AFIRE – Atrial Fibrillation and Ischemic events with Rivaroxaban in patients 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 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.

<table>
<thead>
<tr>
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<th>Combination therapy</th>
<th>Monotherapy</th>
<th>Hazard Ratio</th>
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</thead>
<tbody>
<tr>
<td>Primary Efficacy Events</td>
<td>5.75% / year</td>
<td>4.14% / year</td>
<td>0.72 (CI 0.55 – 0.95)</td>
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<tr>
<td>Primary Safety Events</td>
<td>2.76% / year</td>
<td>1.62% / year</td>
<td>0.59 (CI 0.39-0.89)</td>
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</tbody>
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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.

Presented by: S Yasuda, ESC 2019 Paris, France
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