

Low Dose NOACs in Asian (Insight from J-ROCKET & ELDERCARE-AF)

Low dose NOACs for the very elderly with high bleeding risk

Masaharu Akao, MD, PhD, FJCS, FESC.

Department of Cardiology, National Hospital Organization Kyoto Medical Center

Oral anticoagulant treatment for stroke prevention in very elderly patients with atrial fibrillation is challenging due to concerns regarding bleeding. Indeed, the proportions of patients receiving OAC decline according to advancing age, despite that the risk of stroke is high. Under-dosing of DOAC is sometimes prescribed for those patients in real-world clinical practice, but the definite evidence is lacking. The ENGAGE AF-TIMI 48 trial demonstrated that the use of 15 mg edoxaban is considered off-label because of concerns regarding insufficient prevention of stroke, but it may still be beneficial in patients with a high risk of bleeding, including in very elderly patients. Therefore, the ELDERCARE-AF trial was conducted to compare once-daily edoxaban 15 mg vs placebo in elderly (≥ 80 years) Japanese patients with nonvalvular atrial fibrillation who were considered ineligible for oral anticoagulant therapy at approved doses for stroke prevention. Edoxaban 15 mg remarkably reduced the incidence of stroke or systemic embolism (hazard ratio 0.34, 95% CI 0.19-.061), while showing a nonsignificant increase in major bleeding (hazard ratio 1.87, 95% CI 0.90-3.89). Thus, edoxaban 15 mg was shown to be an acceptable therapeutic option in those patients with high bleeding risk. However, it should be noted that it was so in very selected population of patients who were eligible for the trial criteria.