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Comparative effcomparative effectiveness and safety of factor-xa inhibitors vs phenprocoumon in patients with non-valvular atrial fibrillation and malignant diseases, insights from the RELOADED study

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Background: Data on safety and effectiveness of Factor-Xa inhibitors and phenprocoumon in patients with non-valvular atrial fibrillation (NVAF) and malignant diseases is scarce. Among others, our study aimed to investigate the safety and effectiveness in new users of Factor-Xa inhibitors vs. phenprocoumon, the vitamin-K antagonist (VKA) of choice in Germany.

Methods: We conducted a new user cohort study (one year washout period) in patients with NVAF and malignant diseases. German claims data between January 1st, 2013 and June 30th, 2017 were utilized and a multiple Cox-regression was performed to calculate confounder-adjusted hazard ratios (HRs) for the risk of ischemic stroke (IS)/systemic embolism (SE), intracranial haemorrhage (ICH) as well as renal function worsening, defined by end stage renal disease (ESRD) or dialysis and acute kidney injury (AKI) in Factor-Xa inhibitors and phenprocoumon initiators. Diagnoses of malignant diseases were assessed over the one-year baseline period.

Results: The population comprised 3,779 phenprocoumon initiators, 3,386 rivaroxaban initiators, 2,697 apixaban initiators and 434 edoxaban initiators. In the confounder-adjusted analysis, no difference related to the risk of IS/SE was found for rivaroxaban and edoxaban vs. phenprocoumon, where apixaban showed a numerically increased risk for stroke (figure 1). Point estimates related to the risk of ICH showed the expected beneficial effects for both, rivaroxaban and apixaban. A strong beneficial effect was observed for rivaroxaban when assessing the risk of renal function worsening. Hazard ratios related to the risk of ESRD/dialysis and AKI were 0.27 (0.10; 0.69) and 0.64 (0.38; 1.06), respectively. For apixaban, only the ESRD/dialysis showed a reduction in risk when compared to phenprocoumon, HR 0.42 (0.19; 0.94).

Conclusion: This retrospective database study conducted in Germany adds evidence on the effectiveness and safety profile of Factor-Xa inhibitors over VKA in patients with NVAF and malignant diseases, a critical subgroup of patients where anticoagulation is challenging. However, apixaban showed a numerically increased risk for IS/SE compared to phenprocoumon. Both, rivaroxaban and apixaban showed a risk reduction for renal function worsening within the study period of 63% and 48%, respectively compared to phenprocoumon. Only rivaroxaban showed a risk reduction of 36% for AKI.