Real-world outcomes of edoxaban use in Taiwanese/Korean patients with venous thromboembolism: The ETNA-VTE Registry

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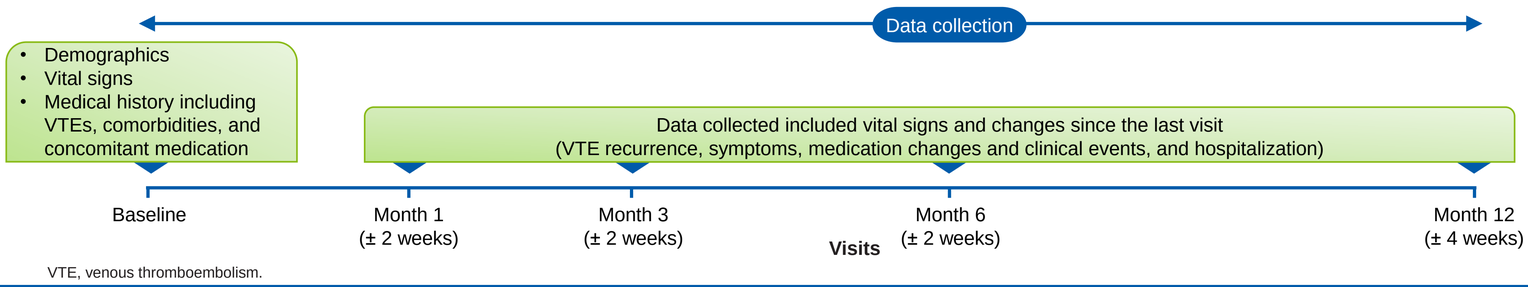
INTRODUCTION

- Venous thromboembolism (VTE) is the third most common life-threatening cardiovascular disease globally[1,2]
- Patients with VTE have a heightened risk of recurrence, particularly in the first 6 months after the initial event. Approximately 17% of patients experience a recurrent VTE within 2 years,[3] highlighting the importance of effective anticoagulation[4]
- Long-term (>6 months), real-world evidence on the effectiveness and safety of edoxaban for VTE treatment, including data from South Korea and Taiwan, remain limited
- The global ETNA-VTE program evaluated real-world outcomes of edoxaban in patients with VTE in South Korea and Taiwan

METHODS

- ETNA-VTE-KOR-TWN (NCT02952599) was a multicenter (20-site), prospective, observational, noninterventional study evaluating edoxaban in patients with acute VTE (initial or recurrent), monitored for up to 12 months
- A schematic representation of the study schedule is presented in **Figure 1**
- Patients were included in the study if they had an acute initial or recurrent VTE and were treated with edoxaban
- Effectiveness (including VTE recurrence) and safety outcomes (bleeding events and hospitalizations) were analyzed
- The analysis was based on the full analysis set (FAS) comprising patients from the baseline analysis set (ie, patients fulfilling the study inclusion criteria) who had any documentation at one of the follow-up data collection points or at the final assessment
- Overall (ie, either on or off edoxaban) annual rates (%/y [95% confidence interval (CI)]) were calculated for effectiveness and safety outcomes

Figure 1. Study schedule of evaluations and data collection points from baseline to month 12 (± 4 weeks)



VTE, venous thromboembolism.

In this analysis of the ETNA-VTE study, patients from Taiwan and Korea with VTE receiving edoxaban had low rates of recurrent VTE, all-cause death, and bleeding complications in routine clinical practice; consistent with results observed in RCTs

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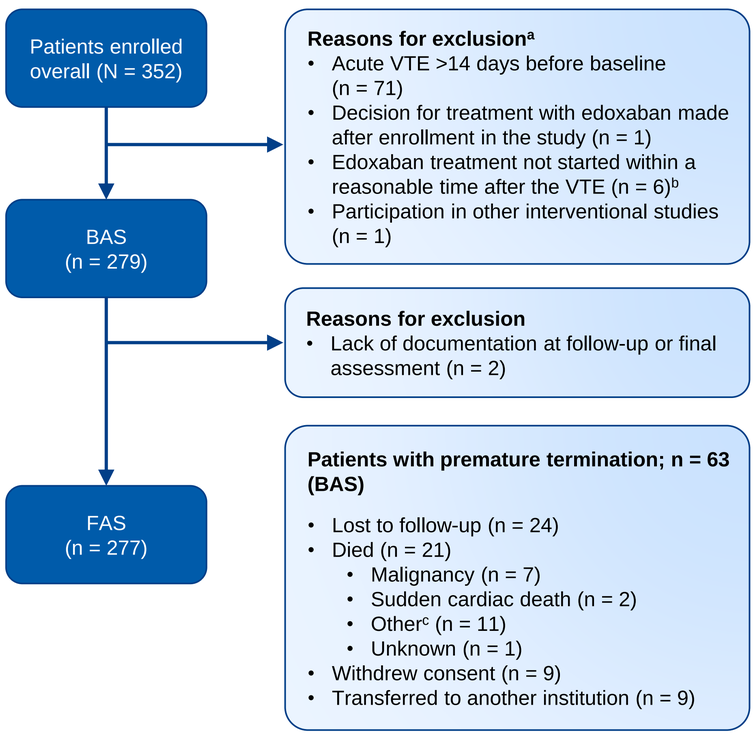
RESULTS

- Of the 352 patients enrolled, 277 met inclusion criteria for the FAS (Taiwan: 119/277 [43.0%]; South Korea: 158/277 [57%]; **Figure 2**)
- The majority of patients (216/277, 78%) completed the 52 ± 4 weeks observational period (FAS). For those who did not complete the observational period (61/277, 22%), the median time from consent to premature study termination was 19.9 weeks (IQR 6.3–26.1; FAS)
- The most prevalent index VTE was pulmonary embolism (PE) only (n = 133), followed by deep vein thrombosis (DVT) only (n = 89); 55 patients had PE with DVT
- Most patients received the 60-mg dose (186/277; 67.1%) vs the 30-mg dose (91/277; 32.9%) and the 60-mg dose group had a larger proportion of male patients (53.2%) vs the 30-mg dose group (36.3%; **Table 1**)
- The median age of patients receiving 60 mg vs 30 mg was 65 years vs 76 years; those receiving 60 mg vs 30 mg had a higher body weight (mean ± standard deviation, 71.2 ± 12.4 kg vs 58.3 ± 10.7 kg; **Table 1**)
- Recurrent VTE occurred in 9/277 patients with an annual rate (95% CI) of 3.9%/y (2.0, 7.5)
- All-cause death occurred in 21/277 patients with an annual rate (95% CI) of 8.9%/y (5.8, 13.7); 0 were due to VTE
- Cardiovascular-related hospitalization occurred in 25/277 patients (annual rate [95% CI], 11.3%/y [7.7, 16.8]), with the highest number occurring in patients with a history of DVT only (n = 14)
- Kaplan-Meier curves illustrated no VTE recurrence in the first 3 months regardless of dose; 9 events occurred during the remainder of the 12-month follow-up (**Figure 3**)
- A time-to-event analysis showed that 16 all-cause deaths occurred within the first 6 months and only 5 deaths occurred in the latter 6 months of the study (**Figure 4**)
- Major bleeding events were observed in 3/277 patients (annual rate [95% CI], 1.3%/y [0.4, 4.0])
- Ischemic/hemorrhagic stroke occurred in 2/277 patients with an annual rate (95% CI) of 0.9%/y (0.2, 3.4)

FIGURES

Figure 2. Patient disposition



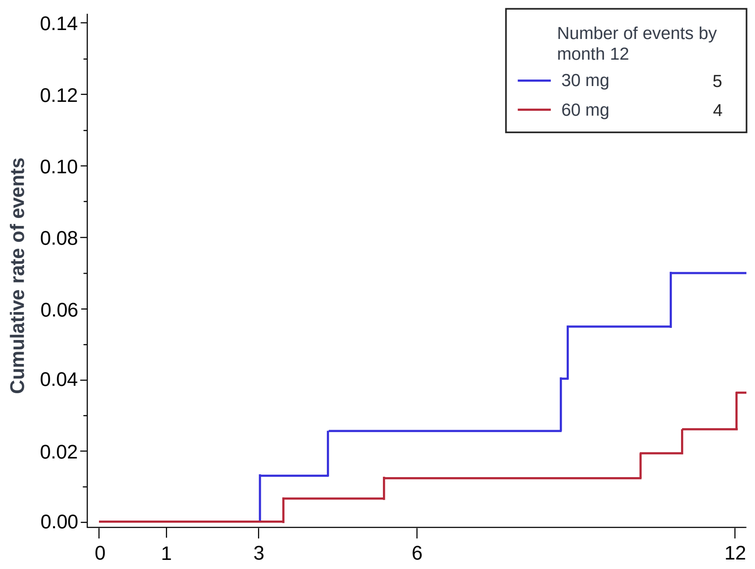
[a]Patients could have multiple reasons for being excluded.
[b]Treatment of acute VTE (by edoxaban or heparin lead-in followed by edoxaban) started 1 day after the baseline data collection point or earlier, and heparin lead-in (if given) lasted for a maximum of 30 days.
[c]Other causes of death included infection, suicide, accidental or trauma, hepatobiliary, renal, and other.
BAS, baseline analysis set; FAS, full analysis set; VTE, venous thromboembolism.

Table 1. Demographics and baseline characteristics by initial edoxaban dose (60 mg vs 30 mg) at study start (FAS)[a]

	Edoxaban 60 mg (n = 186)	Edoxaban 30 mg (n = 91)	Overall (n = 277)
Age (years), median (Q1, Q3)	65 (52, 76)	76 (69, 82)	70 (57, 78)
<65 years, n (%)	88 (47.3)	13 (14.3)	101 (36.5)
≥65 and <75 years, n (%)	41 (22.0)	27 (29.7)	68 (24.5)
≥75 years, n (%)	57 (30.6)	51 (56.0)	108 (39.0)
Male, n (%)	99 (53.2)	33 (36.3)	132 (47.7)
Weight (kg), mean ± SD	71.2 ± 12.4	58.3 ± 10.7	67.0 ± 13.3
Body mass index (kg/m^2), mean ± SD	26.3 ± 3.9	23.4 ± 4.0	25.4 ± 4.1
Frailty (as judged by investigator), n (%)	27 (15.3)	19 (23.5)	46 (17.9)
Modified HAS-BLED risk score,[b] n	165	87	252
Mean ± SD	1.1 ± 1.0	1.8 ± 1.0	1.3 ± 1.0
Median	1.0	2.0	1.0
Q1, Q3	0.0, 2.0	1.0, 2.0	0.0, 2.0
Categorized modified HAS-BLED risk score,[b] n (%)			
Low (0–1 point)	101 (61.2)	27 (31.0)	128 (50.8)
Medium (2 points)	53 (32.1)	43 (49.4)	96 (38.1)
High (>2 points)	11 (6.7)	17 (19.5)	28 (11.1)
CrCl, n (%)			
<15 mL/min (ESRD)	0 (0.0)	0 (0.0)	0 (0.0)
≥15 and <30 mL/min	1 (0.6)	4 (4.7)	5 (1.9)
≥30 and ≤50 mL/min	25 (13.9)	27 (31.4)	52 (19.5)
>50 and ≤80 mL/min	56 (31.1)	33 (38.4)	89 (33.5)
>80 mL/min	98 (54.4)	22 (25.6)	120 (45.1)

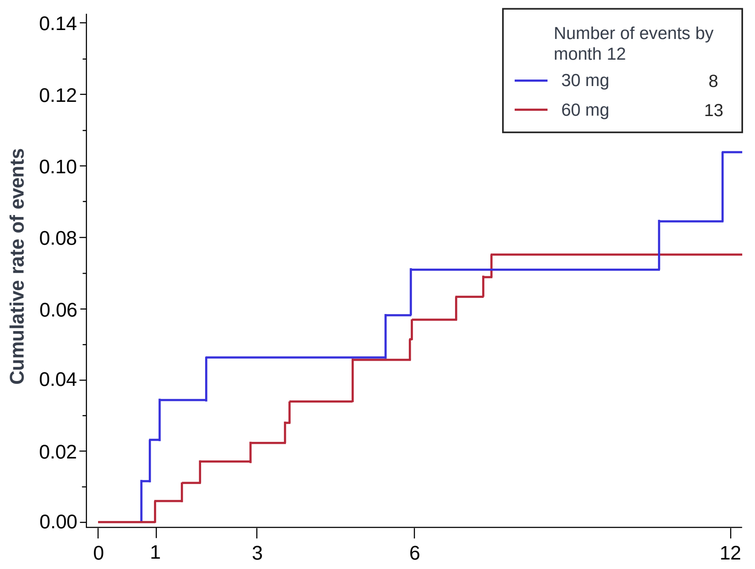
[a]Percentages are based on the total number of patients excluding those with missing or unknown information.
[b]Modified HAS-BLED risk score was derived from single components of the HAS-BLED score without taking unstable or labile INR measurements into account.
CrCl, creatinine clearance; ESRD, end-stage renal disease; HAS-BLED, Hypertension, Abnormal Renal/Liver Function, Stroke, Bleeding History or Predisposition, Labile INR, Elderly, Drugs/Alcohol Concomitantly; FAS, full analysis set; INR, international normalized ratio; Q, quartile; SD, standard deviation.

Figure 3. Kaplan-Meier plot for time to first VTE recurrence by initial edoxaban dose



VTE, venous thromboembolism.

Figure 4. Kaplan-Meier plot for time to all-cause death by initial edoxaban dose



CONCLUSIONS

Rates of VTE recurrence, bleeding complications, and all-cause death in patients receiving edoxaban from South Korea or Taiwan were low and consistent with those in RCTs[5,6]

Although based on a modest sample size (n = 277), this ETNA-VTE analysis provides real-world evidence of the effectiveness and safety of edoxaban in patients with VTE in routine clinical practice

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DISCLOSURES

W-IC and **K-MC** have nothing to disclose; **EM-F** is an employee of Daiichi Sankyo Europe GmbH; **CC**, **MC**, and **MU** are employees of Daiichi Sankyo.

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