ESC: Complications noted after dabigatran heart valve Tx

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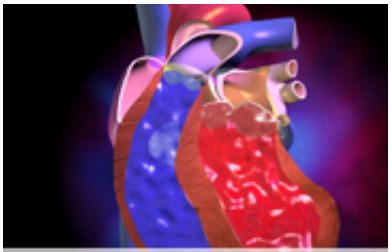

Patients with heart valve replacements have greater rates of thromboembolic and bleeding complications after treatment with dabigatran compared with warfarin, according to a study published online Sept. 1 in the *New England Journal of Medicine* to coincide with presentation at the annual European Society of Cardiology Congress, held from Aug. 31 to Sept. 4 in Amsterdam.

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As part of a phase 2 dose-validation study, John W. Eikelboom, M.D., from Hamilton Health Sciences in Canada, and colleagues randomly assigned (in a 2:1 ratio) 252 patients who had undergone aortic- or mitral-valve replacement to dabigatran (150, 220, or 300 mg twice daily,

adjusted to obtain a trough plasma level of at least 50 ng/mL) or warfarin (adjusted to obtain an international normalized ratio of 2 to 3.5 based on thromboembolic risk).

The researchers terminated the trial early due to an excess of thromboembolic and bleeding events in the dabigatran group. Dose adjustment or discontinuation was required in 32 percent of patients receiving dabigatran. The dabigatran group had a higher occurrence of ischemic or unspecified stroke (5 versus 0 percent) and major bleeding (4 versus 2 percent). Pericardial bleeding was present in all patients with major bleeding.

"The use of dabigatran in patients with mechanical heart valves was associated with increased rates of thromboembolic and bleeding complications, as compared with warfarin, thus showing no benefit and an excess risk," Eikelboom and colleagues conclude.

The study was funded by Boehringer Ingelheim; several authors are employees of the company.

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