

VOYAGER PAD



AMERICAN COLLEGE of CARDIOLOGY

Rivaroxaban in Peripheral Artery Disease After Revascularization


Randomized, parallel, stratified clinical trial



Objective: To evaluate outcomes of treatment with rivaroxaban/aspirin vs. placebo/aspirin for peripheral artery disease (PAD) patients undergoing revascularization.

6,564
patients


Inclusion criteria: Patients aged ≥ 50 years with lower extremity PAD evidenced by abnormal ABIs, imaging, and ischemic symptoms that underwent successful lower extremity revascularization



Rivaroxaban 2.5 mg twice daily/aspirin (n = 3,286)

VS

Placebo/aspirin (n = 3,278)



PRIMARY OUTCOME

17.3

CV death, acute limb ischemia, major amputation, MI, or stroke %
HR 0.85; 95% CI, 0.76 to 0.96; P=0.009

19.9

2.7

Thrombolysis in Myocardial Infarction (TIMI), major bleeding %
HR 1.43; 95% CI, 0.97 to 2.10; P=0.07

1.9

SECONDARY OUTCOME

5.9

ISTH major bleeding %
HR 1.42; 95% CI, 1.10 to 1.84; P=0.007

4.1

Conclusion: In patients with PAD who had undergone lower-extremity revascularization, rivaroxaban + aspirin was associated with a significantly lower incidence of vascular outcomes. The incidence of TIMI major bleeding did not differ significantly between the groups. The incidence of ISTH major bleeding was significantly higher with rivaroxaban and aspirin than with aspirin alone.