

## Annualized clinical event rates during two-year follow-up are low in 27,617 atrial fibrillation patients on edoxaban: results from the global noninterventional ETNA-AF program

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**Background and Purpose:** The large global Edoxaban Treatment in routine clinical practice (ETNA)-AF program was designed to assess the safety and effectiveness of edoxaban, complementing randomized clinical trials.

**Methods:** ETNA collects data on patient characteristics and clinical events in unselected AF patients treated with edoxaban for stroke prevention, integrating data from prospective, noninterventional studies conducted in Europe, Japan, South Korea, and Taiwan.

**Results:** The 2-year follow-up analysis included 27,617 patients, the majority of whom (82.6%) received the recommended dose according to the local label. At baseline, the mean age was 73.6 ± 9.8 years and 58.1% were male. Half of the patients (50.5%) were 75 years or older. The CHA<sub>2</sub>DS<sub>2</sub>-VASc score was 3.3 ± 1.5, and the modified HAS-BLED score was 2.4 ± 1.1. The rate of ischemic stroke was 0.74%/yr, major bleeding 1.02%/yr, intracranial hemorrhage 0.29%/yr, and major gastrointestinal (GI) bleeding 0.51%/yr. All-cause mortality was 3.13%/yr, and cardiovascular (CV) mortality 1.45%/yr (see Table).

**Conclusion:** The rates of ischemic stroke and major bleeding events remained low globally and across regions during the two-year follow-up period in AF patients treated with edoxaban.

	Global (N = 27,617)	Japan (N = 11,330)	Korea/Taiwan (N = 2,870)	Europe (N = 13,417)
Age, mean (SD)	73.6 (9.8)	74.2 (10.1)	71.6 (9.5)	73.6 (9.5)
Gender, male, %	58.1	59.4	60.2	56.6
Weight [kg], median (IQR)	69 (58, 81)	59 (51, 68)	65 (57, 73)	80 (70, 90)
CrCL [mL/min], mean (SD)	68.7 (28.4)	63.9 (25.8)	63.4 (23.7)	74.4 (30.5)
CHA <sub>2</sub> DS <sub>2</sub> -VASc, mean (SD)	3.3 (1.5)	3.5 (1.7)	3.1 (1.4)	3.2 (1.4)
Mod. HAS-BLED <sup>‡</sup> , mean (SD)	2.4 (1.1)	2.4 (1.1)	2.3 (1.1)	2.5 (1.1)
Edoxaban 60mg/30mg, %	53.5 / 46.5	27.6 / 72.4	48.8 / 51.2	76.4 / 23.6
2-year clinical events, N (%/year), [95% CI]				
Major Bleeding (ISTH)	477 (1.02) [0.93; 1.11]	188 (1.09) [0.94; 1.25]	51 (1.00) [0.74; 1.31]	238 (0.97) [0.85; 1.11]
Intracranial Hemorrhage	135 (0.29) [0.24; 0.34]	68 (0.39) [0.30; 0.50]	17 (0.33) [0.19; 0.53]	50 (0.20) [0.15; 0.27]
Major GI Bleeding	241 (0.51) [0.45; 0.58]	122 (0.70) [0.58; 0.84]	18 (0.35) [0.21; 0.55]	101 (0.41) [0.33; 0.50]
Any Stroke	455 (0.97) [0.88; 1.06]	244 (1.41) [1.24; 1.60]	54 (1.06) [0.80; 1.38]	157 (0.64) [0.54; 0.75]
Ischemic Stroke	347 (0.74) [0.66; 0.82]	179 (1.03) [0.89; 1.20]	43 (0.84) [0.61; 1.13]	125 (0.51) [0.42; 0.61]

	Global (N = 27,617)	Japan (N = 11,330)	Korea/Taiwan (N = 2,870)	Europe (N = 13,417)
Hemorrhagic Stroke	99 (0.21) [0.17; 0.26]	67 (0.39) [0.30; 0.49]	9 (0.17) [0.08; 0.33]	23 (0.09) [0.06; 0.14]
All-cause Death	1479 (3.13) [2.98; 3.30]	470 (2.70) [2.46; 2.96]	72 (1.40) [1.09; 1.76]	937 (3.80) [3.56; 4.05]
CV Death	684 (1.45) [1.34; 1.56]	140 (0.80) [0.68; 0.95]	26 (0.50) [0.33; 0.74]	518 (2.10) [1.92; 2.29]

≠Excluding labile INR.