

EXTENDED TREATMENT WITH REDUCED DOSE OF DIRECT ORAL ANTICOAGULANTS IN PATIENTS WITH VENOUS THROMBOEMBOLISM: A RETROSPECTIVE STUDY.

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Introduction

The occurrence of a venous thromboembolism (VTE) event is the result of a variety of risk factors and conditions, that differently affect the risk of a first and/or recurrent VTE. In case of persistent risk factors and unprovoked thrombosis, extended anticoagulation should be considered. Similarly, continuing anticoagulant therapy in VTE provoked by a transient risk factor may be considered in patients with a history of previous VTE, VTE provoked by a minor transient risk factor. The availability of reduced doses of direct oral anticoagulants (DOACs) has simplified the management of patients candidate to long-term anticoagulation. However, there is still paucity of data on long-term outcomes in patients treated with reduced doses of DOACs. To address this gap of knowledge, our study aimed to evaluate the effectiveness and safety of reduced doses of DOACs for the extended phase of VTE treatment beyond 12 months.

Methods

In this no-profit, observational, retrospective, monocenter cohort study, promoted by the Department of Clinical Internal, Anaesthesiological and Cardiovascular Sciences of Sapienza University of Rome, consecutive adults patients from January 2020 through April 2024 were enrolled if affected by VTE requiring reduced dose of DOACs.

The primary effectiveness outcome included on-treatment recurrent VTE while the secondary effectiveness outcome on-treatment arterial events. The safety outcome included on-treatment major and clinically relevant non-major bleeding while the secondary safety outcome minor bleedings.

Continuous variables were expressed as mean (standard deviation) or median (interquartile range), according to data distribution after applying the Wilk-Shapiro test. Categorical

variables were expressed as counts and percentages. The incidence of primary outcomes were expressed as patient-years with 95% confidence intervals (CI). RStudio was used for the analysis.

Results

140 patients were consecutively enrolled. Mean age was 72 ± 15 years and was lower in patients with a persistent risk factor than in patients with unprovoked VTE and with a minor transient risk factor. The proportion of patients with a previous VTE or with a family history of VTE was higher in patients with a persistent risk factor and with unprovoked VTE than in patients with a minor transient risk factor. 55% had lower extremity deep vein thrombosis, followed by pulmonary embolism. Overall, 73.6% of patients received apixaban and 14.3% rivaroxaban. Few patients received edoxaban and dabigatran, without relevant differences across subgroups of patients for type of DOACs.

There was one recurrent LEDVT (0.7%) after 16 months of apixaban in a patient with thrombophilia. During the follow-up, 4 major bleedings (2.9%), all during apixaban administration, and two clinically relevant non-major bleedings (1.4%) occurred. Four acute ischemic strokes (2.9%) occurred, 3 during apixaban and one during dabigatran therapy.

Discussion

Our study including VTE patients up to 3 years follow-up shows a low incidence of recurrent VTE and major bleeding during reduced doses of DOACs. The incidence of arterial thrombotic events exceeded that of recurrent VTE. The lower incidence of recurrent VTE as well as the higher incidence of major bleedings than previously reported may suggest that the decision to extend treatment with reduced dose of DOACs should consider the bleeding risk.

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