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Impact of Real-world Off-label dose of Apixaban on long-term clinical outcomes in Patients with Atrial Fibrillation and Chronic Kidney Disease

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Objectives : Apixaban represent one of the cornerstone treatments to prevent cardioembolic events in patients with nonvalvular atrial fibrillation (NVAF). The objective of the present study is to evaluate the effects of real-world Off-label dose of Apixaban on long-term clinical outcomes in NVAF patients with chronic kidney disease (CKD)

Methods : Our database of AF patients diagnosed with CKD from 2018 to 2023 was used to obtain laboratory, echocardiography, electrocardiogram (ECG), and clinical outcomes data. Inclusion criteria were all AF patients with CKD using Apixaban. And we compared bleeding, systemic thrombotic events including stroke/systemic embolism and death according to off-label real -world dose of Apixaban.

Results : Among 635 patients with AF and CKD (76.9 ± 10.4 years), 335 (52.8%) patients took off-label underdosed Apixaban. Difference in the baseline characteristics was not observed among patients including CHA₂DS₂ VASc score and HASBLED score. During the median 18-month follow-up, a lower incidence of bleeding events ($P=0.001$) was observed in the off-label underdosed Apixaban group compared to those with standard dose or off-label overdosed Apixaban. However, there was no significant difference of systemic thrombotic events including stroke/systemic embolism and death according to off-label real-world dose of Apixaban (off-label underdose vs. standard dose, $P=1.000$; off-label overdose vs. standard dose, $P=1.000$; off-label underdose vs. off-label overdose, $P=0.609$). In multivariate analysis, HASBLED score was independent risk factors for bleeding events (OR 9.650; CI 1.998-46.622; $P=0.005$).

Conclusions : Compared with standard or off-label overdose of Apixaban, off-label underdose of Apixaban was associated with a lower risk of bleeding in patients with AF and CKD, with no difference in the risk of stroke/systemic embolism or death, supporting the apixaban dosing tailored to specific clinical features and drug pharmacokinetics of the Asian patients.

Figure. Kaplan-Meier Curve for (A) total bleeding and (B) stroke/systemic embolism events according to off label of Apixaban in AF patients with CKD

