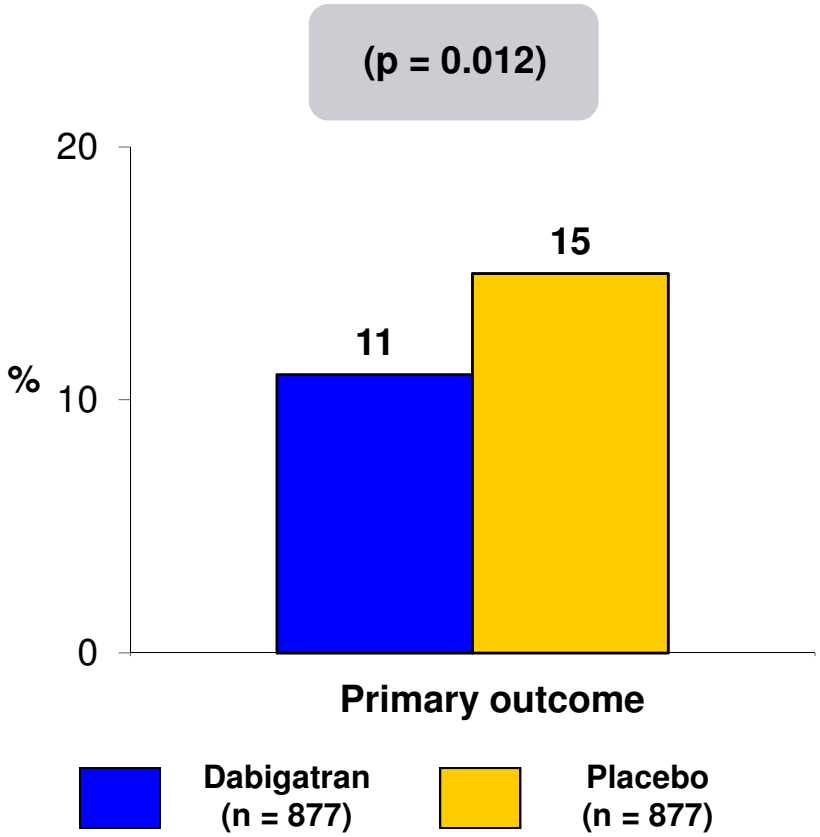
MANAGE

Trial design: Patients with evidence of myocardial injury after noncardiac surgery were randomized in a 1:1 fashion to either dabigatran 110 mg or placebo. Patients were followed for 16 months. The trial was terminated early.



Results

- Primary outcome, vascular death/MI/stroke/peripheral arterial thrombosis/amputation/VTE: dabigatran vs. placebo: 11% vs. 15%, p = 0.012
- Primary safety outcome, composite of life-threatening, major, critical organ bleeding: 3% vs. 4%, p = 0.76
- Vascular mortality: 6% vs. 7%, MI 4% vs. 5%, symptomatic VTE: 1% vs. 2%

Conclusions

- Addition of dabigatran 110 mg BID among patients with evidence of myocardial injury post-noncardiac surgery had lower major vascular event rates compared with placebo; bleeding complications were similar
- Results are interesting. Caveats: trial was terminated early, primary outcome definition was changed mid-way through the trial, >40% drug discontinuation

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Presented by Dr. P.J. Devereaux at ACC 2018