Baseline demographics and characteristics of 2,959 atrial fibrillation patients from Asia (Korea and Taiwan) on edoxaban comparing recommended vs non-recommended dosing

Tze-Fan Chao  
Keun-Sik Hong  
Byung-Chul Lee  
Raffaele De Caterina  
Paulus Kirchhof  
Paul Reimitz  
Heiko Rauer  
Hiroshi Higashiyama  
Cathy Chen  
Martin Unverdorben  
Chun-Chieh Wang

Introduction: Edoxaban is approved for stroke prevention in patients with atrial fibrillation (AF) based on the phase III ENGAGE AF-TIMI 48 trial. Baseline data of patients with recommended and non-recommended dosing may help to understand the reasons of deviation from the dosing recommended as per local approved prescribing information.

Methods: Between 2017 and 2019, 3,008 patients were enrolled from 47 hospitals and medical practices in Korea and Taiwan in the global Edoxaban Treatment in routine clinical practice in patients with non-valvular Atrial Fibrillation (ETNA-AF) programme. We analyzed data of 2,959 patients with baseline information available (67% from Korea and 33% from Taiwan).

Result: Mean age was 71.5 ± 9.5 years and mean BMI 25.0 ± 3.7 kg/m2. The most frequent stroke risk factors and comorbidities were hypertension (71.3%), diabetes mellitus (29.3%), history of ischemic stroke (14.1%), valvular heart disease (11.0%), congestive heart failure (7.7%), and myocardial infarction (1.4%). Edoxaban 60 mg was used in 48.6% and 30 mg in 51.4% of patients. According to the approved local labels, 70.4% of patients received the recommend doses and 29.6% received non-recommended doses (19.4% received non-recommended 30 mg and 10.2% non-recommended 60 mg). Compared with patients receiving recommended 60 mg edoxaban, patients on non-recommended edoxaban 30 mg were older, had a lower creatinine clearance (CrCl), and had more prior history of major or clinically relevant non-major (CRNM) bleedings. Compared with patients on recommended 30 mg dose, those on non-recommended 60 mg dose were younger, had a higher CrCl, had less prior history of major or CRNM bleedings, and had more prior history of ischemic stroke.

Conclusion: Over 70% patients received recommended dose of edoxaban in the Asian countries of Korea and Taiwan of the global ETNA program. It appears that the sickest population is the one on recommended 30mg whereas the least sick population is the one on recommended 60mg. Age, history of major bleeding/CRNM bleeding and ischemic stroke seem to be among the factors that influence non-recommended dosing. Long-term follow-up is needed to assess the impact of non-recommended edoxaban dosing on clinical events.