Risk of stroke overall and by stroke severity among newly diagnosed non-valvular atrial fibrillation patients initiating treatment with rivaroxaban versus warfarin


Background: Standard of care for stroke prevention in patients with non-valvular atrial fibrillation (NVAF) is oral anticoagulation (OAC) therapy. However, the effectiveness of rivaroxaban versus warfarin in risk reduction by stroke severity has not been studied in real-world settings.

Purpose: To compare stroke risk (overall and by severity) between rivaroxaban- and warfarin-initiated NVAF patients.

Methods: This retrospective cohort study (2011–2017) included de-identified patients from the Clinical Database who initiated rivaroxaban or warfarin treatment within 30 days following first NVAF diagnosis. Prior to NVAF diagnosis, patients were required to have 6 months continuous health plan enrollment, CHA2DS2-VASc score ≥ 2, no prior history of stroke or transient ischaemic attack, and no prior OAC use. Rivaroxaban and warfarin patients were followed from treatment initiation until the earliest occurrence of a primary endpoint diagnosis of stroke, death, end of health plan enrollment, or end of study. Patients with ischemic or hemorrhaging stroke defined by ICD-9/-10 codes were included in the study. Stroke severity was determined by the National Institutes of Health Stroke Scale (NIHSS) score, imputed by 127 clinically relevant features selected by a random forest method from our previous study. Cox proportional hazard regression, with adjustment for treatment duration and baseline risk factors, was used to compare stroke risk (overall and by severity) in rivaroxaban- and warfarin-initiated NVAF patients.

Results: In total, 6,384 rivaroxaban- and 13,174 warfarin-initiated patients were included; mean age was 73 and 76 years, respectively. The cohorts were similar for the following baseline characteristics: mean comorbidity index (1.43, rivaroxaban; 1.84, warfarin); mean CHA2DS2-VASc score (3.54, rivaroxaban; 3.92, warfarin); and mean HAS-BLED score (2.28, rivaroxaban; 2.43, warfarin). During follow-up (mean 23 months, rivaroxaban; 28 months, warfarin), 163 (2.6%) rivaroxaban and 515 (3.9%) warfarin patients developed stroke. Rivaroxaban patients had 18% risk reduction (HR 0.82, 95% CI 0.75–0.90; p = 0.027) for stroke overall, 52% risk reduction (HR 0.48, 95% CI 0.32–0.93; p = 0.046) for severe stroke (NIHSS≥16–42), and 32% risk reduction (HR 0.68, 95% CI 0.49–0.94; p = 0.020) for minor stroke (NIHSS=1–5). Risk for moderate stroke (NIHSS≥5–15) was not statistically different between the drug cohorts (HR 0.94, 95% CI 0.69–1.29).

Conclusions: Patients initiating anticoagulant treatment with rivaroxaban showed significant risk reduction relative to warfarin, both in overall stroke and in severe stroke. These data may provide better insight into how anticoagulants perform from real-life practice to inform treatment choices for stroke prevention in the NVAF population.

Watchman implantation in patients with very high stroke risk

O. Wazni, E. Butt, W. Saliba, B. Saqib, A. Barakat, K. Takarai, M. Kanji, B. Lindsay, A. Hussein, V. Vicente, F. Marin, V. Roldan, G.Y.H. Lip

Background: The Watchman device is increasingly used for stroke prevention in patients with CHADSVASC 5.7±0.9 (quartiles 5–6), mean HASBLED 4.0±1.0 (quartiles 3–5). Indications for implantation were significant prior bleeding in 74%, irreversible bleeding in 21% and unacceptable stroke risk alone in 15%. All but 2 patients completed 45 days of anticoagulation: one had retroperitoneal hematoma 30 days post implantation in warfarin and one had intracranial hemorrhage resulting in death (original implantation was associated with better outcomes). Underlying decision-making may improve OAC prescription rates and outcomes in AF.

Purpose: To assess the role of Watchman in patients with CHADSVASC ≥5.

Methods: All patients undergoing Watchman implant at our institution were enrolled in a prospective registry. We included all 104 Watchman recipients with CHADSVASC ≥5.

Results: Median age was 78.5±6.4 years and 56% were male: mean CHADSVASC 5.7±0.9 (quartiles 5–6), mean HASBLED 4.0±1.0 (quartiles 3–5). Indications for implantation were significant prior bleeding in 74%, irreversible bleeding in 21% and unacceptable stroke risk alone in 15%. All but 2 patients completed 45 days of anticoagulation: one had retroperitoneal hematoma 30 days post implantation in warfarin and one had intracranial hemorrhage resulting in death (original implantation was associated with better outcomes). Underlying decision-making may improve OAC prescription rates and outcomes in AF.

Conclusion: In a population of patients with mean CHADSVASC of 5.7, Watchman implantation appeared to be efficacious, with a residual annual stroke risk of only 2.8%. This population would otherwise have an estimated annual risk of stroke of ≥12% off anticoagulation and >4% on warfarin.