

Rivaroxaban has less risk of brain bleeding in patients at high risk for stroke

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For patients with a type of irregular heart beat called atrial fibrillation (AF), a new anti-clotting drug might be better at preventing clot-related strokes while minimizing the risk of causing a bleeding stroke. The research was presented at the American Stroke Association's International Stroke Conference 2012.

The finding stems from a sub-analysis of data in a large, [randomized clinical trial](#) called ROCKET AF, conducted in 45 countries at 1,178 sites. ROCKET AF tested the new drug rivaroxaban against [warfarin](#) — a medicine long used to thin the blood and prevent strokes from blockages, called ischemic strokes — in patients with [atrial fibrillation](#). People with the condition face about five times the risk of [stroke](#) compared with the general public.

Among patients with the most common type of atrial [fibrillation](#), without any history of heart valve damage, those who received rivaroxaban were 34 percent less likely to experience an intracranial hemorrhage, compared with those on warfarin, the study found.

"We have to be very careful about giving anticoagulants to patients at risk of bleeding into the brain, and therefore need to be able to identify who these patients are," said Graeme J. Hankey, lead author and neurologist at the Royal Perth Hospital and University of Western Australia. "Anticoagulant drugs can prevent ischemic strokes, but paradoxically, they can cause intracranial bleeding, including hemorrhagic strokes."

The new study also identified five risk factors, independent of the treatment used, that increased the likelihood that AF patients would suffer intracranial bleeding:

- Blacks had a 4.2-fold increased risk compared to whites; Asians' increased risk was two-fold. Other races did not have a meaningful higher risk.
- In older people, risk increased by one third for every 10 years of age.
- A prior stroke or transient ischemic attack (TIA), also called a "mini-stroke," boosted the risk 51 percent.
- Decreased levels of serum albumin, a protein that helps keep fluid from leaking out of blood vessels, increased the risk 42 percent for every decrease in albumin by 0.5 g/l.
- A low platelet count also increased the risk of intracranial bleeding.

Stroke ranks fourth among the leading causes of death in the United States. New or recurrent strokes strike about 795,000 Americans annually. Ischemic strokes account for 87 percent of all strokes, and 10 percent are from an intracranial hemorrhage. The remaining 3 percent result from bleeding in the subarachnoid space between the brain and the tissues covering it.

ROCKET AF's primary finding, reported last year at the American Heart Association's Scientific Sessions 2010, showed rivaroxaban equal to warfarin in preventing stroke or systemic blood clots in the AF patients. However, rivaroxaban patients had less intracranial bleeding and fatal bleeding. The new research aimed to determine the rate and locations of intracranial bleeding that occurred in ROCKET AF. None of the study participants had experienced intracranial bleeding at enrollment, but 53 percent had suffered a prior ischemic stroke.

After a median follow-up of about two years, researchers found 136 of the 14,264 participants had experienced an intracranial bleed – a low rate overall of about 0.5% per year according to Hankey.

Use of aspirin or a thienopyridine drug was associated with an increased risk of intracranial [bleeding](#) during the trial. However, taking [rivaroxaban](#) during the trial was associated with a lower risk of intracranial hemorrhage than taking warfarin.

The findings apply only to nonvalvular AF patients at moderate or high risk of stroke, such as those enrolled in the ROCKET AF trial, Hankey said. The validity of these findings in other populations of [patients](#) with AF awaits further study.

Provided by American Heart Association

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