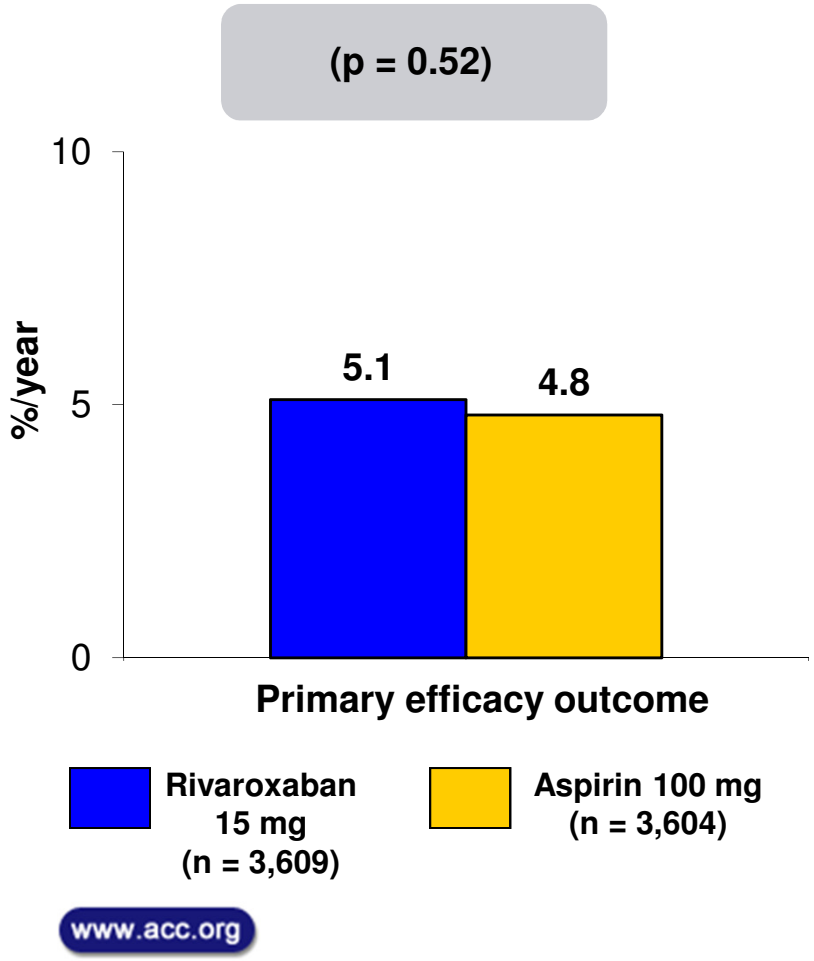
NAVIGATE ESUS

Trial design: Patients with recent embolic stroke of undetermined source (ESUS) were randomized in a 1:1 fashion to either rivaroxaban 15 mg daily or aspirin 100 mg daily. Both arms also received a placebo. Patients were followed for 11 months. Trial terminated early.



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Results

- Primary efficacy outcome, recurrent stroke or systemic embolism, for rivaroxaban vs. aspirin 5.1%/yr vs. 4.8%/yr, p = 0.52
- Primary safety outcome, ISTH major bleeding: 1.8%/yr vs. 0.7%/yr, p < 0.001
- Hemorrhagic stroke: 0.4%/yr vs. 0.1%/yr; p < 0.05; Intracranial hemorrhage: 0.6%/yr vs. 0.1%/yr; p = 0.003

Conclusions

- Rivaroxaban 15 mg is not superior to low-dose aspirin in reducing recurrent strokes among patients with ESUS; it however increased major bleeding, including hemorrhagic strokes and symptomatic ICH; this strategy is thus inferior to aspirin
- Unclear if reduced-intensity rivaroxaban (similar to COMPASS trial) would have shown benefit

Hart RG, et al. N Engl J Med 2018;May 16:[Epub]