

Blood thinner dangerous for patients with artificial heart valves, study finds

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Trial, which was halted early, found Pradaxa increased risk for strokes and bleeding in this group.

(HealthDay)—When used by patients with mechanical heart valves, the blood thinner Pradaxa raises the risk of both dangerous clots and bleeding around the heart, a new study says.

The bottom line for lead researcher Dr. Frans Van de Werf, chairman of the department of [cardiovascular medicine](#) at the University Hospitals Leuven in Belgium, is "don't use Pradaxa in patients with a [mechanical valve](#)."

In fact, the trial was halted early and the U.S. Food and Drug Administration subsequently issued a 'black box' warning that said this particular group of [heart patients](#) should not take Pradaxa because of an increased chance of a stroke or heart attack.

Pradaxa (dabigatran) is a drug that prevents clotting. It has been approved as an alternative to [warfarin](#) for patients with an abnormal heartbeat called atrial fibrillation, the researchers noted.

"It was hoped that a novel oral direct clotting inhibitor would provide similar or better protection for patients with mechanical heart valves without the need for [the] monitoring or dietary restrictions associated with warfarin," said Dr. Gregg Fonarow, a professor of cardiology at the University of California, Los Angeles.

After a [heart valve replacement](#), patients are typically put on [blood thinners](#) or drugs that combat clotting to prevent a heart attack or stroke, but the danger of these drugs is a risk for severe bleeding.

"While the vitamin K antagonist warfarin is very effective at preventing clotting-related complications of mechanical heart valves, its use requires lifetime monitoring, with at least monthly blood tests, dietary restrictions and the potential for multiple medication interactions," Fonarow explained.

Unfortunately, this [randomized clinical trial](#) showed that Pradaxa was even more problematic than warfarin in terms of side effects, he said.

"As a result of these findings, the FDA added a 'black box' warning to the medication label warning against using dabigatran and similar medications in patients with mechanical heart valves," Fonarow said.

The report was published Sept. 26 in the *New England Journal of Medicine* and the trial was funded by Boehringer Ingelheim, the maker of Pradaxa.

For the study, an international team of researchers randomly assigned 252 patients who had an aortic or mitral valve replacement to either

Pradaxa or warfarin. Some patients had the valve replacement within a week before the study began and others had the surgery three months earlier, the researchers noted.

Of those taking Pradaxa, 32 percent had their treatment stopped or dose changed. In addition, 5 percent of those on the drug suffered a stroke, compared with none of those taking warfarin.

Moreover, 4 percent of those taking Pradaxa had major bleeding around the heart, compared with 2 percent of those taking warfarin, the researchers found.

More information: For more on heart valve replacement, visit the [American Heart Association](#).

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