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Topic 1: Ischemic Heart Disease
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PublishedNameofTrail: VOYAGER PAD
TrialType: Late-breaking clinical trial: major study
Publishing Title: Reductions In Total Ischemic Events With Rivaroxaban In Patients With Symptomatic Pad After Revascularization: The VOYAGER PAD Trial

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Abstract Body:

Background: Patients with peripheral artery disease (PAD) undergoing lower extremity revascularization (LER) are at high risk of major adverse limb and cardiovascular (CV) events. VOYAGER PAD demonstrated that rivaroxaban 2.5 mg twice daily with aspirin versus aspirin alone reduced first events by 15%. The benefit of rivaroxaban on total (first and potentially subsequent) events in this population is unknown.

Methods: VOYAGER PAD was a double-blind, placebo-controlled trial of PAD patients undergoing LER randomized to rivaroxaban 2.5 mg twice daily or placebo on a background of aspirin 100 mg daily. The primary endpoint was time to first event in a composite of acute limb ischemia, major amputation of a vascular cause, myocardial infarction, ischemic stroke, or CV death. The present total events analysis was prespecified, with hazard ratios estimated by a shared log-normal frailty model.

Results: Among 6,564 randomized patients there were 1,092 first and 522 subsequent primary events. Rivaroxaban reduced first events by 15% (HR 0.85, 95% CI 0.76 - 0.96, p=0.0085; 76 first events avoided). Rivaroxaban also reduced total events (HR 0.82, 95% CI 0.71 - 0.94, p=0.0049; 124 total events avoided).

Conclusion: In VOYAGER PAD, among patients with symptomatic PAD undergoing LER, the total number of events prevented with rivaroxaban 2.5 mg twice daily with aspirin was nearly twice the number of first events avoided. Total event reduction may be useful metric to quantify the efficacy of rivaroxaban in this setting.