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CLINICAL RESEARCH

Reduced dose of rivaroxaban and dabigatran vs. vitamin K antagonists in very elderly patients with atrial fibrillation in a nationwide cohort study

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Background

- The real-life benefits and risks of the non-vitamin K antagonist oral anticoagulants for stroke prevention in very elderly patients with atrial fibrillation (AF) are still debated.

Aim of the study

- To evaluate the 1-year benefits and risks of NOACs for patients ≥ 85 years old, comparing new users of dabigatran or rivaroxaban to new users of VKA.
- The analysis compared rivaroxaban 15mg (being indicated in individuals with moderately impaired renal function) and dabigatran 110mg (being indicated in case of moderately impaired renal function, concomitant use of verapamil, if age > 80 years or to be considered between 75 and 80 years) to VKA.

Methods

- Cohorts of new users of rivaroxaban 15mg, dabigatran 110mg, or vitamin K antagonists (VKA) for AF \geq 85 years old in 2013 or 2014 were identified in the nationwide French claims database and followed-up for 1 year.
- Cohorts were compared after 1:1 matching using high-dimensional propensity score.

Results

Compared to VKA use:

- risk of stroke, and systemic embolism was not different with rivaroxaban use and lower with dabigatran use ;
- risk of major bleeding was not different with rivaroxaban use and with dabigatran use;
- risk of all-cause death was borderline to significance lower with rivaroxaban use , and lower with dabigatran use;
- risk for a composite of all events above was not different with rivaroxaban use and lower with dabigatran use;
- risk for the composite of all events was not different with rivaroxaban use as compared with dabigatran use.

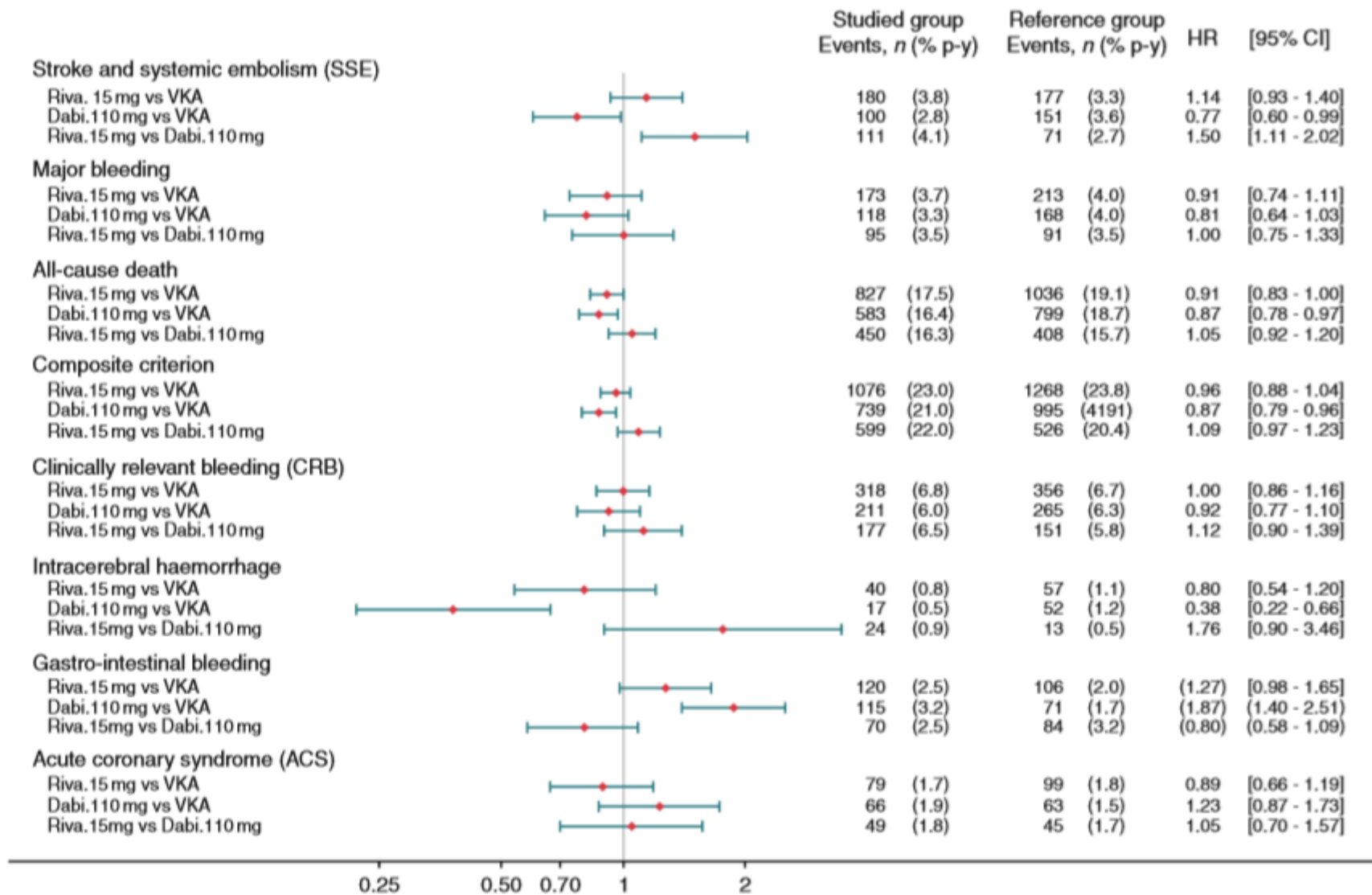


Figure 2 AF population (≥ 85 years old)—outcome hazard ratios in matched patients during the 1st drug exposure period in the 1-year follow-up period—Fine and Gray hazard risk models. AF, atrial fibrillation; CI, confidence interval; VKA, vitamin K antagonists.

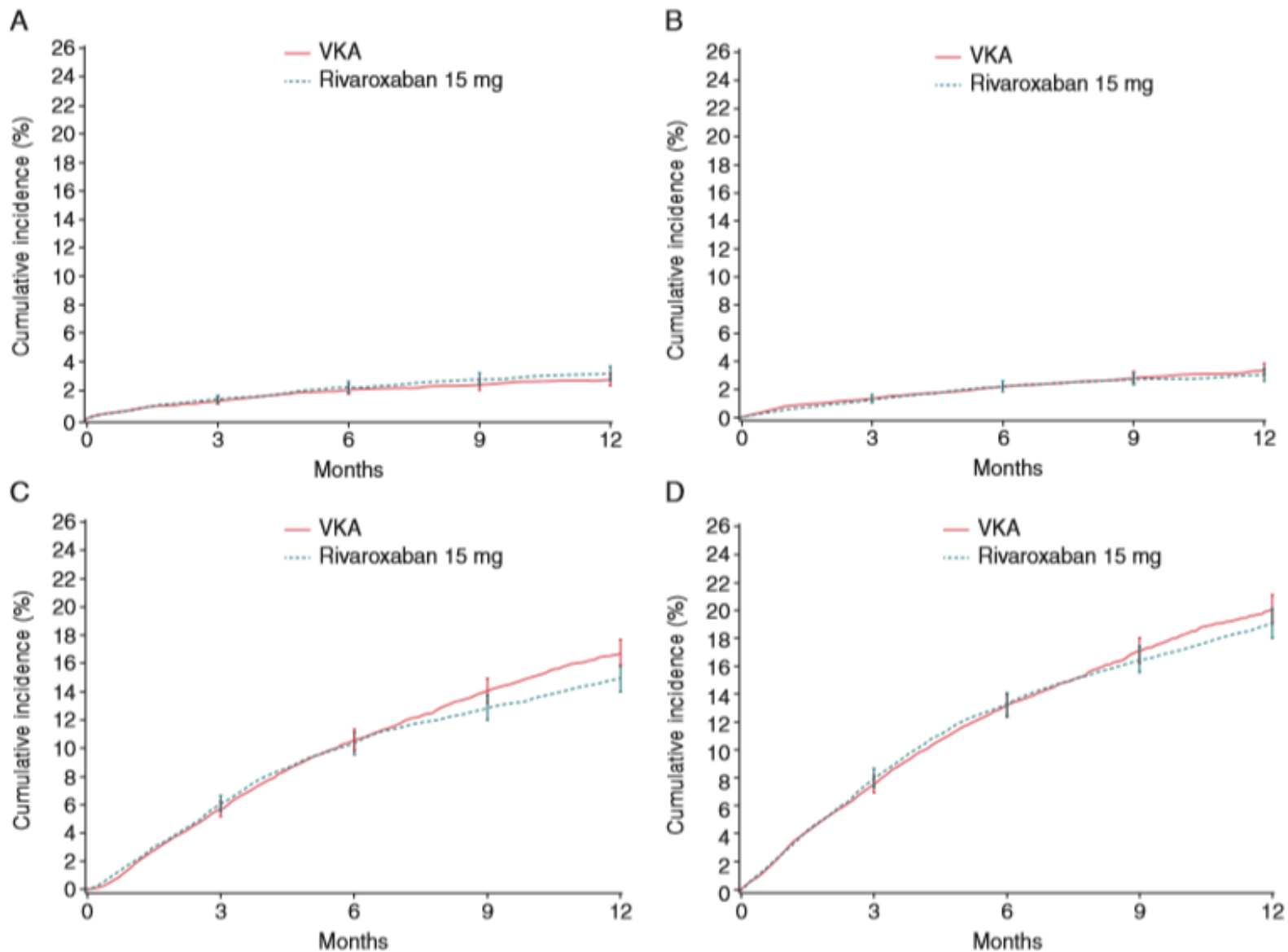


Figure 3 AF population (≥ 85 years old)—matched patients (rivaroxaban 15 mg vs. VKA)—cumulative incidence of events during the 1st drug exposure period (Kaplan–Meier curve). (A) Stroke and systemic embolism. (B) Major bleeding. (C) All-cause death. (D) Composite criterion of A, B, and C. AF, atrial fibrillation; VKA, vitamin K antagonists.

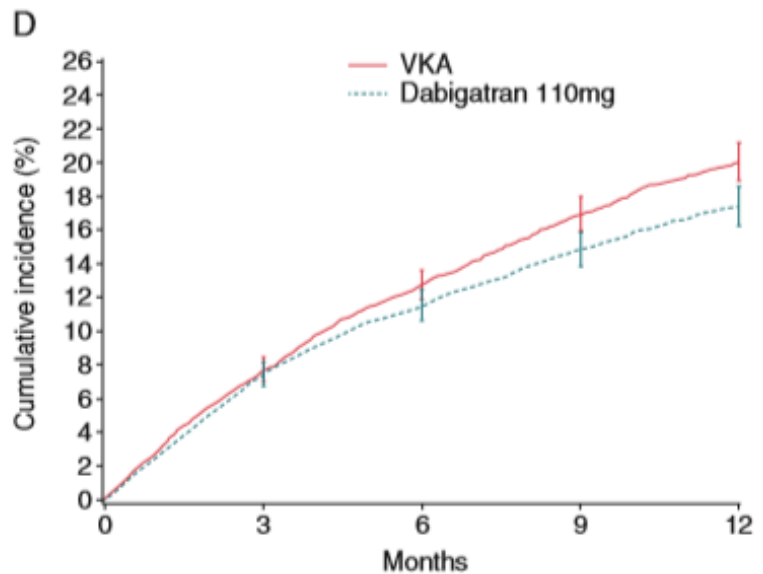
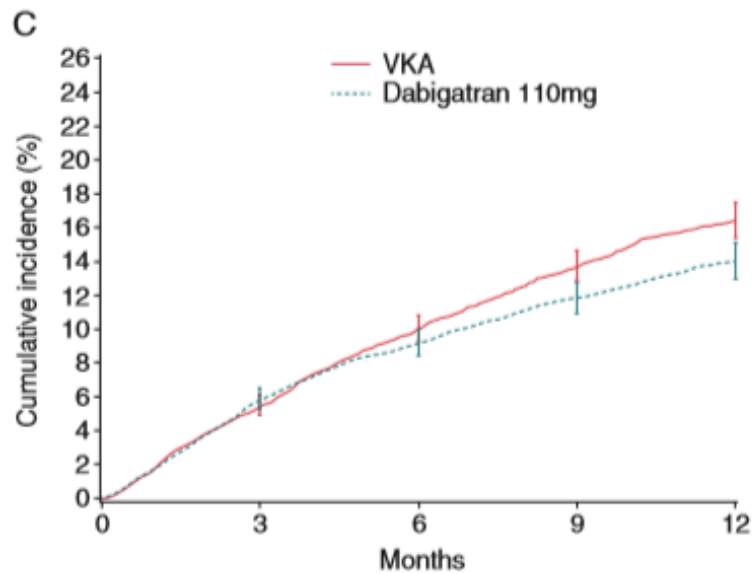
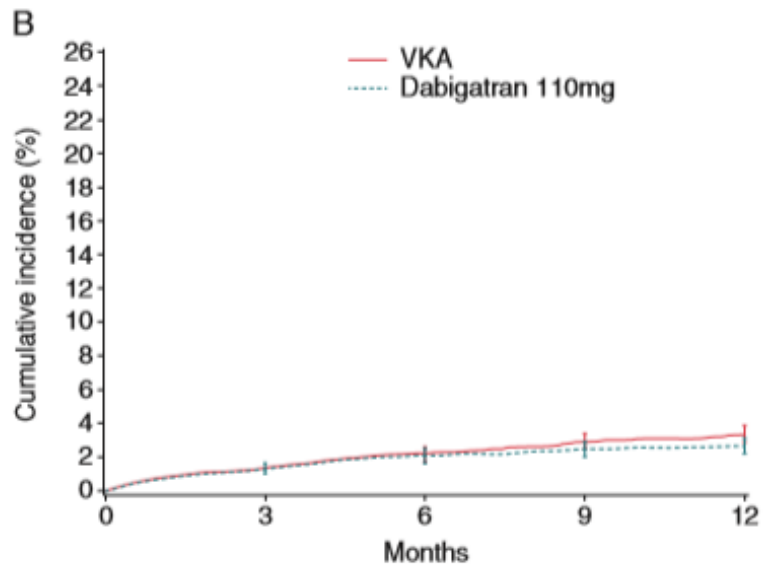
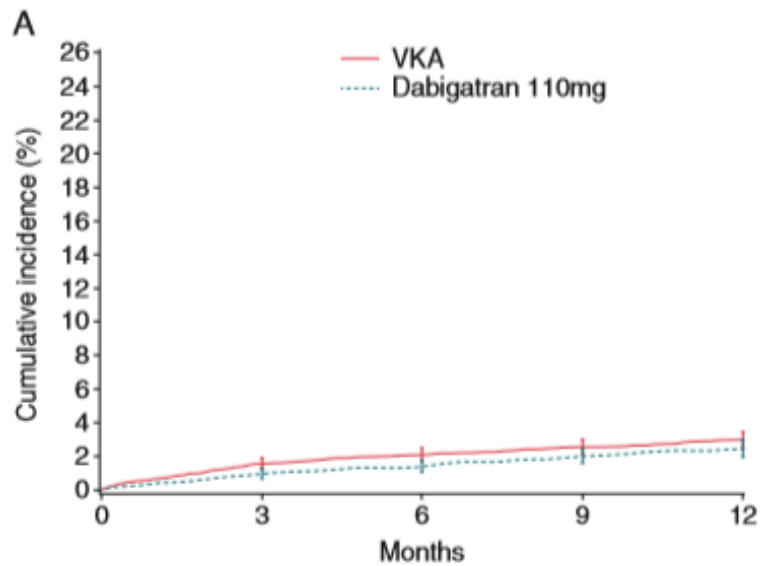


Figure 4 AF population (≥ 85 years old)—matched patients (dabigatran 110 mg vs. VKA)—cumulative incidence of events during the 1st drug exposure period (Kaplan–Meier curve). (A) Stroke and systemic embolism. (B) Major bleeding. (C) All-cause death. (D) Composite criterion of A, B, and C. AF, atrial fibrillation; VKA, vitamin K antagonists.

Conclusions

- This study shows for the first time in more than 25 000 new real-life anticoagulant users for AF aged ≥ 85 years a neutral overall benefit-risk of rivaroxaban 15mg vs VKA and a favourable overall benefit-risk of dabigatran 110mg vs VKA on relevant clinical events.
- These results may have significant implications for daily practice since the majority of very elderly AF patients in general practice do not receive oral anticoagulant despite their higher stroke risk.