AFIRE – Atrial Fibrillation and Ischemic events with Rivaroxaban in patienEnts with stable coronary artery disease

Purpose: To investigate whether rivaroxaban monotherapy is non-inferior to combination therapy (rivaroxaban plus an antiplatelet agent) in patients with AF and stable CAD more than 1 year after revascularization or in those with angiographically confirmed CAD not requiring revascularization.

Trial Design: Randomize to Rivaroxaban monotherapy 10 or 15 mg/day. Or combination therapy Rivaroxaban 10 or 15 mg/day plus with a aspirin 81 or 100mg/day or clopidogrel 50 or 75 mg/day, Prasugrel 2.5 or 3.75mg/day

Primary Endpoints: ***Efficacy:*** stroke, systemic embolism, MI, UAP requiring revascularization, or death from any cause. ***Safety:*** major bleeding (ISTH criteria)

Due to the higher risk of death from any cause in the combination – therapy group, the independent DSMC recommended early termination of the trial in July 2018.

	Combination therapy	Monotherapy	Hazard Ratio
Primary Efficacy Events	5.75% / year	4.14% / year	0.72 (CI 0.0.55 – 0.95)
Primary Safety Events	2.76% / year	1.62% / year	0.59 (CI 0.39-0.89)

Key takeaways:

- At 24 months monotherapy was noninferior to combination therapy for ischemic events and superior for major bleeding.
- Monotherapy with rivaroxaban without antiplatelet therapy is a better approach to treatment in patients with AF and stable CAD.

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