

TEV E PATOLOGIE CARDIOVASCOLARI

LONG TERM EFFECTIVENESS AND SAFETY OF DIRECT ORAL ANTICOAGULANTS IN PATIENTS WITH FACTOR V LEIDEN AND/OR PROTHROMBIN GENE MUTATION AND VENOUS THROMBOEMBOLISM: A SINGLE CENTRE, RETROSPECTIVE COHORT STUDY.

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Background: Data on long term outcomes of anticoagulation with direct oral anticoagulants (DOACs) in patients affected by venous thromboembolism (VTE) and thrombophilia are scarce. Aim of this study was to evaluate effectiveness and safety of DOACs in patients with factor V Leiden (FVL) and/or prothrombin gene mutation (PGM) referring to a tertiary anticoagulation centre.

Methods: We performed a retrospective cohort study, including VTE patients referred to the Atherotrombosis Centre of Policlinico Umberto I, Rome, between 2014 and 2024. Baseline characteristics and presence of thrombophilia (i.e., FVL and PGM) were collected. The primary effectiveness outcome included on-treatment recurrent VTE, while the secondary effectiveness outcome were acute arterial events. Safety outcomes included major and clinically-relevant non-major bleedings. Cumulative incidence was calculated for primary effectiveness outcome with Kaplan-Meier curves. The other outcomes were descriptively reported.

Results: We included 192 patients. Among them, 35 carried FVL, 18 PGM, 10 FVL and/or PGM, and 123 were wild-type.

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Mean age was significantly lower in patients with FVL and/or PGM compared with wild-type patients (64 versus 71 years). There weren't significant differences according to personal or family history of VTE. Most of patients had lower extremity deep vein thrombosis with/without pulmonary embolism and a small proportion an atypical site thrombosis with similar proportions between subgroups. Treatment duration with DOACs was 42 months and 40 months in patients with and without thrombophilia. During DOACs, the cumulative incidence of recurrent VTE was 16.5% (95% confidence intervals - CI -, 4.7%-34.7%) in patients with FVL, 19.4% (95% CI, 4.1%-43%) in patients with PGM, and 3.3% (95% CI, 0.9%-8.7%) in wild-type patients. No recurrences occurred in patients with FVL and PGM. A similar proportion of patients with and without thrombophilia had arterial events (3.2% versus 2.4%), major (1.6% versus 3.3%), clinically-relevant non-major bleedings (6.3% versus 2.4%).

Conclusions: Patients with FVL and/or PGM have significantly higher incidence of recurrent VTE during DOACs, compared with wild-type patients, with similar incidence of arterial events and bleedings. Further studies are needed to assess the best therapeutic management of these patients.