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Comparative safety of factor-xa inhibitors vs phenprocoumon in patients with non-valvular atrial fibrillation and renal disease - insights from the RELOADED study

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Background: Data on safety of Factor-Xa inhibitors and phenprocoumon in patients with non-valvular atrial fibrillation (NVAF) and renal disease is scarce. Among others, our study aimed to investigate the safety risks of fatal bleeding and intracranial haemorrhage (ICH) 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 renal disease. 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 fatal bleeding and ICH in Factor-Xa inhibitors and phenprocoumon initiators. Additionally, a propensity score matching and an inverse probability of treatment weight analysis were performed as sensitivity analyses. Cases of fatal bleeding were defined as hospitalization with a primary hospital discharge diagnoses for bleeding with documented death as reason for hospital discharge or within 30 days after hospital discharge.

Results: The overall population comprised 23,552 phenprocoumon initiators, 22,338 rivaroxaban initiators and 16,201 apixaban initiators, where the number of patients with renal disease initiating these agents were 7,289 for phenprocoumon, 5,121 patients for rivaroxaban 15mg or 20mg and 4,750 patients for apixaban 2.5mg or 5mg, respectively. In the confounder-adjusted analysis, a beneficial effect for rivaroxaban and apixaban over phenprocoumon was observed for the risk of ICH and fatal bleeding (figure 1) for both the overall and renal disease population. Hazard ratios for rivaroxaban and the risk of ICH were calculated as 0.57 (0.43; 0.75) for the overall population and 0.62 (0.37; 1.01) for the renal disease population where hazard ratios for apixaban were calculated as 0.43 (0.31; 0.60) for the overall population and 0.41 (0.23; 0.74) for the renal disease population, respectively. There was not sufficient data to conduct the analyses for edoxaban.

Conclusion: This large retrospective database study conducted in Germany confirms the safety profile of rivaroxaban and apixaban over VKA in patients overall and specifically in patients with renal disease when assessing the risk of ICH and fatal bleeding. Our study adds evidence in a relevant subgroup of patients where anticoagulation is often challenging.

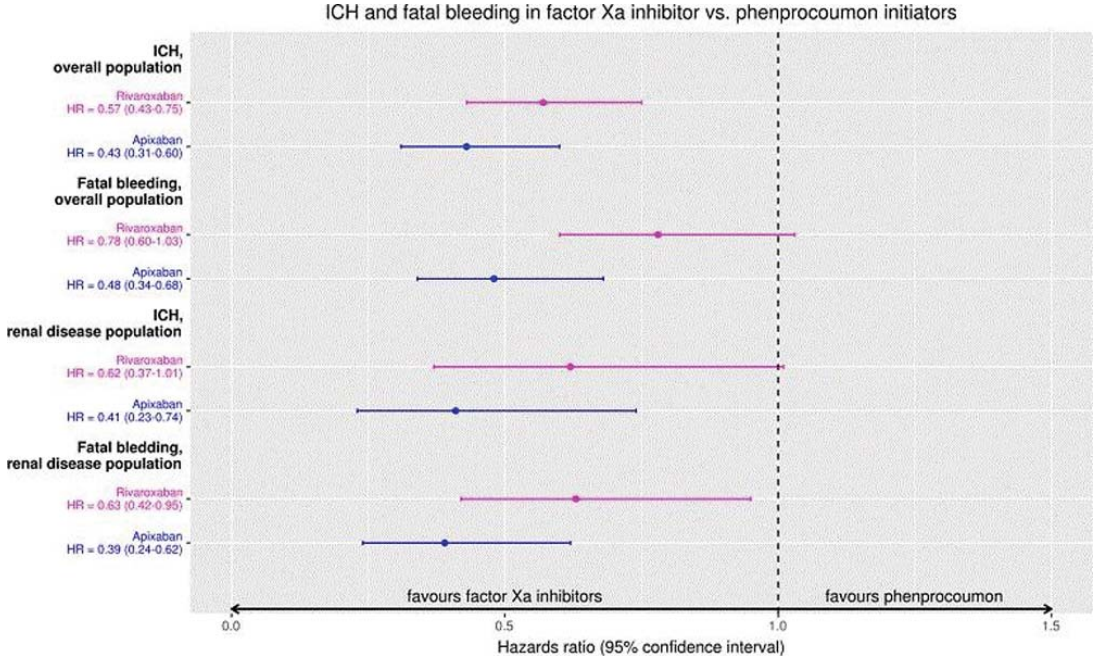

Figure 1

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