

Trial results for anticoagulants for cardioversion in AF patients published

30 August 2016

The results of the largest known clinical trial to investigate the use of anticoagulants prior and post cardioversion in atrial fibrillation patients, published in *The Lancet*, show that non-vitamin K antagonist oral anticoagulants (NOACs) could be equally as effective as the currently used warfarin.

The study found that edoxaban, a NOAC, could be used as a safe alternative to the traditionally used warfarin, and could expedite the process from initial standard treatment including enoxaparin/warfarin to elective cardioversion when applying a TEE-guided approach (transesophageal echocardiography).

The prospective, randomised clinical trial was carried out across multiple centres in 19 countries, and compared a 60 mg daily dose of edoxaban with the current treatment of enoxaparin-warfarin.

2199 patients due to undergo electrical cardioversion for non-valvular atrial fibrillation were recruited to the trial and randomly assigned to receive one of the two treatments.

Five of the 1067 who received edoxaban, and 11 of the 1082 who received enoxaparin-warfarin, experienced a stroke, systemic embolism, myocardial infarction, or significant event of a similar nature during the course of treatment.

Atrial fibrillation is the most common [heart rhythm abnormality](#) worldwide, affecting around approximately 33.5 million people worldwide, and if over 40 years of age, there is a 1 in 4 lifetime risk of developing this arrhythmia. Atrial fibrillation carries a substantial risk of stroke and death, and the incidence of this condition has continued to rise in recent years.

Atrial fibrillation is represented by an irregular heartbeat caused by abnormal electrical impulses in the atria. Restoring a regular heartbeat is often attempted through the use of electrical

cardioversion, antiarrhythmic drugs, or a combination of both.

Current guidelines recommend a minimum of three weeks of therapeutic anticoagulation prior to the cardioversion in order to reduce the risk of thromboembolism (ie. blood clotting) which can lead to stroke events. This time may be shortened when imaging techniques (such as transesophageal echocardiography) are used to visualise presence of thrombi in the atria. Strokes related to atrial fibrillation are more likely to be fatal or disabling compared to non-atrial fibrillation related strokes.

Stroke prevention in atrial fibrillation is typically done via Vitamin K antagonists, such as warfarin, but these come with limitations. There are significant variabilities on how warfarin works for individual patients, and as such requires regular monitoring and adjustment, which can cause delays before cardioversion may commence.

While there have been previous smaller studies, the NOACs have not been investigated on a large scale as with the ENSURE-AF trial, and have not been compared against the optimised standard of care for warfarin.

Dr. Gregory Lip, Professor of Cardiovascular Medicine from the University of Birmingham, explained, "The purpose of this trial was to optimise care for patients undergoing restorative treatment for [atrial fibrillation](#). Both the optimised use of warfarin, and in this case edoxaban, displayed very low numbers of events and can be considered as safe. What we present here is the option for using NOACs such as edoxaban as a more efficient, user-friendly choice before cardioversion. But before that comes into place, it needs the support of revised guidelines and supporting education for healthcare practitioners and patients alike."

More information: *The Lancet*, [DOI:](#)

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