

# ENVISAGE-TAVI AF trial

#ESCCongress

## 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.

### Who and what?

14 countries in 3 continents

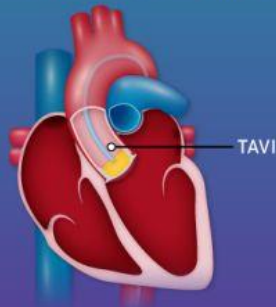
173 medical centres

1,426 patients with AF

randomised



Between 12 hours and 5 days after successful completion of TAVI

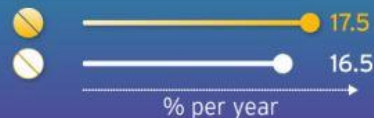


Average follow-up: 18 months

### Primary efficacy endpoint

Composite of adverse clinical events

- all-cause death
- MI
- ischaemic stroke
- systemic thromboembolism
- valve thrombosis
- major bleeding



HR: 1.05; 95% CI: 0.85-1.31;  $p=0.01$  for noninferiority

### Primary safety endpoint

Incidence of major bleeding



HR: 1.40; 95%CI: 1.03-1.91

- ↑ risk of major bleeding vs. VKA group, mainly due to gastrointestinal bleeding

### Secondary analyses

- Patients who required a downward dose adjustment and those not prescribed oral antiplatelet therapy had a similar rate of major bleeding compared to the VKA group