PB2434 | ETNA VTE Europe: A Contemporary Snapshot of VTE Patients Treated with Edoxaban in Clinical Practice across Eight European Countries

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Background: Edoxaban, a direct oral anticoagulant inhibiting FXa, has proven its efficacy and safety in the ENGAGE AF-TIMI 48 and Hokusai-VTE clinical trials. Clinical practice patients, however, may differ from those of clinical trials.

Aims: Using an observational study design, we aimed to compare Hokusai-VTE patients with those treated in clinical practice, and expand the knowledge about edoxaban's clinical effectiveness and safety in the treatment and prevention of venous thromboembolism (VTE).

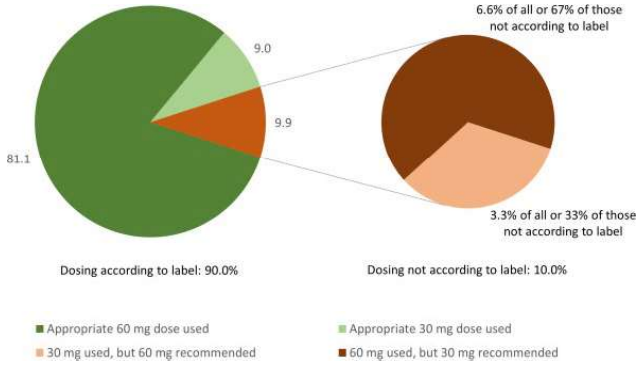

FIGURE 1 Dosing according to edoxaban label based on bodyweight, creatinine clearance and P-gp inhibitor use

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

Results: A total of 2,879 patients presenting with acute VTE (median age 65 years, 46.5% female) were enrolled at 339 sites (133 office-based physicians and 206 hospitals). Of the 2,680 patients with complete data, 23.6% reported prior VTE and 2.8% had a history of bleeding.

Patients in ETNA-VTE were older (65 vs. 57 years), more likely to be female (46.5 vs. 39.8%) and had a higher prevalence of chronic venous insufficiency (11.1 vs. 1.6%) than in the European cohort of the Hokusai-VTE clinical trial (n=1,512). Body weight and creatinine clearance were substantially lower in clinical practice with more patients having a bodyweight ≤60 kg (9.3% vs. 5.6%) and a CrCl ≤50 ml/min (10.2% vs. 4.1%).

Edoxaban dosing was adherent to label in 90% of patients, with higher than recommended (60 mg) doses and lower than recommended doses (30 mg) used in 6.6% and 3.3% of the patients, respectively. Heparin lead-in was used in 84.7% of patients. It was more frequently used in PE than DVT patients (91.3% vs. 80.1%; p< 0.0001).

TABLE 1 Patient characteristics of those in clinical practice (ETNA-VTE) overall and by VTE presentation and those in clinical trials (HOKUSAI-VTE)

	HOKUSAI-VTE [N = 1,512]	ETNA-VTE [N = 2,680]	ETNA-VTE DVT only [N = 1,559]	ETNA-VTE PE ± DVT [N = 1,121]	p-value DVT vs. PE
Age, years/Female patients	57/39.8	65/46.5	64/45.3	66/48.2	0.0052/0.1577
Body weight, kg	84.0 (73.9-95.3)	80 (70-92)	80 (70-90)	81 (70-94)	0.0031
Acute DVT only	854 (56.5)	1,559 (58.2)	1,559 (100.0)	0 (0.0)	n.a.
PE with or without DVT	658 (43.5)	1,121 (41.8)	0 (0.0)	1,121 (100.0)	n.a. n.a.
Chronic Venous Insufficiency	24 (1.6)	297 (11.1)	214 (13.7)	83 (7.4)	<0.0001
Cancer	136 (9.0)	253 (9.4)	133 (8.5)	120 (10.7)	0.0566
Stroke	18 (1.2)	79 (2.9)	29 (1.9)	50 (4.5)	0.0001
CrCL*,**, ml/min	104.3 (79.0-128.9)	90.1 (65.7-117.7)	91.2 (65.5-120.4)	89.3 (65.9-115.0)	0.2238
Edoxaban 60 mg	1,371 (90.7)	2,351 (87.7)	1,349 (86.5)	1,002 (89.4)	0.0317

Conclusions: The data describe a clinical practice population of VTE patients that is partially different from prior randomised controlled trials. Edoxaban is largely used adequately in these patients, respecting the recommendations for treatment initiation, dosing, and dose adjustments in special patient populations.

Patient characteristics of those in clinical practice (ETNA-VTE) overall and by VTE presentation and those in clinical trials (HOKUSAI-VTE)

PB2435 | Upper Extremities Deep Vein Thrombosis and DOAC Treatment: a Prospective Cohort Study

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Background: Limited data are available on the use of direct oral anticoagulants (DOACs) in patients with upper extremities deep vein thrombosis (UEDVT).

Aims: To assess the effectiveness and safety of DOACs in the treatment of UEDVT.

Methods: Data on patients with an objective diagnosis of acute UEDVT treated with DOACs were merged from prospective cohorts of patients with venous thromboembolism to obtain a collaborative database. Study outcomes were recurrent venous thromboembolism (VTE) and major bleeding occurring during DOAC treatment.

Results: Overall, 132 patients were included: mean age was 47.7±18.0 years (range 18 to 97), males were 42.4%. Twenty-seven percent of patients had 2 or more risk factors for VTE, 29.5% had UEDVT complicating a central venous line or after pacemaker implantation (see Table).

Ninety-two patients (70%) were managed as outpatients. Increased age (OR 1.03, 95% CI 1.0-1.05) and anemia (OR 1.35, 95% CI 1.07-1.70) were associated with in-patient management. Among patients treated with apixaban (40) or rivaroxaban (85) loading dose was used in 72%; in patients treated with dabigatran (5) or edoxaban (2) mean heparin pre-treatment was 8 days. DOACs were started after 1 month from UEDVT diagnosis in 12.9% of patients; active cancer was a main predictor for delayed initiation (OR 22.2, 95% CI 5.8-84.4).

Mean treatment duration in patients with a scheduled stop was 4.9 months, while mean follow-up in those who continued DOACs was 9.3 months.

No recurrence of VTE nor major bleedings occurred during DOAC treatment; one patient had acute limb ischemia (1.38% patient-year), 7 clinically relevant non-major bleedings (3 genital, 2 epistaxis, 1 gingival, 1 genital bleeding plus epistaxis; 10.51% patient-year), 5 deaths (4 cancer, 1 advanced age; 9.69% patient-year).

Conclusions: Our data support the effectiveness and safety of DOACs for the treatment of acute UEDVT. Further studies are required to confirm these findings.

PB2436 | Saddle Pulmonary Embolism in the Era of Incidental Events: Incidence, Clinical Findings and Outcomes in a Single Center Cohort

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Background: Incidental or unsuspected PE (UPE) currently represents about half of the PEs diagnosed in the setting of cancer. The specific prognostic role of PE burden and more specifically 'saddle PE' remains controversial.

TABLE 1 Characteristics and risk factors of patients with UEDVT treated with DOACs

	Overall (n= 132)	Active cancer (n= 34)	Non-cancer risk factor (n= 62)	Unprovoked (n= 36)
Age, years mean±SD	47.7±18.0	55.4±13.2	46.1±18.1	43.3±19.9
Male, n (%)	56 (42.4)	14 (41.2)	23 (37.1)	19 (52.8)
Concomitant pulmonary embolism, n (%)	11 (8.3)	3 (8.8)	5 (8.1)	3 (8.3)
Weight, kg mean±SD	71.6±14.9	67.3±10.5	74.8±16.0	69.6±15.6
CVC, PICC or PMK, n (%)	39 (29.5)	19 (55.9)	20 (32.3)	-
Recent surgery or trauma, n (%)	19 (14.4)	2 (5.9)	17 (27.4)	-
Effort thrombosis or thoracic outlet syndrome, n (%)	12 (9.1)	0	12 (19.4)	-
Thrombophilia or estrogen-progestin therapy, n (%)	17 (12.9)	1 (2.9)	16 (25.8)	-
Patients with a scheduled stop treatment, n (%)	79 (59.8)	10 (29.4)	44 (70.9)	25 (69.4)