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effectiveness and safety of reduced dose of direct oral anticoagulants in real world practice in asia

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Introduction

Direct oral anticoagulants (DOACs) have demonstrated noninferiority to warfarin for ischemic stroke, systemic embolism, and bleeding in phase III trials; however, evidence of the effectiveness of reduced dosing of DOACs in Asians is insufficient, although the use of off-label dosing is prevalent in real-world practice. We assessed the effectiveness and safety of DOACs compared to warfarin after balancing covariates in patients with non-valvular atrial fibrillation (NVAF).

Methods

Consecutive patients with NVAF who were on anticoagulants were retrospectively investigated. We defined well-controlled anticoagulation with warfarin as time in therapeutic range (TTR) = 60%. Dosing of DOACs was categorized as standard, reduced, on-label, and off-label.

Results

The study included 4325 patients; 34.8% were female, with a mean age of 66.4 years and a mean CHA2DS2-VASc score of 2.71. The patients treated with warfarin (2296, 53.1%) showed a median TTR of 27.2%. Off-label dosing was prescribed in 35.7% of patients using DOACs. During the 11.8 ± 11.5 months of mean follow-up, on-label reduced dosing and off-label reduced dosing of DOACs were associated with a higher incidence of thromboembolism compared to well-controlled warfarin (adjusted hazard ratio [HR] 7.61, 95% confidence interval [CI] [1.97–29.39] and 8.68 [1.13–66.62], respectively). Off-label reduced dosing of DOACs showed a similar incidence rate of thromboembolism but a lower incidence rate of major bleeding than in those with use of on-label standard dosing (1.26 vs. 1.25 and 0.77 vs. 1.31 100 person-years, respectively).

Conclusions There was no significant difference in thromboembolism and major bleeding between the off-label reduced and on-label standard dose of DOACs. The reduced dose of DOACs was associated with higher risk for thromboembolism compared to well-controlled warfarin in real-world practice. This study suggests that new criteria for dose adjustment of DOACs may be needed in Asian patients with AF.