New Blood Thinner Linked to Higher Heart Attack Risk

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Tue, Jan 10, 2012

MONDAY, Jan. 9 (HealthDay News) -- The anticoagulant Pradaxa (dabigatran) is associated with a small increase in the risk of heart attack, a new review finds.

Researchers from the Cleveland Clinic in Ohio looked at seven trials involving Pradaxa that included more than 30,000 patients. This process, called a meta-analysis, uses data from published clinical trials to tease out a pattern that might not show up in a single study.

The researchers found Pradaxa was associated with an increased risk of heart attack or acute coronary syndrome (heart attack or angina), compared with two other commonly used blood thinners, warfarin (Coumadin, Jantoven) and enoxaparin (Lovenox).

Among those taking Pradaxa, 1.19 percent had a heart attack or suffered from acute coronary syndrome compared with 0.79 percent of those taking either of the other drugs, they noted.

Although there was a 33 percent increase in relative risk for a heart attack among those taking Pradaxa, the absolute increased risk -- that is, the added risk for any one individual of having a heart attack if on Pradaxa -- was 0.27 percent, researchers said.

Pradaxa was approved by the U.S. Food and Drug Administration in October 2010 for people with a common heart rhythm problem called atrial fibrillation. People with atrial fibrillation are at a higher risk for stroke and are often prescribed medication to prevent clotting.

Pradaxa is often prescribed as an alternative to warfarin, a medication that has been used for a long time but which can raise the risk of bleeding and is difficult to dose properly.

Pradaxa is also used to prevent blood clots in people who've had joint replacement surgery.

"For persons with atrial fibrillation, dabigatran has a favorable benefit-risk profile, but for other uses the risk of heart attack has to be taken into account," said lead researcher Dr. Ken Uchino, director of the Vascular Neurology Fellowship Training Program at the Cleveland Clinic.

The report was published in the Jan. 9 online edition of the *Archives of Internal Medicine*.

In the large study that led to the approval of Pradaxa, there was a suggestion that Pradaxa might be associated with an increased risk of heart attacks, Uchino

explained.

However, the drug's benefit for patients with atrial fibrillation outweighs the risk, he said.

"The increase of [heart attack] risk associated with dabigatran is small, and the benefit in prevention of stroke among persons with atrial fibrillation is greater," Uchino said.

Why Pradaxa is associated with an increased heart attack risk isn't clear, they say. It's possible Pradaxa doesn't increase heart attack risk directly, but it may not be as effective as warfarin and aspirin in preventing heart attacks, he added.

Dr. John Smith, senior vice president for clinical development and medical affairs at Boehringer Ingelheim, the makers of Pradaxa, said that "we don't agree with the conclusion and the method used for this meta-analysis. Based on all the data, we conclude that heart attack is not an adverse consequence of Pradaxa treatment."

Another expert said that the risk of heart attack does not outweigh the benefits of the drug, especially taking the risk of serious bleeding with warfarin into account.

"I would be cautious about this meta-analysis. It doesn't convince me," Dr. William O'Neill, a professor of cardiology and executive dean for clinical affairs at the University of Miami School of Medicine, said. "I am unimpressed by the data."

Warfarin, O'Neill added, "is a pretty lousy drug."

Although he estimated about one in 10 patients can't tolerate Pradaxa because of severe gastrointestinal side effects, "you don't have to monitor it the way you have to with warfarin. It's a big improvement over warfarin."

Dr. Jeremy Jacobs, a lecturer in geriatric medicine at Hebrew University Medical Center in Jerusalem and author of an accompanying editorial, said the study shows the importance of continuing to track new drugs after they've been approved and placed on the market.

"The dabigatran debate is a good example which raises issues concerning post-marketing surveillance, and pharmaco-vigilance," Jacobs said. "Who takes responsibility? Industry? Independent researchers? National bodies?"

"I personally tend to favor the latter, since the stakes are very high for new drugs, and it is difficult for industry-backed research to overcome conflicts of interest that inevitably arise," he added.

As far as dabigatran is concerned, Jacobs said that physicians should be cautious, especially when prescribing it to patients with known heart disease. The issue will only be clarified as more data about the risk accumulates and how it measures up against the dangers of bleeding posed by warfarin, he said.

More information

For more on Pradaxa, visit the

U.S. National Library of Medicine .

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