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Study shows ability of new agent to prevent strokes in patients with atrial fibrillation

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In the primary result from the largest double-blind study ever completed to assess a drug's effect in the prevention of stroke in patients with atrial fibrillation, a common heart rhythm abnormality, rivaroxaban, an anti-clotting drug, was shown to be an attractive alternative to warfarin, the current standard for treatment of atrial fibrillation.

The full intention-to-treat analysis, which includes patients who discontinued study drug, showed that rivaroxaban was noninferior to warfarin for the prevention of stroke or blood clots. Importantly, rivaroxaban use led to less intra-cranial and fatal bleeding.

The findings, co-authored by a research team from the Duke Clinical Research Institute, were published online today in the *New England Journal of Medicine*.

"Warfarin has been a standard treatment for decades, but requires a rigorous monitoring schedule to ensure therapeutic dosing levels, and is subject to the potential of food and drug interactions that present treatment obstacles for patients and doctors alike," said the study's lead author, Manesh R. Patel, MD assistant professor of medicine at Duke University School of Medicine.

"The results of this large global trial have convincingly shown rivaroxaban to be an alternative to warfarin in treating patients with atrial fibrillation and, importantly, with no increase in bleeding."

Atrial fibrillation is the most common abnormal heart rhythm disorder in the U.S. and is characterized by an unusual and dangerously fast heart beat. It can cause blood to pool in the heart resulting in the formation of clots that may become lodged in the artery to the brain resulting in a stroke, or in formation of non-central nervous system blood clots.

Approximately 2.2 million Americans suffer from atrial fibrillation, which increases a person's stroke risk by four to six times on average.

Warfarin has been documented over the years to reduce the rate of stroke for those who have atrial fibrillation by approximately one-half to two-thirds, at the cost of increased bleeding.

"In addition to addressing an important therapeutic need for patients with atrial fibrillation, ROCKET AF provides a model for how clinical trials of investigational therapies should be conducted to assess safety and efficacy prior to FDA submission," said Robert M. Califf, MD, the study's co-chair, who is vice chancellor for clinical research at Duke University School of Medicine, and director of the Duke Translational Medicine Institute.

"The sponsors of the study should be congratulated for taking this approach in which an international committee of leaders in the field designed the trial and provided independent oversight, including an independent analysis of the trial results," Califf added.

The ROCKET AF (Rivaroxaban once daily oral direct factor xa inhibition compared with vitamin K antagonism for prevention of stroke and embolism trial in atrial fibrillation) study included 14,264 patients with atrial fibrillation who had a history of stroke or additional independent risk factors for future stroke and were randomized to receive either rivaroxaban or warfarin. The trial included more than 1,100 centers in 45 countries.

In the analysis of the intent to treat population -- patients followed from the time of entry and throughout the full study duration, even if they discontinued study medication -- rivaroxaban was not inferior to warfarin (p

Rates of bleeding and adverse events were similar between treatment groups. Compared to warfarin, rivaroxaban showed similar rates for the principal safety measure of major and non-major clinically relevant bleeding events (event rates = 14.9 vs. 14.5, p=0.442). Rates of major bleeding were also comparable between rivaroxaban and warfarin (event rates = 3.6 vs. 3.4, p=0.576).

Patients treated with rivaroxaban had significantly fewer intracranial hemorrhages (event rates = 0.4 vs. 0.7), critical organ bleeds (event rates = 0.8 vs. 1.2) and bleeding-related deaths (event rates = 0.2 vs. 0.5) compared with warfarin, respectively. However, patients treated with rivaroxaban did show increased rates of hemoglobin/hematocrit drop (event rates = 2.8 vs. 2.3) and transfusions (event rates = 1.7 vs. 1.3), compared to warfarin.

"Atrial fibrillation is becoming increasingly prevalent and can be life-threatening if not properly managed. Stroke prevention is a key treatment goal in atrial fibrillation management," said Keith A. A. Fox, MB ChB, professor of cardiology at the University and Royal Infirmary of Edinburgh, Centre for Cardiovascular Science, in Edinburgh, UK, and one of the study's co-leaders "Rivaroxaban appears to be an attractive and well-tolerated clinical alternative to warfarin for patients with atrial fibrillation."

Provided by Duke University Medical Center

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