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Bleeding risk with rivaroxaban compared with vitamin K antagonists in patients aged 80 years or older with atrial fibrillation

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Abstract

Objective: Direct oral anticoagulants have been evaluated in the general population, but proper evidence for their safe use in the geriatric population is still missing. We compared the bleeding risk of a direct oral anticoagulant (rivaroxaban) and vitamin K antagonists (VKAs) among French geriatric patients with non-valvular atrial fibrillation (AF) aged ≥ 80 years.

Methods: We performed a sequential observational prospective cohort study, using data from 33 geriatric centres. The sample comprised 908 patients newly initiated on VKAs between September 2011 and September 2014 and 995 patients newly initiated on rivaroxaban between September 2014 and September 2017. Patients were followed up for up to 12 months. One-year risks of major, intracerebral, gastrointestinal bleedings, ischaemic stroke and all-cause mortality were compared between rivaroxaban-treated and VKA-treated patients with propensity score matching and Cox models.

Results: Major bleeding risk was significantly lower in rivaroxaban-treated patients (7.4/100 patient-years) compared with VKA-treated patients (14.6/100 patient-years) after multivariate adjustment (HR 0.66; 95% CI 0.43 to 0.99) and in the propensity score-matched sample (HR 0.53; 95% CI 0.33 to 0.85). Intracerebral bleeding occurred less frequently in rivaroxaban-treated patients (1.3/100 patient-years) than in VKA-treated patients (4.0/100 patient-years), adjusted HR 0.59 (95% CI 0.24 to 1.44) and in the propensity score-matched sample HR 0.26 (95% CI 0.09 to 0.80). Major lower bleeding risk was largely driven by lower risk of intracerebral bleeding.

Conclusions: Our study findings indicate that bleeding risk, largely driven by lower risk of intracerebral bleeding, is lower with rivaroxaban than with VKA in stroke prevention in patients ≥ 80 years old with non-valvular AF.

Keywords: atrial fibrillation; epidemiology; pharmacology.

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