Results suggest extending post-stenting DAPT beyond one year

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Extending clot-preventing dual antiplatelet therapy (DAPT) beyond the recommended 12 months after coronary stenting "should be considered" in patients at low risk for bleeding, investigators for the OPTIDUAL trial recommend.

Results of the trial were presented at a Hot Line session at ESC congress 2015 today.

While the investigator-initiated study showed that DAPT (a combination of aspirin and the P2Y12-receptor blocker clopidogrel) does not decrease the rate of major adverse cardiovascular and cerebrovascular events (MACCE), there was nevertheless a hint that it might reduce ischemic outcomes without excess bleeding.

"Given the lack of harm and the signal for benefit of prolonged DAPT in the OPTIDUAL trial, and the results from prior randomised trials testing long durations of DAPT, prolongation of DAPT beyond 12 months should be considered in patients without high-risk bleeding, who have received a drug-eluting coronary stent and are event-free at 12 months," said principal investigator Gérard Helft, MD, PhD from the Institut de Cardiologie, Hôpital Pitié-Salpétrière, in Paris, France.

The study included 1,385 patients from 58 French sites who had undergone percutaneous coronary intervention (PCI) with placement of at least one drug-eluting stent (DES) for either stable coronary artery disease or acute coronary syndrome.

All patients had been on DAPT for one year and were randomly assigned to continue or to remain on aspirin alone for an additional 36 months.

The study found no statistical difference between the groups for the primary MACCE endpoint, a composite of all-cause death, myocardial infarction, stroke, and major bleeding (5.8% in the extended-DAPT group and 7.5% in the aspirin only group, P=0.17).

Rates of death were 2.3% in the extended-DAPT group and 3.5% in the aspirin group (P=0.18).

However, there was a borderline but non-statistically significant reduction in ischaemic outcomes (a post-hoc outcome composite rate of death, myocardial infarction, or stroke) with extended DAPT (4.2% in the extended-DAPT group and 6.4% in the aspirin group (hazard ratio [HR] 0.64, 95% CI 0.40–1.02, P=0.06) without increased bleeding (2.0% in both groups, P=0.95) or increased all-cause mortality.

The OPTIDUAL trial was designed as a superiority trial, and while it failed to show superiority for extended DAPT, "the results are consistent with the recent findings on ischemic outcomes from the DAPT trial regarding the value of prolonging DAPT after DES placement," said Professor Helft.

"There was no apparent harm, and the post hoc efficacy signal on MACE is consistent with the benefit seen in the DAPT trial. Thus, OPTIDUAL adds to the evidence suggesting benefit to extended DAPT after DES in patients who are event free at 12 months."

Professor Helft commented that the optimal duration of dual antiplatelet therapy after PCI with drug-eluting stent (DES) "is one of the hottest topics in interventional cardiology. The use of DAPT is critically important for the prevention of coronary stent thrombosis, but the optimal duration remains highly debated. This is a major clinical issue, given the large number of patients treated with DES, the costs and risks of antiplatelet therapy, the potentially life-threatening consequences of stent thrombosis and the potential benefits of antiplatelet therapy in preventing ischemic outcomes beyond stent thrombosis."

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