Documents

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ETNA-VTE Europe: Benefits and risks of venous thromboembolism treatment using edoxaban in the first 3 months

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Abstract
Introduction: Edoxaban had a positive risk-benefit ratio for the treatment of venous thromboembolism (VTE) compared to conventional therapy with warfarin. The objective of this analysis of the ongoing ETNA-VTE Europe study was to assess the real-world benefits and risks of edoxaban during the first 3 months of treatment, the highest risk period for further VTE events. Methods: ETNA-VTE Europe is a prospective, non-interventional, post-authorization study, conducted in eight European countries. Participants had initial or recurrent acute VTE (deep vein thrombosis [DVT] and/or pulmonary embolism [PE]) that occurred ≤2 weeks prior to enrolment and received edoxaban therapy. Results: The analysis set included 2672 patients (PE ± DVT, n = 1117; DVT only, n = 1555); mean age 62.9 ± 16.0 years, bodyweight 81.9 ± 17.4 kg, estimated glomerular filtration rate 95.4 ± 42.8 mL/min; 46.4% were female. Overall, 66.4% of patients (PE ± DVT, 68.5%; DVT-only, 64.8%) received heparin lead-in treatment for at least 5 days. Most patients (87.7%) received edoxaban at a dose of 60 mg once daily. Event rates at 3 months were: recurrent VTE 0.34% (n = 9), major bleeding 0.97% (n = 26), all-cause mortality 0.79% (n = 21). Rates were numerically higher in the PE ± DVT group compared with the DVT-only group (recurrent VTE, 0.45% (n = 5) versus 0.26% (n = 4); major bleeding, 1.34% (n = 15) versus 0.71% (n = 11); and all-cause mortality 1.16% (n = 13) versus 0.51% (n = 8)). Conclusions: The results support the safety and effectiveness of edoxaban in a general VTE population during the most critical time period, the first 3 months. The outcomes of this study extend the principal efficacy and safety data on edoxaban into the routine clinical practice setting. © 2020

Author Keywords
Clinical outcomes; Deep vein thrombosis; Edoxaban; Pulmonary embolism; Registry; Routine clinical practice; Venous thromboembolism

Index Keywords
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