

## Apixaban superior to warfarin across range of patient risk scores

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A new anticoagulant called apixaban is superior to warfarin in preventing stroke with consistent effects across a wide range of stroke and bleeding risk in patients with atrial fibrillation, according to Duke University Medical Center researchers.

Their results, published online today in *The Lancet*, suggest that the current <u>risk</u> scoring systems for tailoring anticoagulation treatment to individual patients may be less relevant when using apixaban for patients with <u>atrial fibrillation</u> who have at least one risk factor for stroke.

"The benefits of apixaban are preserved regardless of the <u>risk score</u> used and regardless of the patient risk category," said Renato Lopes, M.D., a Duke cardiologist and the lead author of the study. Importantly, apixaban was safer than warfarin in the overall population and tended to cause less intracranial <u>bleeding</u> in those patients whose risk scores defined them as being at the highest risk of bleeding.

"With new oral anticoagulants, such as apixaban, we might not need risk scores to guide <u>treatment decisions</u> for <u>stroke prevention</u> in patients with atrial fibrillation. This may simplify how physicians make decisions and also improve patient care," Lopes said.

Practice guidelines have allowed use of either <u>antithrombotic therapy</u> with warfarin or with aspirin, which is less effective but has lower risk of bleeding, for patients with atrial fibrillation and one risk factor for stroke. Apixaban, with better prevention of stroke and lower risk of



bleeding than warfarin, may remove aspirin as an attractive option for this group of patients.

Atrial fibrillation is a common <u>abnormal heart rhythm</u> that affects more than 2.6 million people in the United States. It occurs when the heart's electrical activity becomes disorganized, resulting in an <u>irregular</u> <u>heartbeat</u> with ineffective contraction of the upper chambers of the heart. The potential for blood clots to form, and one's risk for stroke, increases as a result.

Risk scores for bleeding and thromboembolism (blood clots) have been used to predict the risk of these events to guide use of warfarin, a vitamin K antagonist that is standard treatment to help prevent stroke and blood clots. Only about half of patients who could benefit from warfarin actually do because the drug has several limitations, including a requirement for regular monitoring and increased bleeding risk such as intracranial hemorrhage.

Apixaban is an oral direct factor Xa inhibitor that has already been shown to be safer and more effective than warfarin for patients with atrial fibrillation. Last year, Duke researchers presented the Apixaban for Reduction in Stroke and Other Thromboembolic Events in Atrial Fibrillation (ARISTOTLE) trial at the European Society of Cardiology. It showed apixaban resulted in an additional 21 percent relative reduction in stroke or systemic embolism when compared to warfarin, a 31 percent relative reduction in major bleeding, and an 11 percent relative reduction in overall mortality.

The analysis published in The *Lancet* used the ARISTOTLE data to assess safety and efficacy of apixaban versus warfarin in 18,201 patients based on the most popular risk assessment scores. CHADS2, CHA2DS2VASc, and HAS-BLED are used to estimate risk of stroke and bleeding in patients with atrial fibrillation and help guide warfarin



treatment decisions.

"Risk stratification has been a key element in identifying patients at risk for stroke and bleeding and in helping to guide antithrombotic treatment for patients with atrial fibrillation," Lopes said. "However, most of patients at high risk for stroke are also at high risk for bleeding. This makes the treatment of these patients a challenge in clinical practice.

"Our study shows that irrespective of the risk of stroke or bleeding, apixaban is more effective and safer than warfarin across all patients with atrial fibrillation and at least one additional risk factor for <u>stroke</u>," Lopes said. "Thus, the current risk scores used in clinical practice for <u>patients</u> with atrial fibrillation may play less of a role in decision-making because we now have more efficacious and safer drugs."

Provided by Duke University Medical Center

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