

Low bleeding and stroke rates in AF patients given rivaroxaban for stroke prevention

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Atrial fibrillation (AF) patients treated with rivaroxaban for stroke prevention have low rates of bleeding and stroke, reveals real-world data from the XANTUS study presented at ESC Congress today. The findings confirm clinical trial data and demonstrate that oral anticoagulation with rivaroxaban, a direct Factor Xa inhibitor, is safe and effective for stroke prevention in patients with AF at both high- and low-risk of thromboembolic events.

"With 10 million people in Europe alone affected by AF, a number that is only expected to increase, real-world insights on routine anticoagulation management in everyday [clinical practice](#) is increasingly important for physicians and [patients](#) with AF," said XANTUS principal investigator Professor A. John Camm, professor of clinical cardiology in the Cardiovascular and Cell Sciences Research Institute at St George's University of London, UK.

XANTUS is the first international, prospective real-world non-vitamin K antagonist oral anticoagulant (NOAC) study in patients with AF. These patients are five times more likely than the general population to have a stroke. However, [oral anticoagulation](#) therapy can prevent many cases of AF-related stroke.

This single-arm, observational study evaluated the safety and effectiveness of rivaroxaban for stroke prevention in 6 784 patients with non-valvular AF from 311 centres across Europe and Canada in routine clinical practice. All treatment and dosing decisions were at the

discretion of the treating physicians and patients were followed up for one year or until 30 days after premature discontinuation. Bleeding events and major thromboembolic events were centrally adjudicated by an independent committee.

By the end of the observation period the majority (96.1%) of patients had not experienced treatment-emergent major bleeding, all-cause death or stroke / systemic embolism. The rate of on-treatment all-cause mortality was 1.9% per year. Overall, 2.1% of patients per year experienced treatment-emergent major bleeding and most of these cases were treated using standard clinical measures. The rate of fatal bleeding was 0.2% per year, while stroke occurred in 0.7% patients per year, and critical organ bleeding occurred at a rate of 0.7% per year with 0.4% per year of patients experiencing an intracranial haemorrhage.

"These results demonstrate low rates of both major bleeding and stroke in patients taking rivaroxaban in routine clinical practice," said Professor Camm. "The findings reaffirm the positive benefit-risk profile of rivaroxaban established in the phase III clinical trial ROCKET AF, in which rivaroxaban was shown to provide effective [stroke prevention](#) with a similar overall bleeding profile and significantly lower rates of the most feared intracranial and fatal bleeds compared with vitamin K antagonists (VKAs)."

He continued: "The patients included in ROCKET AF were at moderate to high risk of stroke with a mean CHADS2 score of 3.5, and the incidence of major bleeding in those taking rivaroxaban was 3.6 per 100 person-years. In XANTUS, patients seen in daily clinical practice had a lower risk of stroke with a mean CHADS2 score of 2.0 and the incidence rate of [major bleeding](#) was lower at 2.1 per 100 person-years."

Furthermore, XANTUS showed that the majority of patients (80%) persisted on their treatment with rivaroxaban throughout the one year

study period, whereas other recent data on VKAs has shown a persistence rate of 62% after one year. "Treatment persistence is especially important as discontinuation of anticoagulation leaves patients with AF unprotected from the risk of stroke," said Professor Camm.

He concluded: "These real-world insights from XANTUS complement and expand on what we already know from clinical trials, and provide physicians with reassurance to prescribe rivaroxaban as an effective and well-tolerated treatment option for the broad range of patients with AF seen in their everyday clinical practice."

More information: Professor Camm will present the abstract 'XANTUS: Low rates of bleeding and stroke in a real-world, prospective, observational study of patients treated with rivaroxaban for stroke prevention in atrial fibrillation'

Patel MR, Mahaffey KW, Garg J, et al. Rivaroxaban versus warfarin in nonvalvular atrial fibrillation. *N Engl J Med.* 2011;365:883-891.

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