FDA: Pradaxa not for patients with mechanical heart valves

December 21 2012

Pradaxa (dabigatran etexilate mesylate) should not be used to prevent stroke or blood clots (major thromboembolic events) in patients with mechanical heart valves, according to a Dec. 19 safety announcement issued by the U.S. Food and Drug Administration.

(HealthDay)—The blood thinner Pradaxa should not be used to prevent stroke or blood clots in patients with mechanical heart valves, the U.S. Food and Drug Administration said in a warning issued Wednesday.

As the agency noted, a clinical trial in Europe was halted recently because patients taking Pradaxa (dabigatran) were more likely to suffer strokes, heart attacks and clots forming on their mechanical heart valves than patients who were taking the older blood thinner warfarin.

Patients in the study who were taking Pradaxa also had more bleeding after valve surgery, the agency said.

Doctors should immediately switch patients with a mechanical heart

valve who are taking Pradaxa to another medication, the FDA said. The use of Pradaxa in patients with heart valve replacements made of natural biological tissue has not been evaluated and cannot be recommended, the agency added.

The message for patients is that anyone who has received any type of heart valve replacement and is taking Pradaxa should talk to their doctor as soon as possible to determine the most appropriate type of blood thinner (anticoagulant) to take, the FDA said.

Consultation with a physician is crucial, agency officials said, because stopping anticoagulant drugs without seeking advice from their doctor first can increase the risk of blood clots and stroke.

Pradaxa is approved to treat patients with a common heart rhythm disorder called atrial fibrillation. It is not approved to treat patients with atrial fibrillation caused by heart valve problems, the FDA said.

One expert noted another problem with Pradaxa.

"Pradaxa belongs to a class of anticoagulants known as direct-thrombin inhibitors, and while these class of drugs have shown both promise and usefulness in clinical practice, there remains a significant downside, namely there is no "antidote" to this medication [as there is for example with Coumadin]," said Dr. Abe DeAnda, an associate professor in the department of cardiothoracic surgery at NYU Langone Medical Center. "Additionally, surveillance of the effectiveness of the medication and the systemic effect is more difficult to monitor and thus more difficult to titrate. I think that eventually we will move away from Coumadin as our drug of choice, but we are not at that point yet."

More information: More Information