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RETROSPECTIVE COHORT STUDY OF VTE RECURRENCE BY WARFARIN OR DOAC USE IN FACTOR V LEIDEN DEFICIENCY

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Umer Rizwan, Rida Hussain, Ahmed Umer

West Virginia University Camden Clark Medical Center, Parkersburg, West Virginia, United States

Background: Factor V Leiden deficiency is a common inherited thrombophilia, that increases the risk of venous thromboembolism (VTE). While both warfarin and direct oral anticoagulants (DOACs) are used in VTE treatment and prevention, their relative efficacy and safety in pediatric patients with Factor V Leiden deficiency remain unclear.

Objectives: This study compared the risk of VTE recurrence, development of anemia, and all-cause

mortality in pediatric patients with Factor V Leiden deficiency treated with either warfarin or DOAC

therapy.

Design/Method: We conducted a retrospective cohort study using a large, multi-hospital-system

database. The time period for this study was limited to January 1, 2000 through December 1, 2023. All patients were under 18 years old and diagnosed with Factor V Leiden deficiency via blood testing. Inclusion criteria were at least one episode of pulmonary embolism or deep venous thrombosis of any extremity, and treatment with warfarin or DOAC. Treatment cohorts were matched based on age and risk factors for VTE including malignancy, asparaginase chemotherapy use, presence of central venous catheter and trauma. Primary outcomes were VTE recurrence, development of anemia, and all-cause mortality. Log-rank tests, relative risk and hazard ratio calculations were performed using commercially available statistical analysis software.

Results: A total of 94 patients on DOACs and 51 on warfarin were included. Compared to warfarin,

DOACs were associated with a significantly higher rate of VTE recurrence (hazard ratio: 1.862, 95%

confidence interval [CI]: 1.072-3.232, p=0.027). No significant differences were observed in acute blood loss anemia, gastrointestinal bleeding or all-cause mortality risks between the two groups. Notably, among patients without VTE recurrence, DOACs exhibited a lower risk of acute blood loss anemia or gastrointestinal bleeding compared to warfarin (relative risk: 0.488, 95% CI: 0.301-0.792).

Conclusion: Our study suggests that DOACs may be associated with a higher VTE recurrence risk than warfarin in pediatric patients with Factor V Leiden deficiency. However, DOACs potentially pose a lower bleeding risk among patients without VTE recurrence. Further research is warranted to confirm these findings and guide optimal anticoagulation strategies in this population.