

LONG TERM EFFECTIVENESS AND SAFETY OF VENOUS THROMBOEMBOLISM WITH FONDAPARINUX: DATA FROM THE START REGISTRY.

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Background: Fondaparinux is licensed for the initial treatment of venous thromboembolism (VTE), but for its favourable characteristics it is sometimes used also long term. This study aimed to evaluate long term effectiveness and safety of fondaparinux in VTE.

Methods: We performed a preliminary retrospective analysis on data from the START Registry about patients receiving long term anticoagulation with fondaparinux (i.e., > 7 days). Effectiveness was evaluated as recurrent VTE and arterial events, and safety as major bleedings. Baseline characteristics of patients and outcome of interest are reported as descriptive statistics. Continuous variables were expressed as mean (standard deviation) or median (interquartile range - IQR -) values, according to data distribution after applying the Wilk-Shapiro test. Categorical variables were expressed as counts and percentages.

Results: We included a total of 133 patients receiving long-term fondaparinux. Median age was 66 years (IQR, 55 to 76 years), 48.1% of patients were male, and median BMI was

27.3 kg/m². Most of patients had a lower extremity deep vein thrombosis (72.2%), followed by pulmonary embolism (10.5%) and upper extremity deep vein thrombosis (9.0%). A small proportion of patients had atypical site thrombosis (2.3% splanchnic, 0.8% cerebral, and 0.8% caval vein thrombosis). Most of patients had an unprovoked vein thrombosis (46.7%). Median hemoglobin values was 13.1 g/dl (IQR, 11,8 to 14,7 g/dl), median platelet 226000/ul (IQR, 176000 to 296000/ul), and media creatinine value 0.85 mg/dl (IQR, 0.73 to 1.03 mg/dl). Median treatment duration was 34 days (IQR, 12 days to 112 days). One patient (0.8%) had an on-treatment recurrent VTE, two patients (1.5%) an on-treatment arterial event, and one patient (0.8%) an on-treatment major bleeding.

Conclusions: In this preliminary analysis, fondaparinux appeared to be an effective and safe therapy for the long-term treatment of VTE. Caution is needed for the interpretation of these results, which are limited by the small sample size of our cohort. Larger cohorts are needed to confirm these findings.

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