**Title: EHRA 24: Non-Vitamin K Antagonist Oral Anticoagulant in AHRE Patients: NOAH**

**Participants: Dr Julius Nikorowitsch**

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**Dr Julius Nikorowitsch**

"So, my name is Julius Nikorowitsch, I'm from the University Heart and Vascular Centre in Hamburg, Germany. I am going to present data on oral anticoagulation in device detected atrial fibrillation effects of age, sex, cardiovascular comorbidities and kidney function on outcomes from the NOAH AFNET 6 trial.

**What is the importance of this substudy?**

So the importance of this substudy is that implanted pacemakers, defibrillators and loop recorders record device detected atrial fibrillation in up to 30% of patients. And there were two recent controlled trials, the NOAH AFNET 6 trial and the ARTESiA trial, which both expected a stroke rate of around two per 100 patient years, but observed much lower stroke rates of around 1.1 to 1.2% per patient care.

So current guidelines still suggest to do anticoagulation in patients with device detected atrial fibrillation if they have multiple stroke risk factors. Therefore, it was the aim of our study to compare patients with device detected atrial fibrillation with a high CHA2DS2-VASc score of four or more than four to those with lower CHA2DS2-VASc factors.

**What was the substudy design and patient cohort**

The substudy consisted of 2534 patients from the main trial. Of those, there were 741 patients with a CHA2DS2-VASc score of more than four. They were randomised to edoxaban or placebo. Placebo contained aspirin if patients had an established indication, and there were 380 patients randomised to placebo compared to 361 randomised to edoxaban. Patients were followed up for a median of 21 months.

The outcomes were the same as in the main trial. The primary outcome was a composite of stroke, systemic embolism and cardiovascular death. The safety outcome was a composite of all cause death and major bleeding, and secondary outcomes were components of these outcomes.

So the patient cohort was obviously different. Those with a CHA2DS2-VASc score of more than four were older at a higher CHA2DS2-VASc score and were more often female compared to those with a lower CHA2DS2-VASc score, but the intergroup differences between the treatment arms were comparable.

**What are your key findings?**

So our key findings were that patients randomised to edoxaban and to placebo had basically no statistically significant difference rates of the primary endpoint. The stroke rates were basically the same. Concerning the safety outcome, patients randomised to edoxaban showed many more bleeding events and a higher all cause mortality compared those which are randomised to placebo. In addition, we assess major predictors of the primary and safety outcome. Major predictors of both outcomes were, among them, age and decreasing kidney functioning. Predictors for the safety outcome, major bleeding and all cause death were randomization to edoxaban, heart failure, prior stroke or TIA.

**How do the findings from this substudy shed new light on the NOAH findings revealed at ESC 23?**

Our findings shed new light on the findings from the NOAH study published in 2023 because we could show that our data do not suggest that patients benefit from anticoagulation, although they have a very high stroke risk. If you consider the CHA2DS2-VASc score, which was above four, patients were more prone to bleeding if they were randomised to edoxaban, especially if they had a CHA2DS2-VASc score more than four. And the major predictors, which I just told, also add to the findings published in 2023.

We are definitely eager awaiting new studies which include the patient level metre analysis of NOAH, AFNET 6 and ARTESiA, which might shed more light on subgroups which might benefit from oral anticoagulation in patients with device detected atrial fibrillation and following this, maybe those might form the basis for new randomised controlled trials.

**What are your take-home messages?**

Our key take home messages are that our data do not suggest that patients with multiple stroke risk factors and device detected atrial fibrillation benefit from oral anticoagulation. The stroke risk was low in our patient cohort, even in those patients with CHA2DS2-VASc score of more than four randomised to edoxaban or to placebo, and patients with a CHA2DS2-VASc of more than four were prone to more bleeding if they were randomised to edoxaban and major predictors of the safety and primary outcome were age and kidney function.”