XANTUS-EL: A Real-World, Prospective, Observational Study of Patients Treated With Rivaroxaban For Stroke Prevention In Atrial Fibrillation In Eastern Europe, Middle East, Africa And Latin America

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ABSTRACT

AIMS: The real-world, international, prospective, observational XANTUS study demonstrated low rates of stroke and major bleeding in an unselected atrial fibrillation (AF) patient population treated with rivaroxaban in routine clinical practice in Europe, Canada and Israel. XANTUS-EL is a sister study to XANTUS with the aim to investigate the safety and effectiveness of rivaroxaban in routine clinical use in patients with AF in Eastern Europe, Middle East, Africa and Latin America.

METHODS AND RESULTS: XANTUS-EL was a prospective, observational study of unselected patients with non-valvular AF newly starting rivaroxaban for stroke prevention. Patients were followed for 1 year, at ~3-month intervals, or for ≥30 days after permanent discontinuation. Primary outcomes were major bleeding, adverse events (AEs) or serious AEs (SAEs) and allcause mortality. Secondary outcomes included symptomatic thromboembolic events and non-major bleeding. All events were collected as AEs or SAEs. Major outcomes were adjudicated by a central committee. 2064 patients were enrolled from January 2013 to January 2016. 80.3% received rivaroxaban 20 mg once daily (od) and 18.9% received 15 mg od; 59.2% had prior anticoagulation therapy. Mean age was 67.1 (11.32) years (≥75 years: 28.2%); first available weight was 82.9 (17.06) kg; 49.3% were male; 57.4% had first available CrCl of ≥50 mL/min (missing values: 29.8%); 14.1% had newly diagnosed AF, 33.8% paroxysmal AF, 14.5% persistent AF and 37.4% permanent AF. Co-morbidities included congestive heart failure (30.9%), hypertension (84.2%), diabetes mellitus (26.5%), prior stroke/non-CNS systemic embolism (SE)/transient ischaemic attack (TIA; 16.2%) and prior myocardial infarction (MI; 10.7%). Mean $CHADS_2$ and CHA_2DS_2-VASc scores were 2.0 and 3.6, respectively; mean HAS-BLED score was 1.6. Rates of treatment-emergent major outcomes were as follows (events/100 patient-years, [95% CI]): major bleeding 0.9 (0.5–1.4) (fatal 0.1 [0.0–0.3]; intracranial 0.16 [0.03–0.46]); all-cause mortality 1.7 (1.2–2.4); stroke/non-CNS SE 0.7 (0.4–1.2); stroke 0.6 (0.3–1.1); non-CNS SE 0.1 (0.0– 0.3); TIA 0.3 (0.1–0.6); MI 0.3 (0.1–0.7); and any AE 18.1 (16.2–20.1) and SAE 8.3 (7.0–9.7). Incidence of haemorrhagic and ischaemic stroke was 0.05% and 0.5%, respectively. Treatment persistence was 81.9%.

CONCLUSIONS: In the XANTUS-EL real-world, prospective, observational study of rivaroxaban in patients with AF in Eastern Europe, Middle East, Africa and Latin America, rates of stroke/non-CNS SE and major bleeding were low. This patient population was younger than that in XANTUS, but with a similar baseline risk of stroke. Ischaemic stroke rates were similar to those in XANTUS and major bleeding rates were lower.

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