



#ESCCongress: ENVISAGE-TAVI AF Trial

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In another Hot Line session at the ESC Congress 2021, findings from the ENVISAGE-TAVI AF showed that edoxaban is non-inferior to warfarin and its analogues for adverse clinical events in patients with atrial fibrillation after transcatheter aortic valve implantation.

The prevalence of pre-existing or new-onset atrial fibrillation after TAVI ranges from 20 to 40%. Oral anticoagulation is generally recommended to prevent stroke in patients with atrial fibrillation. However, very little is known about the safety and efficiency of direct-acting oral anticoagulants (DOACs) versus vitamin K antagonists (VKAs) after TAVI.

In the ENVISAGE-TAVI AF trial, researchers compared the safety and efficacy of the edoxaban, a direct-acting oral anticoagulant, with warfarin and its analogues (vitamin K antagonists). One thousand four hundred twenty-six patients with atrial fibrillation were included in the study. Study participants received either edoxaban or VKA between 12 hours and five days after successful completion of TAVI. The primary endpoint of the study was a composite of adverse clinical events, including all-cause death, myocardial infarction, ischaemic stroke, systemic thromboembolism, valve thrombosis, and major bleeding.

Findings show that edoxaban was noninferior to VKAs for the primary composite endpoint of adverse clinical events - 17.5% per year in the edoxaban group and 16.5% in the VKA group. The edoxaban group had a higher risk of bleeding compared to the VKA group. Major bleeding per year was 9.7% in the edoxaban group and 7% in the VKA group. Patients in the edoxaban group required a dose adjustment, and patients who were not prescribed oral platelet therapy had a similar rate of major bleeding as the VKA group.

## ENVISAGE-TAVI AF trial

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### Edoxaban vs. vitamin K antagonists after TAVI in patients with atrial fibrillation

#### Conclusion



Edoxaban is noninferior to warfarin and its analogues for adverse clinical events in patients with atrial fibrillation (AF) after transcatheter aortic valve implantation (TAVI). The incidence of major bleeding was higher with edoxaban compared with VKAs.

#### Impact on clinical practice



The prevalence of pre-existing or new-onset AF after TAVI ranges from 20% to 40%. Oral anticoagulation is recommended to prevent stroke in patients with AF but there is little information on the safety and efficacy of direct-acting oral anticoagulants (DOACs) versus VKAs after TAVI.

#### Study objectives



ENVISAGE-TAVI AF compared the safety and efficacy of the DOAC edoxaban with VKAs (warfarin and its analogues) in AF patients with an indication for oral anticoagulation after successful TAVI.

Overall, these findings demonstrate the non-inferiority of edoxaban compared to warfarin in terms of composite efficacy endpoint of adverse clinical events. However, it is important to consider the higher bleeding risks associated with edoxaban. Researchers conclude that treatment with edoxaban can be valuable in the management of high-risk patients with atrial fibrillation after TAVI.

Source: [ESC Congress 2021](#)

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