The Official Journal of the Italian Society for the Study of Hemostasis and Thrombosis
SISET
Società Italiana per lo Studio dell'Emostasi e della Trombosi
Corso Nazionale SISET
Bergamo | 23-25 ottobre 2025

29TH NATIONAL CONFERENCE OF THE ITALIAN SOCIETY FOR THE STUDY OF HEMOSTASIS AND THROMBOSIS, 2025

ABSTRACT N. CO04

TEV E PATOLOGIE CARDIOVASCOLARI

DIRECT ORAL ANTICOAGULANTS IN ANTIPHOSPHOLIPID SYNDROME: A SINGLE CENTER REAL-LIFE EXPERIENCE.

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Background and Aims: Current guidelines recommend against using Direct Oral Anticoagulants (DOACs) in patients with antiphospholipid syndrome (APS). However, there is little evidence to support these recommendations, except for triple-positive aPL profiles. Real-life studies have shown conflicting data regarding the treatment of so-called low-risk APS patients, i.e., those not triple-aPL positive.
To evaluate the efficacy and safety of DOACs versus Vitamin K antagonist (VKA) in real-life APS patients and to identify risk factors predictive of the efficacy of DOACs in APS.

Patients and Methods: We conducted a retrospective cohort study enrolling APS patients attending the Thrombotic and Haemorrhagic Outpatient Clinic, Department of Medicine at the University of Padua, from 2010 until December 2024. All patients were retrospectively classified according to the 2023 ACR/EULAR classification criteria. The patients in stable therapy regimens for at least 6 months were included in the study. The primary outcome was the incidence of recurrent thromboembolism events; secondary endpoints were damage accrual and major bleeding, or clinically relevant nonmajor bleeding defined following the ISTH guidelines.

Results: One hundred fifty-seven patients were enrolled, with a median age of 41 years [interquartile range (IQR) 30-54], of which 106 (67.5%) were female. One hundred twenty-seven (80.9%) patients were treated with VKA and 30 (19.1%) with DOACs. Ninety-two (58.6%) patients had arterial thrombosis, 105 (66.9%) had venous thrombosis, and 98 (62.4%) had triple-aPL positivity. Patients in the DOACs group were significantly older (54, [IQR 34-59] vs 40, [IQR 30-50] years, p = 0.01) than those in the VKA group and had a lower proportion of females, 50% vs 71.7%, p = 0.02. Moreover, those had a higher rate of venous thromboembolism (VTE) and a lower rate of arterial thrombosis (ATE) and microvascular thrombosis, respectively, 96.7 % vs. 59.8%, p<0.0001, 23.3% vs. 66.9 %, p<0.0001 and 13.3 % vs. 40.2 %, p = 0.006. The triple-aPL positivity rate was significantly higher in the VKA group (67.7 % vs 40.0%, p=0.012).
During a median follow-up of 150 months [IQR 74-173], we observed 27 (17.2%) thrombotic events. Patients in the DOACs group had a significantly higher rate of recurrent thromboembolism events (rTE) (40.0% vs. 11.8%, p=0.0007) and a significantly shorter median time to event (40, [IQR 14-73] vs 126, [IQR 63-174], p<0.0001 months) concerning VKA group. There was no difference between the clinical APS subsets and aPL profile in patients with rTE in the DOACs group compared to the VKA group. However, patients with rTE in the VKA group had a significantly higher rate of microvascular involvement (OR 4.9, 95% CI [1.5-16.6], p = 0.009) and a higher DIAPS score at baseline (p = 0.003). Instead, those in the DOACs group had a significantly higher rate of ATE and microvascular thrombosis, respectively, with odds ratios of 16.9 (95% CI [1.7-171], p = 0.02) and 10.6 (95% CI [1.4-129.5], p = 0.02). The two groups had no difference regarding major and clinically relevant nonmajor bleeding.

Conclusions: In real-life APS patients, DOACs were associated with a higher rTE rate than VKA, regardless of clinical subsets and aPL profile.

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