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Efficacy and safety of ticagrelor monotherapy in patients with complex percutaneous coronary intervention: insights from the Global Leaders trial

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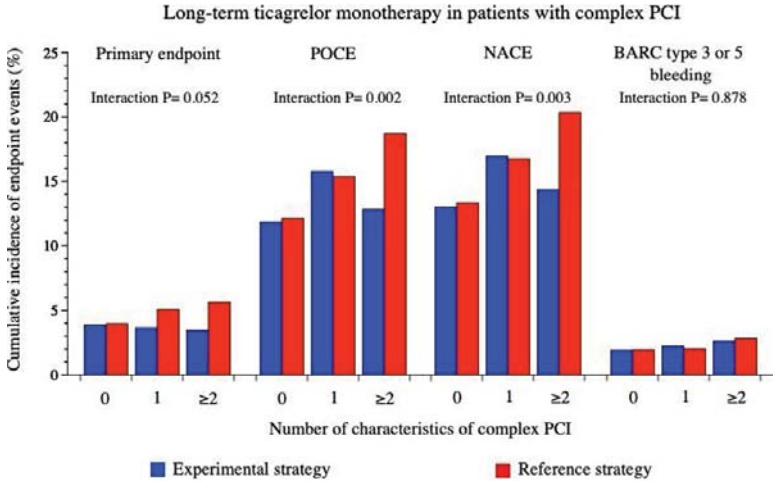
Background/Introduction:
Optimal dual antiplatelet therapy (DAPT) in patients with complex percutaneous coronary intervention (PCI) with drug-eluting stents (DES) has not been fully investigated.

Purpose:
To evaluate the efficacy and safety of 1-month DAPT followed by 23-month ticagrelor monotherapy in patients who underwent complex PCI.

Methods: The Global Leaders trial recruited 15,991 patients treated by default with a biolimus A9-eluting stent, and randomised in a 1:1 ratio either to the experimental strategy (1-month dual antiplatelet therapy [DAPT] followed by 23-month ticagrelor monotherapy) or to the reference regimen (12-month DAPT followed by 12-month aspirin monotherapy). Complex PCI includes at least one of the following characteristics; left main and/or multivessel PCI, long stenting (defined as total stent length≥46mm), and bifurcation treatment with two stents. The present sub-analysis of the trial evaluated at two years the primary endpoint (composite of all-cause death and new Q-wave myocardial infarction [MI] centrally adjudicated with the Minnesota code). In addition, the patient-oriented composite endpoint (POCE) (composite of all-cause death, any stroke, any MI, and any revascularization) and the net adverse clinical events (NACE) (composite of POCE and Bleeding Academic Research Consortium [BARC] type 3 or 5 bleeding) were also evaluated at two years.

Results: Of 15,450 patients included in the present analysis, 5,188 (26.7%) patients underwent complex PCI. The experimental strategy, when compared with the reference one, had a significantly lower risk of the primary endpoint (3.56% vs. 5.33%, HR: 0.66; 95% CI: 0.51–0.86; p-value= 0.002; p-value for interaction= 0.019) in patients with complex PCI. Similarly, the experimental treatment was associated with a significantly reduced risk of POCE (14.41% vs. 16.88%, HR: 0.84; 95% CI: 0.74–0.97; p=0.016, p-value for interaction= 0.099) and NACE (15.77% vs. 18.37%, HR: 0.85; 95% CI: 0.74–0.97; p=0.014; p-value for interaction= 0.096). The reduction in ischemic events was predominantly observed in patients with 2 or more characteristics of complex PCI (Figure). In contrast, there was no significant difference in the risk of BARC type 3 or 5 bleeding between the two regimens (2.40% vs. 2.38%, HR: 1.01; 95% CI: 0.71–1.44; p-value=0.956; p-value for interaction= 0.935).

Conclusion: Together with other well-established clinical risk factors, the extent and complexity of stenting should be taken into account in tailoring antiplatelet regimens for secondary prevention. The 1-month DAPT followed by 23-month ticagrelor monotherapy reduced the ischemic events without increasing the risk of bleeding in patients who underwent complex PCI, when compared with the conventional DAPT.



Central illustration