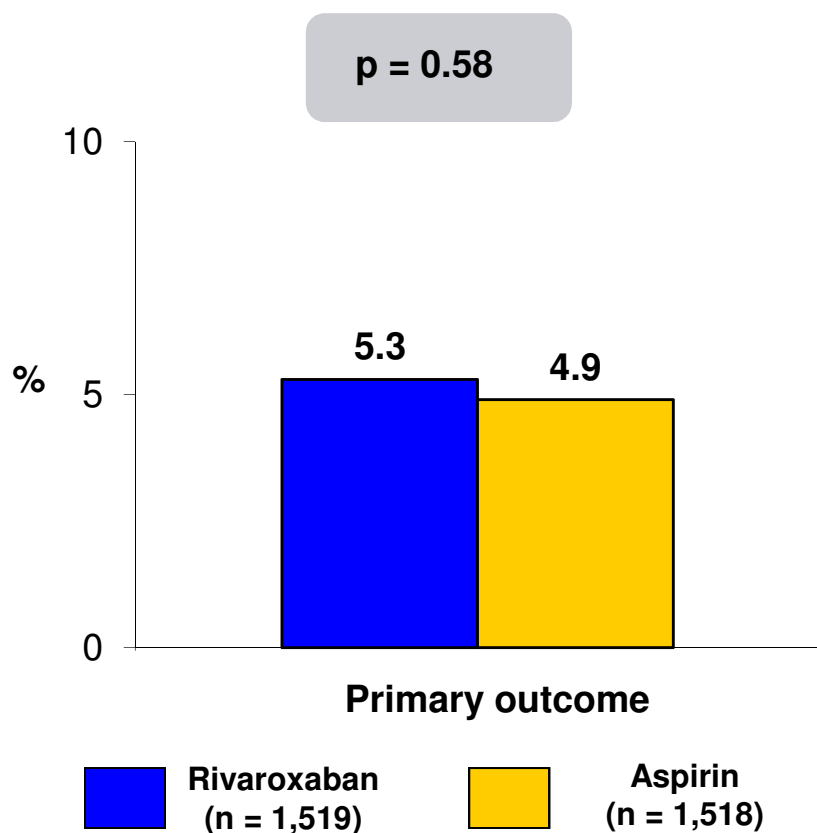


GEMINI-ACS-1

Trial design: Following an ACS event, patients already on a P2Y12 inhibitor were randomized in a 1:1 fashion to either continuing aspirin 100 mg daily or to rivaroxaban 2.5 mg BID. Patients were followed for 1 year.



Results

- Primary endpoint: TIMI non-CABG clinically significant bleeding: rivaroxaban vs. aspirin: 5.3% vs. 4.9%, $p = 0.58$
- GUSTO moderate/severe/life-threatening bleeding: 0.7% vs. 0.5%, $p = 0.34$
- CV death/MI/stroke/definite stent thrombosis: 5.0% vs. 4.7%, $p = 0.73$

Conclusions

- Phase II trial; indicates that low-dose rivaroxaban (2.5 mg BID) does not result in higher bleeding compared with aspirin 100 mg daily in patients already on a P2Y12 inhibitor post-ACS
- Ischemic endpoints were also similar, but the trial was not powered to assess these independently