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Comparative effectiveness and safety of non-VKA oral anticoagulants versus warfarin in non-valvular atrial fibrillation patients with differential treatment duration: an ARISTOPHANES study analysis

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BACKGROUND: The ARISTOPHANES (Anticoagulants for Reduction In STroke: Observational Pooled analysis on Health outcomes ANd Experience of patientS) study showed that non-vitamin K antagonist oral anticoagulants (NOACs) were associated with lower risks of stroke/systemic embolism (S/SE) and variable comparative risks of major bleeding (MB) versus warfarin.

PURPOSE: To assess long-term use of non-VKA oral anticoagulants (NOACs) vs. warfarin in ARISTOPHANES by evaluating the risk of S/SE and MB among non-valvular atrial fibrillation (NVAF) patients by duration of treatment (<1 and ≥1 year).

METHODS: In the ARISTOPHANES study, NVAF patients initiating apixaban, dabigatran, rivaroxaban, or warfarin from 01/01/2013-09/30/2015 were identified from the CMS Medicare data and four US commercial claims databases, covering >180 million beneficiaries annually (~56% of US population). After 1:1 propensity score matching (PSM) in each database between NOACs and warfarin (apixaban-warfarin, dabigatran-warfarin, and rivaroxaban-warfarin), the resulting patient records were pooled. Treatment duration was defined as time between the day after the treatment index date and discontinuation (30 days after a 30-day gap in the prescription), treatment switch, death, end of study period, or end of continuous medical and pharmacy enrollment, whichever occurred first. Matched patients with observed treatment duration <1 or ≥1 year were separately examined. Cox models were used to estimate hazard ratios of S/SE and MB (identified by inpatient claims) during observed treatment duration.

RESULTS: The mean treatment duration for patients with shorter (<1 year) vs longer (≥1 year) duration was 4-5 months vs 18-21 months across the three matched cohorts. All the matched baseline variables remained balanced. The incidence rates of S/SE and MB and the proportion of patients with treatment discontinuation were higher in patients with shorter treatment duration. Regardless of treatment duration, apixaban patients had a lower risk of S/SE and MB versus warfarin; dabigatran patients had a lower risk of MB versus warfarin; and rivaroxaban patients had a lower risk of S/SE versus warfarin. Compared to warfarin patients, dabigatran patients with treatment duration <1 year had a similar risk of S/SE, while those with treatment duration ≥1 year had lower S/SE risk; rivaroxaban patients with treatment duration <1 year had a higher risk of MB, while those
with treatment duration =1 year had similar MB risk.

CONCLUSIONS: Among NVAF patients with duration of treatment <1 and =1 year in the ARISTOPHANES study, apixaban and rivaroxaban were associated with lower risk of S/SE, while apixaban and dabigatran were associated with lower risk of MB, compared to warfarin. These findings indicate varying long-term effectiveness and safety outcomes between NOACs and warfarin.