

Dabigatran for Patients with Atrial Fibrillation and Prior TIA or Stroke?

The drug compared favorably to warfarin in patients with previous transient ischemic attack or stroke.

In the large RE-LY study of patients with atrial fibrillation at risk for stroke, the novel oral thrombin inhibitor dabigatran (Pradaxa) reduced stroke with similar bleeding risk or reduced bleeding with a similar risk for stroke as compared with warfarin, depending on the dose used ([JW Cardiol Sep 1 2009](#)). But how does dabigatran compare with warfarin in high-risk patients with histories of stroke and transient ischemic attack (TIA)?

In a subgroup analysis of 3623 patients followed for a median of 2 years, the annual rate of stroke or systemic embolism was 2.78% in the warfarin group as compared with 2.32% and 2.07% in the 110-mg and 150-mg dabigatran dose groups, although neither comparison with warfarin was statistically significant. However, hemorrhagic stroke was significantly lower with both doses of dabigatran. The rate of major bleeding was significantly lower in the 110-mg dabigatran group than in the warfarin group (relative risk, 0.66) and similar in the 150 mg-group (RR, 1.01).

Comment: In this subgroup analysis of the RE-LY study, dabigatran compared favorably to warfarin in the high-risk subgroup of patients with prior TIA or stroke, although patients with very recent stroke were excluded from the trial. Patients with prior TIA or stroke were younger than other patients and more likely to have been on anticoagulation at enrollment. The lack of compelling advantage for the 150-mg dose suggests the 110-mg dose has an edge, but only 75- and 150-mg tablets have been marketed. Editorialists emphasize that an individualized assessment of embolic and bleeding risk is warranted.

— [Kirsten E. Fleischmann, MD, MPH](#)

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