

Azithromycin not tied to increased risk of CV death

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Current use of the antibiotic azithromycin is not associated with an increased risk of death from cardiovascular causes in a general population of young and middle-aged adults, according to a study published in the May 2 issue of the *New England Journal of Medicine*.

(HealthDay)—The widely used antibiotic azithromycin (Zithromax or Zmax)—under scrutiny recently because it may increase the risk of death for those with existing heart disease—appears to be safe for young and middle-aged adults without heart problems, according to a large new study.

Danish researchers evaluated more than a million episodes of azithromycin use, comparing it to both the use of no antibiotics and to the use of penicillin V, from 1997 through 2010. Patients were aged 18 to 64.

"We believe that the results are reassuring," said Henrik Svanstrom, a

researcher at Statens Serum Institute, in Copenhagen. His study is published in the May 2 issue of the *New England Journal of Medicine*.

"Our study shows no increased risk in the general population of young and middle-aged adults," he said. That, he added, "would reinforce the hypothesis that any increased risk of cardiovascular [death] associated with azithromycin is restricted to high-risk patients—for instance [those] with a history of cardiovascular disease."

More than 56 million prescriptions were written for azithromycin in the United States in 2011, according to the IMS Institute for Healthcare Informatics. That compares to about 54 million written in 2011 for amoxicillin, another popular antibiotic.

Azithromycin is prescribed for bacterial sinusitis, pneumonia, skin infections and infections linked with lung disease, among other problems.

Concern about azithromycin surfaced in 2012, after a study in which researchers estimated an absolute risk of 47 cardiovascular deaths for every 1 million prescriptions for azithromycin. The study prompted a statement from the U.S. Food and Drug Association, cautioning that those taking the drug should be aware of the potential for heart problems.

In March 2013, the FDA renewed the warning, cautioning that the drug and others in its class, known as macrolides, can cause abnormal changes in the electrical activity of the heart. That, in turn, may lead to a potentially fatal irregular heart rhythm. The FDA warned that those especially at risk of developing the abnormality are those who have existing heart problems such as rhythm abnormalities.

That begged the question about the safety of the antibiotic for those

without heart problems.

In the Danish study, supported by grants from the Danish Medical Research Council, Svanstrom and his team looked at data on filled prescriptions, causes of death and patient characteristics.

They looked at azithromycin use compared to no antibiotic use. Patients not using an antibiotic, Svanstrom said, likely did not have an infection at the time.

Using azithromycin for the typical five-day treatment increased the risk of cardiovascular death nearly three times compared to no antibiotic use. When researchers compared azithromycin use to penicillin V use, however, there was no increased risk with the azithromycin.

When they compared each antibiotic by use per 1.1 million people, 17 people on azithromycin died and 16 on penicillin died.

"This indicates that the increased risk in comparison to non-use is entirely explained by an increased risk of cardiovascular death associated with acute infection, rather than the treatment with azithromycin," Svanstrom said.

Decisions about medication use need to be made after weighing pros and cons, Svanstrom said. "Our study is just one piece of the puzzle," he said. "However, if this drug is needed in the general population, our results do not argue against its use."

The results are good news for those without heart problems, said Dr. Gregg Fonarow, director of the Ahmanson-UCLA Cardiomyopathy Center, who reviewed the study.

"This study provides welcome and reassuring news regarding the

cardiovascular safety of the antibiotic azithromycin in the general population," Fonarow said. The large numbers are a strength of the study, he added.

"These findings suggest that for the general population of adults azithromycin can be safely prescribed without concerns regarding an increased risk of cardiovascular events," he said.

The risk for those with existing heart disease is still unclear, he said. Fonarow said those patients should talk with their doctors about the risks and benefits of each treatment option.

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