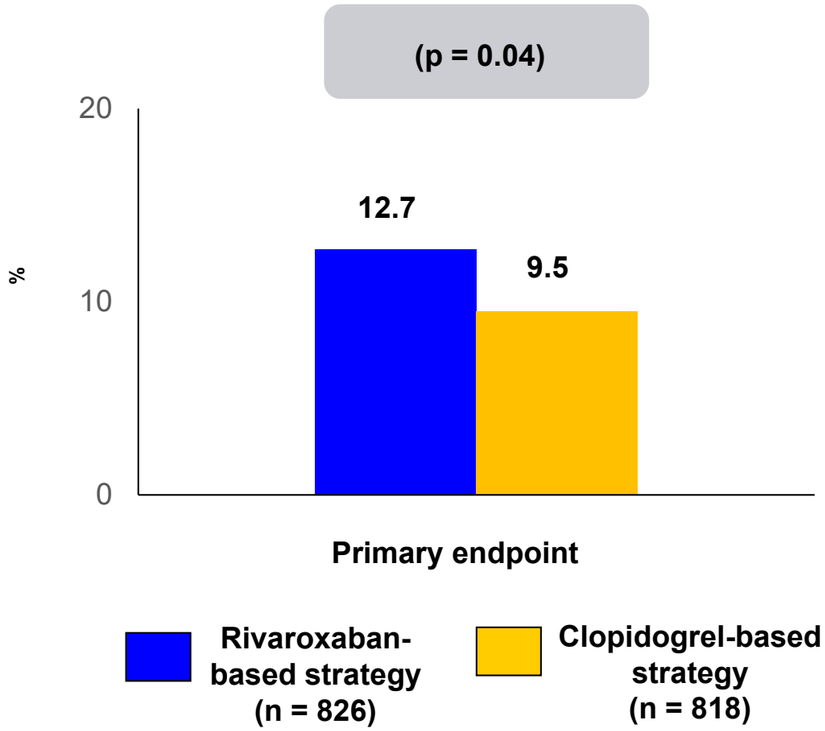
GALILEO

#AHA19

Trial Description: Patients were randomized 1-7 days after TAVR to rivaroxaban 10 mg daily/aspirin 75-100 mg daily vs. clopidogrel 75 mg daily/aspirin 75-100 mg daily. At 90 days, rivaroxaban alone was continued in the experimental group, while aspirin alone was continued in the control group.



RESULTS

- The trial was terminated early due to safety concerns
- The primary efficacy outcome of death, MI, stroke, systemic thromboembolism, symptomatic valve thrombosis, or DVT/PE occurred in 12.7% of the rivaroxaban group vs. 9.5% of the clopidogrel group (p = 0.04)
- The primary safety outcome of VARC-2 major, disabling, or life-threatening bleeding occurred in 5.6% of the rivaroxaban group vs. 3.8% of the clopidogrel group (p = 0.08)

CONCLUSIONS

- Among patients who underwent TAVR and who did not have an indication for anticoagulation, a rivaroxaban-based strategy was not effective at preventing major adverse cardiovascular events compared with a clopidogrel-based strategy

Dangas GD, et al. N Engl J Med 2019;Nov 16:[Epub]