

New study highlights low bleeding risk of Xarelto in Asian patients

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First study of its kind across 10 Asian countries reinforces safety benefit of Xarelto in Asian patients.



Singapore – The full results from the XANAP (Xarelto for Prevention of Stroke in Patients with Atrial Fibrillation in Asia) study were recently published in the *Journal of Arrhythmia*, the official publication of the Asia Pacific and Japan Heart Rhythm Societies. XANAP, which was conducted across 10 Asian countries, is the first and largest prospective study to date in Asia investigating the use of the non-vitamin K antagonist oral anticoagulant (NOAC) Xarelto (Rivaroxaban) in a broad patient population with the heart rhythm disorder non-valvular atrial fibrillation (AF). The real-world data highlight low bleeding rate (1.5% per year) and low stroke rate (1.7% per year) in AF patients treated with Xarelto, and confirm Xarelto's robust safety and efficacy benefit in Asian patients.

"The prevalence of AF is growing in Asia, with an estimated 72 million patients by 2050. These patients will have a five-fold increased risk of stroke due to blood clots. While NOACs offer a new standard of care in preventing AF-related strokes, major bleeding is a key consideration of doctors when prescribing NOACs for AF patients. This data confirms the low bleeding risk of Rivaroxaban in Asian patients, thus reaffirming its positive benefit/risk profile, and demonstrate its value in preventing the negative impact of stroke on patients and society," said XANAP Principal Investigator Professor Young-Hoon Kim, Korea University Medical Centre, Seoul, S. Korea. In XANAP, the major bleeding rate of patients treated with Xarelto was low at 1.5% per year. Specifically, the rates of gastrointestinal (GI) bleeding and fatal intracranial (skull) bleeding was relatively low at 0.5% and 0.7% per year respectively. Stroke rate was also, low at 1.7% per year, reaffirming Xarelto's effectiveness in preventing AF-related strokes. Over 96% of patients treated with Xarelto in the study did not experience any major bleeding, stroke/systemic embolism (SE), or all-cause death. The study includes elderly patients across varying levels of stroke risk, with significant medical co-morbidities including heart failure, hypertension, diabetes mellitus, prior stroke/ SE/transient ischemic attack and myocardial infarction.

Major bleeding and stroke rates generally rise with increasing CHADS2 scores or CHA2DS2-VASc scores. CHADS2 score or CHA2DS2-VASc score defines a patient's stroke risk (0=low risk; 1=intermediate risk; ? 2=high risk). In the XANAP study, the

mean CHADS2 score is 2.3 and CHA2DS2-VASc score is 3.71. This study adds to the robust experience and evidence that establish the safety profile of Xarelto across patients with varying risk profiles. In the Phase III trial ROCKET AF which determined the regulatory approval of Xarelto in stroke prevention in AF globally, patients have a higher risk of stroke with a mean CHADS2 score of 3.52. This study has more high-risk patients with comorbidities than any other NOACs in Phase III clinical trials^{2,3,4,5}. Despite this, low bleeding and stroke rates were observed, attesting to the safety of Xarelto in high-risk patients.

“It is important to consider a patient’s individual risk factors to prescribe the right NOAC to the right patient for AF stroke prevention. Rivaroxaban’s robust experience and evidence in patients across different risk profiles, including those with high stroke risk, will best support doctors and patients in their treatment decision in AF management. The positive data of XANAP further add to this and reaffirm the proven safety profile of Rivaroxaban in Asian patients,” said XANAP Principal Investigator Professor Chia-Ti Tsai, National Taiwan University Hospital, Taipei, Taiwan.

XANAP is part of the global XANTUS program which comprises three prospective, non- interventional studies, spanning three regions and 47 countries. Results from a large pooled analysis of XANTUS in 11,121 patients were recently published in the Journal of the American College of Cardiology, confirming the global safety profile of Xarelto in routine clinical practice.