

Predictors of adverse clinical outcomes in atrial fibrillation patients with concomitant renal impairment under rivaroxaban therapy

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Background: Atrial fibrillation (AF) increases the risk of stroke and mortality, and concomitant renal impairment confers a worse prognosis. However, those factors that may limit the use of direct-acting oral anticoagulants in AF patients with renal impairment have not been further investigated, as they confer a higher risk of adverse events in this patient population.

Purpose: To investigate predictors of adverse clinical outcomes in AF patients with renal impairment who were treated with rivaroxaban.

Methods: The EMIR study is an observational, multicenter study including patients with AF treated with rivaroxaban for at least the previous 6 months. During 2.5 years of follow-up, the occurrence of thromboembolic events (the composite of ischemic stroke, transient ischemic attack, systemic embolism and myocardial infarction [MI]), major bleeding (ISTH definition) and major adverse cardiovascular events (MACE: fatal/non-fatal MI, myocardial revascularization and cardiovascular death) were recorded. For the present analysis, creatinine clearance (CrCl) was estimated by using the Cockcroft-Gault equation and renal impairment was defined as a CrCl <60 mL/min.

Results: 1433 patients were included (44.5% female; mean age 74.2±9.7 years), of which 498 (35.1%) had CrCl <60 mL/min. The mean CHA2DS2-VASc and HAS-BLED were 3.5±1.5 and 1.6±1.0, respectively. During the follow-up, 7 (1.4%) patients with CrCl <60 mL/min suffered a throm-

boembolic event, 16 (3.2%) suffered major bleeding, and 19 (3.8%) suffered a MACE. Compared to patients with normal renal function, patients with CrCl <60 mL/min showed a higher annual rate of major bleeding (0.62%/year vs. 1.87%/year; p=0.003) and MACE (0.62%/year vs. 1.97%/year; p=0.002). Multivariate analyses demonstrated that the CHA2DS2-VASc score (OR 1.84; 95% CI 1.11–3.07) was associated with a higher risk of thromboembolic events; whereas the HAS-BLED score (OR 2.25; 95% CI 1.41–3.59) and any dependency level (OR 3.42; 95% CI 1.17–9.98) were associated with a higher risk of major bleeding; and male sex (OR 3.55; 95% CI 1.08–11.63) and heart failure (OR 4.67; 95% CI 1.62–13.51) with a higher risk of MACE. The use of antiplatelet agents was also independently associated with an increased risk of thromboembolic events and MACE (OR 12.28; 95% CI 2.50–60.18; and OR 8.72; 95% CI 2.86–26.59; respectively).

Conclusions: Rivaroxaban showed excellent results in moderate renal impairment. However, the annual rate of major bleeding and MACE was higher in AF patients with impaired renal function. In patients with AF and renal impairment, male sex, the presence of heart failure, dependency, the concomitant use of antiplatelets, and greater comorbidity according to the CHA2DS2-VASc and HAS-BLED, were associated with higher risk of adverse clinical outcomes.