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Association between index venous thromboembolism (VTE) event and 12-months outcomes for patients in routine clinical practice enrolled in the Edoxaban Treatment in routine cliNical prActice for patients with acute VTE in Europe (ETNA-VTE-Europe) registry

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Introduction

- Edoxaban, a direct FXa inhibitor, is approved for the treatment and secondary prevention of acute VTE, based on its comparable efficacy and superior safety versus warfarin during the 12 month Hokusai-VTE trial[1]
- The ETNA-VTE-Europe (NCT02943993) study is being conducted to gain further insight into the efficacy and safety of extended treatment with edoxaban up to 18 months in routine clinical practice[2]
- There are data to suggest that the index clinical manifestation of venous thromboembolism (VTE; either deep vein thrombosis [DVT] or pulmonary embolism [PE] with or without DVT) strongly predicts the type of recurrence. However, data on the association between index manifestation and absolute recurrent VTE rates are conflicting[3]
- This poster assesses the patient characteristics and evaluates the rates and associations between the index VTE event (PE with or without DVT versus DVT alone) and 12-month outcomes

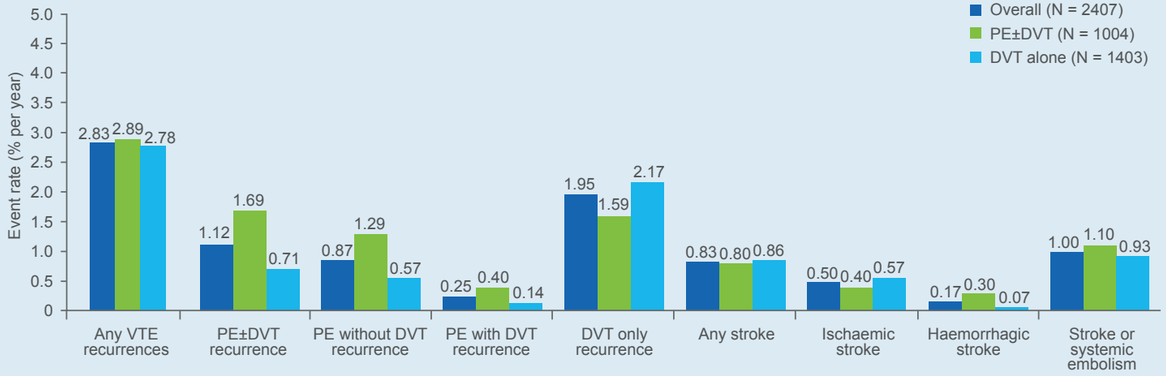
Methods

- ETNA-VTE-Europe is an 18-month, prospective, single-arm, non-interventional, multinational, post-authorisation safety study[2]
- A total of 2407 patients with acute symptomatic VTE who were receiving edoxaban in routine practice were enrolled from eight European Countries (Austria, Belgium, Germany, Ireland, Italy, the Netherlands, Switzerland and the United Kingdom)
- At 12 months, patients with an index event of PE with or without DVT (PE±DVT) were compared with those with an index event of DVT without PE

Results

- Patients with acute PE±DVT had a slightly higher age, a higher percentage of frailty, more hypertension and a more frequent history of PE than patients with DVT only (**Table 1**)
- Patients with DVT alone had more history of chronic venous insufficiency and an increased history of prior DVT (**Table 1**)
- Overall, VTE recurrence was 2.83%, rates of any bleeding 13.00%, any stroke 0.83%, major bleeding 1.91% and all-cause mortality 3.37% (**Figure 1–3**)
- Patients with index PE±DVT had numerically higher rates of all-cause mortality (4.08% versus 2.85%), cardiovascular mortality (1.69% versus 1.21%) and major bleeding (2.39% versus 1.57%) rates than those with index DVT alone (**Figure 2 and 3**)

Figure 1. Events of venous thromboembolism and stroke during 12-month follow-up



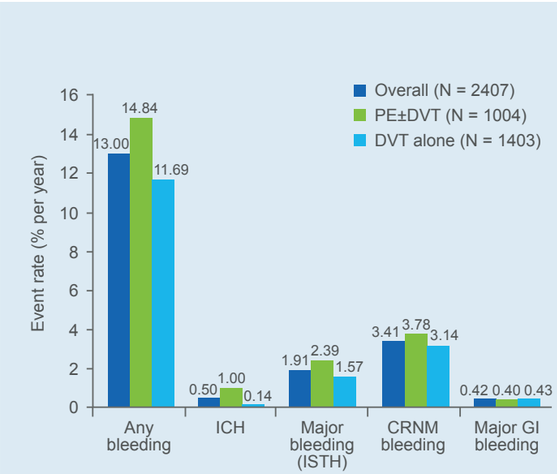
DVT, deep vein thrombosis; **PE**, pulmonary embolism; **VTE**, venous thromboembolism

Table 1. Patient baseline characteristics by type of index event

Patient characteristics	Overall [N=2407]	PE±DVT [N=1004]	DVT alone [N=1403]
Female, n (%)	1121 (46.6)	485 (48.3)	636 (45.3)
Age, years, mean ± SD	63.2 ± 15.87	64.4 ± 15.29	62.3 ± 16.23
Recalc. eGFR (Cockroft-Gault, mL/min), mean ± SD	94.2 ± 38.97	92.8 ± 38.30	95.3 ± 39.47
Frailty (physician judgement), n (%)	306 (12.7)	140 (14.0)	166 (11.8)
Medical history, n (%)			
Hypertension	1041 (43.2)	476 (47.4)	565 (40.3)
Chronic venous insufficiency	264 (11.0)	75 (7.5)	189 (13.5)
COPD	162 (6.7)	86 (8.6)	76 (5.4)
Cancer	234 (9.7)	110 (11.0)	124 (8.8)
Cancer still active*	89 (38.2)	38 (34.9)	51 (41.1)
Bleeding history	71 (2.9)	47 (4.7)	24 (1.7)
History of major or CRNM bleeding	46 (1.9)	28 (2.8)	18 (1.3)
History of major bleeding	22 (0.9)	12 (1.2)	10 (0.7)
Ischaemic stroke	58 (2.4)	37 (3.7)	21 (1.5)
Prior VTE, n (%)			
Prior PE±DVT	177 (7.4)	112 (11.2)	65 (4.6)
Prior DVT only	388 (16.1)	110 (11.0)	278 (19.8)
Edoxaban treatment at baseline, n (%)			
Edoxaban 60 mg	2100 (87.2)	891 (88.7)	1209 (86.2)
Edoxaban 30 mg	307 (12.8)	113 (11.3)	194 (13.8)

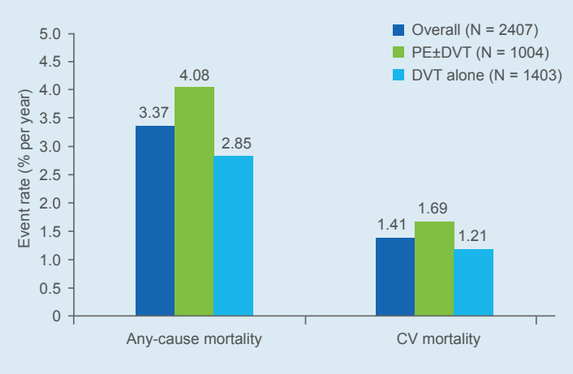
*Percentage based on patients with cancer history
COPD, chronic obstructive pulmonary disease; **CRNM**, clinically relevant non-major; **DVT**, deep vein thrombosis; **eGFR**, estimated glomerular filtration rate; **PE**, pulmonary embolism; **SD**, standard deviation; **VTE**, venous thromboembolism

Figure 2. Bleeding events during 12-month follow-up



CRNM, clinically relevant non-major; **DVT**, deep vein thrombosis; **GI**, gastrointestinal; **ICH**, intracranial haemorrhage; **ISTH**, International Society on Thrombosis and Haemostasis; **PE**, pulmonary embolism

Figure 3. Deaths reported during 12-month follow-up



CV, cardiovascular; **DVT**, deep vein thrombosis; **PE**, pulmonary embolism

Conclusions

- **Low rates of bleeding and venous thromboembolism events were reported after 12 months of treatment with edoxaban in clinical practice reinforcing the safety and effectiveness of edoxaban treatment in VTE patients**
- **Patients with index pulmonary embolism with or without deep vein thrombosis reported a higher mortality and bleeding events than those with deep vein thrombosis alone**
- **The 18-month outcomes results are awaited**

References
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