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Standard dose of rivaroxaban in Asian patients with atrial fibrillation: 20ms vs.15mg? Off label dose reduction of rivaroxaban should be avoided

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Background: Rivaroxaban emerged as potential alternatives to warfarin for the prevention of thromboembolism in patients with atrial fibrillation (AF). Because of the concern for the risk of major bleeding with rivaroxaban in Asian patients, off label rivaroxaban dose reduction to 15mg is common in Asian real-world practice. We aimed to set standard rivaroxaban dose in Asian patients with AF by comparison between on-label rivaroxaban 20mg and off-label reduced rivaroxaban dose 15mg.

Methods: A total of 2,208 consecutive non-valvular AF patients were enrolled between 2011 and 2017. After propensity score matching, both warfarin (n=804) and rivaroxaban group (n=804) had comparable baseline characteristics. Rivaroxaban group was further divided into on-label rivaroxaban 20mg group (n=390) and off-label reduced rivaroxaban 15mg group (n=333). Efficacy outcome was stroke/systemic embolism. Safety outcome was major bleeding. Primary net clinical benefit (NCB) was defined as the composite of stroke, systemic embolism, major bleeding and all-cause mortality. Secondary NCB was defined as the composite of stroke, systemic embolism and major bleeding. Patients were followed upto one-year or until the first occurrence of any study outcomes.

Results: Both Rivaroxaban groups had comparable efficacy compared to warfarin. However, both on-label rivaroxaban 20mg (hazard ratio [HR] 0.40, 95% confidence interval [CI] 0.18-0.90, p=0.026) and off-label reduced rivaroxaban 15mg (HR 0.37, 95% CI 0.16-0.88, p=0.025) significantly reduced major bleeding. There were no differences in efficacy and safety outcomes between on-label rivaroxaban 20mg and off-label reduced rivaroxaban 15mg group. On-label rivaroxaban 20mg significantly reduced primary (HR 0.44, 95% CI 0.25-0.79, p=0.006) and secondary (HR 0.51, 95% CI 0.27-0.96, p=0.038) NCBs compared to warfarin. However, off-label reduced rivaroxaban 15mg did not reduce both primary and secondary NCBs.

Conclusion: Off-label rivaroxaban dose reduction to 15mg had no benefit compared to on-label rivaroxaban 20mg. Compared to warfarin, on-label rivaroxaban 20mg significantly improved primary and secondary NCBs, whereas off-label reduced rivaroxaban 15mg did not. Therefore, rivaroxaban 20mg is favorable as standard dose in Asian patients.