OPT-BIRISK trial

#ESCCongress

Extended clopidogrel monotherapy versus DAPT in high-risk patients

Conclusion

Extended P2Y12 inhibitor monotherapy beyond 12 months after percutaneous coronary intervention (PCI) reduces bleeding and ischaemic events in acute coronary syndrome (ACS) patients at high risk for both types of events.

Impact on clinical practice

Extended P2Y12 inhibitor monotherapy benefits high-risk ACS patients.

Study objectives

The OPT-BIRISK trial examined whether in ACS patients with both high bleeding and ischaemic risk characteristics who remained event-free after a standard course of dual antiplatelet therapy (DAPT) following PCI, an extended course of clopidogrel monotherapy would be superior to ongoing DAPT treatment with aspirin and clopidogrel.

Study population

Patients who

- completed 9 to 12 months of DAPT (aspirin plus either clopidogrel or ticagrelor) after drug-eluting stent implantation for the treatment of ACS
- were free from major adverse clinical events during the prior 6 months
- were at both high bleeding and ischaemic risk

Where?

101 Chinese centres

Who and what?

7,758 patients

randomised 1:1

clopidogrel (75 mg/day) + placebo

clopidogrel (75 mg/day) + aspirin (100 mg/day)

for 9 months

open-label aspirin monotherapy (100 mg/day) for an additional 3 months to exclude rebound events

Primary endpoint

Rate of clinically-relevant bleeding 9 months after randomisation, defined as Bleeding Academic Research Consortium (BARC) types 2, 3, or 5 bleeding.

Rate%

+ placebo — 2.5%

+ aspirin — 3.3%

Hazard ratio 0.75, 95% CI 0.57–0.97
difference -0.8%, 95% CI -1.6% to -0.1%
p=0.03

Key secondary endpoint

Rate of major adverse cardiac and cerebral events (MACCE) 9 months after randomisation, defined as a composite of all-cause death, myocardial infarction, stroke or clinically-driven revascularisation

Rate%

+ placebo — 2.6%

+ aspirin — 3.5%

Hazard ratio 0.74, 95% CI 0.57–0.96
difference -0.9%, 95% CI -1.7% to -0.1%
p<0.001 for non-inferiority, p=0.02 for superiority

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