Direct oral anticoagulant rivaroxaban in very old and frail patients: A one-year prospective follow-up of a large-scale cohort (SAFIR-AC)

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Background/Introduction: Age is one of the strongest predictors/risk factors for ischemic stroke in subjects with atrial fibrillation (AF). Direct oral anticoagulants (DOACs) have been shown to be effective in the prevention of this condition; however, clinical evidence on bleeding risk with this therapeutic strategy in very old and frail geriatric patients is poor.

Purpose: To assess bleeding risk in French geriatric patients aged ≥ 80 years and diagnosed with AF newly treated with rivaroxaban.

Methods: Subjects, presenting to one of 33 geriatric centers, with non-valvular AF and recent initiation of a treatment with rivaroxaban were enrolled in the study and followed-up every 3 months for 12 months. Clinical and routine laboratory data and evaluation scores, such as HAS-BLED, HEMORR2HAGES, ATRIA, and CHA2DS2-VASc, as well as comprehensive geriatric evaluation were reported. Major bleeding, as defined in ROCKET AF study, was reported at each visit, and this primary outcome was adjudicated by an independent committee. Results of this cohort were compared with findings from a similar cohort treated with vitamin K antagonists (VKA) from the same centers (n=924).

Results: A total of 1045 subjects were enrolled in the study of whom 995 (95%) had a one-year follow-up (analyzed population). The mean (standard deviation (SD)) age was 86.0 (4.3) years, with the majority of patients being female (61%), 23% aged 90 years or older, and 48% having an estimated glomerular filtration rate (eGFR) < 50 mL/min. The main comorbidities were hypertension in 77% of subjects, malnutrition 49%, anemia 43%, dementia 39%, heart failure 36%, and falls 27%. The mean (SD) score for CHA2DS2-VASc was 4.8 (1.4), HAS-BLED 2.4 (0.9), Mini-Mental State Examination (MMSE) 21.5 (6.9), Activities of Daily Living (ADL) 4.4 (1.9), and Charlson Comorbidity Index 6.7 (2.0). The one-year rate of major bleeding events was 6.4% of which 0.8% were fatal and 1.1% intracranial hemorrhages (ICH), whereas the one-year rate of ischemic stroke was 1.4% and all-cause mortality 17.9%. Computed with VKA cohort findings and adjusted for age, gender, eGFR and Charlson score, this would result in a hazard ratio of 0.54 (95% confidence interval [CI], 0.38 to 0.78) for major bleeding, 0.36 (0.17 to 0.76) for ICH, 0.62 (0.29 to 1.33) for ischemic stroke, and 0.82 (0.65 to 1.02) for all-cause mortality, in favor of rivaroxaban.

Conclusions: This is the first large-scale prospective study in geriatric population in AF subjects treated with 

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DOAC (rivaroxaban) Major bleeding risk appeared higher in very old than younger population, however major bleeding and ICH rates were significantly lower with rivaroxaban than with VKAs when used in the same geriatric population. This study indicates that Rivaroxaban can be used in very old and frail patients for the treatment of non-valvular AF.