is needed to confirm the findings, but still, he said patients with heart disease "should probably be steered away" from Zithromax for now.

The study appears in Thursday's New England Journal of Medicine. The National Heart, Lung and Blood Institute helped pay for the research.

Zithromax, marketed by Pfizer Inc., has been available in the United States for two decades. It's often used to treat bronchitis, sinus infections and pneumonia. Wayne Ray, a Vanderbilt professor of medicine, decided to study the drug's risks because of evidence linking it with potential heart rhythm problems. Also, antibiotics in the same class as Zithromax have been linked with sudden cardiac death.

Zithromax is among top-selling antibiotics. U.S. sales last year totaled \$464 million, according to IMS Health, a health care information and services company.

Pfizer issued a statement saying it would thoroughly review the study. "Patient safety is of the utmost importance to Pfizer and we continuously monitor the safety and efficacy of our products to ensure that the benefits and risks are accurately described," the company said.

Patients studied were age 50 on average and not hospitalized. Most had common ailments, including sinus infections and bronchitis. Those on Zithromax were about as healthy as those on other antibiotics, making it unlikely that an underlying condition might explain the increased death risk.

Medicaid patients generally have more disability and lower incomes than other patients, so whether the same results would be found in the general population is uncertain, Ray said.

Dr. Bruce Psaty, a professor of medicine at the University of Washington, said doctors and patients need to know about the potential risks. He said the results also raise concerns about long-term use of Zithromax, which other research suggests could benefit people with severe lung disease. Additional research is needed to determine if that kind of use could be dangerous, he said.