Atrial Fibrillation (AF) - Oral Anticoagulation

Safety and effectiveness of edoxaban in a real-world clinical setting: Two-year follow-up of the ETNA-AF-Europe study

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Background: Oral anticoagulation (OAC) for stroke prevention is essential in the management of patients with atrial fibrillation (AF). The assessment of OAC use in routine clinical care and the effects of this therapy on outcomes and safety are important. Purpose: We analysed two-year outcome data with adjudicated follow-up results in 13,417 patients with AF treated with edoxaban. Methods: ETNA-AF-Europe (Clinicaltrials.gov: NCT02944019) enrolled 13,417 consecutive patients with AF treated with edoxaban in 825 centres in 10 European countries and 2-year prospectively collected, real world data is presented. Results: Edoxaban was prescribed according to licence recommendations in 83.1% (n = 11,146) of patients (Table). Whilst three quarters of patients were prescribed edoxaban 60 mg (n = 10,248, 76.4%), the quarter prescribed edoxaban 30 mg were older (79.5 versus 71.8 years), had a higher stroke risk (CHA2DS2-VASc score: 3.9 versus 3.0) and a higher bleeding risk (HAS-BLED score: 2.9 versus 2.4). Thromboembolic and bleeding events were more common in patients receiving edoxaban 30 mg OD without differences in intracranial haemorrhage (ICH) (Figure). Patients prescribed a non-recommended dose of edoxaban had a numerically higher stroke risk (CHA2DS2-VASc score: 3.6 versus 3.1) with subsequent higher rates of ischemic stroke and mortality, however they also had higher bleeding rates, with the exception of ICH (table) despite a similar initial bleeding risk (HAS-BLED score: 2.7 versus 2.5). Conclusions: In this large, European data set reporting two-year outcomes on edoxaban therapy, no additional safety signals were observed and event rates were in line with those observed in ETNA-AF after 1 year and in ENGAGE AF-TIMI 48, re-affirming the safety and effectiveness of edoxaban licence recommendations in a real world setting of patients with AF. All key events of interest, other than intracranial haemorrhage, were numerically lower in patients prescribed the licenced recommended dose.

Outcomes with rec. vs non-rec. doses

n (%/year [95%CI])	Recommended dose (n = 11,146; 83.1%)	Non-recommended dose (n = 2271; 16.9%)
Any stroke/SEE	138 (0.68 [0.57;0.80])	31 (0.76 [0.51;1.07])
Ischaemic stroke	99 (0.48 [0.39;0.59])	26 (0.63 [0.41; 0.93])
Major bleeding	189 (0.93 [0.80;1.07])	49 (1.20 [0.89;1.59])
Intracranial haemorrhage	43 (0.21 [0.15;0.28])	7 (0.17 [0.07;0.35])
All-cause mortality	729 (3.55 [3.30;3.82])	208 (5.04 [4.38;5.78])
CV mortality	405 (1.97 [1.79;2.18])	113 (2.74 [2.26;3.30])
CI, confidence interval; CV, cardiovascular; rec., recommended; SEE, systemic embolic event.		

Abstract Figure. Annualised event rates at 2-year FU