## Introduction

- Edoxaban is a non-vitamin K antagonist oral anticoagulant (NOAC) that is approved for the treatment and prevention of venous thromboembolism (VTE; deep vein thrombosis [DVT] and pulmonary embolism [PE]) in adults, based on its comparable efficacy and superior safety compared with warfarin in a broad spectrum of patients with VTE during the Hokusai-VTE trial.

- Although randomised controlled trials are the gold standard for comparing treatments and interventions, real-world evidence (RWE) provides a better representation of the range and distribution of patients and management patterns in clinical practice.

- Consequently, RWE should be used to complement RCT data to establish whether the results observed in RCTs are applicable to community practice.

- ETNA-VTE-Europe (NCT02943993) was initiated in agreement with the European Medicines Agency (EMA) to assess benefits and risks of edoxaban in the treatment and secondary prevention of VTE for up to 18 months in routine clinical practice.

- Using an observational study design, we aimed to compare Hokusai-VTE patients with those treated in clinical practice during ETNA-VTE Europe, and to expand the knowledge about edoxaban’s clinical effectiveness and safety in the treatment and prevention of VTE.

## Methods

- ETNA-VTE-Europe is a prospective, non-interventional post-authorisation safety study conducted in eight European countries.

- The study included patients with an initial or recurrent acute VTE that occurred 32 weeks prior to enrolment and in which a decision (at the treating physician’s discretion) to use edoxaban had already been made.

- Descriptive comparisons of Hokusai-VTE and ETNA-VTE Europe are presented.

- Explanatory comparisons between subgroups (DVT vs PE or PE) were performed using a Chi-square test for categorical variables and a Wilcoxon test for continuous variables. Note that the HOKUSAI-VTE population was confined to those enrolled in Europe and those receiving Edoxaban. Frailty was calculated using the Charlson Comorbidity Index (CCI) as a continuous variable.

## Results

- A total of 2879 patients presenting with acute VTE (median age 65 years, 46.5% female) were enrolled at 339 sites (130 office-based physicians and 209 hospitals).

- Of the 2680 patients with complete data, 23.6% reported prior VTE, 2.9% prior stroke, and 2.8% had a history of bleeding (Table 1).

- Patients in ETNA-VTE were older (65 versus 57 years), more likely to be female (48.5 versus 39.8%), and had a higher prevalence of chronic venous insufficiency (11.1 versus 6.5%) than in the European cohort of the Hokusai-VTE clinical trial (n=1512; Table 1).

- In ETNA-VTE, 90.5% of edoxaban dosing was adherent to the label (Figure 1) – 6.6% of patients qualifying for dose reduction were incorrectly prescribed edoxaban 60 mg – 3.3% of patients were dose-reduced to 30 mg without a formal indication to do so.

- Patients who had a body weight ≤60 kg (9.3% vs 5.6%) and a CrCl ≤50 ml/min (10.2% vs 4.1%) were less frequently prescribed edoxaban 60 mg (Table 2).

- Dosing according to edoxaban label on bodyweight, creatinine clearance and P-gp inhibitor use.

## Conclusions

- The data describe a clinical practice population of VTE patients that is partially different to prior randomised controlled trials.

- The clinical practice population was older and had more comorbidities.

- Edoxaban is largely used adequately in these patients, respecting the recommendations for treatment initiation, dosing, and dose adjustments in special patient populations.

## References