

ARISTOTLE trial finds new drug may revolutionize the treatment of atrial fibrillation

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New research has the potential to revolutionize the treatment of atrial fibrillation (AF), a condition affecting a quarter of a million Canadians which is expected to strike even more in the coming years, as the Canadian population ages.

AF is the most common type of [heart arrhythmia](#) and puts those affected at a three to five times greater risk for [stroke](#). Now, there is a new drug poised to battle the condition.

"The majority of patients with atrial fibrillation need an anticoagulant. The current anticoagulant can be a burden for physicians and patients due to its side effects and narrow therapeutic range," Dr. Justin Ezekowitz, from the University of Alberta, told a late breaking clinical trial session at the Canadian Cardiovascular Congress 2011, co-hosted by the Heart and Stroke Foundation of Canada and the Canadian Cardiovascular Congress. It is associated with a risk of bleeding and needs very close monitoring, whereas this new drug is taken twice a day and does not require monitoring. Our trial also shows it is not just equivalent, but better than [warfarin](#) for preventing strokes. These are important advantages."

The mainstay of treatment for AF, in which the heart's rhythm becomes very irregular and rapid, has been warfarin, an anticoagulant which has been highly effective in preventing stroke in patients with AF. However,

it requires patients to come in to their doctor's office for frequent blood tests, is associated with bleeding, and it also can interact with a variety of foods and drugs that patients might also be taking. Apixaban, a new type of oral anticoagulant known as a factor Xa inhibitor, resulted in fewer strokes (ischemic or hemorrhagic) and fewer systemic embolisms, caused less bleeding and resulted in fewer deaths in patients with atrial fibrillation, said Dr. Ezekowitz.

"We have a drug that can increase reductions in death and stroke and it is safer in terms of bleeding," says Dr. Ezekowitz. "It is also easier to use."

Dr. Ezekowitz presented the results from the large, international, multicentre Apixaban for Reduction In Stroke and Other ThromboemboLic Events (ARISTOTLE) in atrial fibrillation trial. It is the largest prospective trial yet reported for stroke prevention in atrial fibrillation. The trial randomized 18,201 patients with at least one additional risk factor for stroke, such as age greater than 75 years, prior stroke or transient ischemic attack, systemic embolism, heart failure or left ventricular ejection fraction less than 40 per cent, diabetes, or high blood pressure.

The patients came from over 1,000 sites in 39 countries. Their mean age was 70 years and 31 per cent were 75 or older. There were 19 per cent with prior stroke, 87 per cent had high blood pressure, 28 per cent had heart failure or reduced left ventricular ejection fraction, and 24 per cent had diabetesmellitus. Canada supplied a very large cohort of 1,057 patients, said Dr. Ezekowitz, who led the Canadian arm of the trial with Dr. Paul Dorian from the University of Toronto.

The patients were randomized to apixaban 5 mg twice daily versus dose-adjusted warfarin – which is often used to treat AF – using a double-blind, double-dummy design. Warfarin or warfarin placebo was monitored adjusted to a target INR of two to three using a blinded,

encrypted point-of-care device. "This was the best possible clinical trial design," says Dr. Ezekowitz.

A bit more than half of the patients (57 per cent) had used warfarin before entering the study, and 43 per cent were new to warfarin. The patients were followed for 1.8 years, on average.

The study found that apixaban is effective at treating AF. It was also better at reducing all-cause mortality and was associated with less bleeding.

Specifically, apixaban reduced the chance of stroke and systemic embolism by 21 per cent, reduced major bleeding by 31 per cent, and reduced mortality, or all cause death, by 11 per cent.

[Clinical trials](#) have resulted in major advances in the management of AF over the past number of years," says Dr. Blair O'Neill, president of the Canadian Cardiovascular Society, which publishes the Canadian AF guidelines for clinicians. "Stroke is a major public health issue and in many instances as a result of AF. These novel anticoagulants are important advances and apply to most patients with AF."

Atrial fibrillation is becoming more common due to the aging of the population, not only in Canada but around the world.

It is also being seen in younger people due to lifestyle factors, especially stress. Also, it is increasing as cardiologists have become better at diagnosing the condition.

Some facts about atrial fibrillation:

- Atrial fibrillation is associated with a four- to five-fold increased risk of ischemic stroke. It is responsible for 15 per cent to 20 per cent of all

ischemic strokes.

- Atrial fibrillation affects approximately 250,000 [Canadians](#).
- Atrial fibrillation is the most common arrhythmia managed by emergency physicians and accounts for approximately one-third of hospitalizations for cardiac rhythm disturbances.
- Hospital admissions for atrial fibrillation have increased by 66 per cent over the past 20 years due to an aging population and a rising prevalence of chronic heart disease.
- After the age of 55, the incidence of atrial fibrillation doubles with each decade of life.
- After age 60, one-third of all strokes are caused by [atrial fibrillation](#).

Provided by Heart and Stroke Foundation of Canada

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