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Ticagrelor monotherapy beyond one month after PCI in ACS or stable CAD in elderly patients: a pre-specified analysis of the GLOBAL LEADERS trial.

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Ticagrelor monotherapy beyond one month after PCI in ACS or stable CAD in elderly patients: a pre-specified analysis of the GLOBAL LEADERS trial

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Abstract: AIMS Antiplatelet treatment in the elderly post percutaneous coronary interventions (PCI) remains a complex issue. Here we report the results of the pre-specified subgroup analysis of the GLOBAL LEADERS trial evaluating the long-term safety and cardiovascular efficacy of ticagrelor monotherapy among patients categorised according to the pre-specified cut-off value of 75 years of age. METHODS AND RESULTS This was a pre-specified analysis of the randomised GLOBAL LEADERS trial (n=15,991), comparing 23-month ticagrelor monotherapy (after one month of DAPT) with the reference treatment (12-month DAPT followed by 12 months of aspirin). Among elderly patients (>75 years; n=2,565), the primary endpoint (two-year all-cause mortality or new Q-wave core lab-adjudicated myocardial infarction [MI]) occurred in 7.2% and 9.4% of patients in the ticagrelor monotherapy and the reference group, respectively (hazard ratio [HR] 0.75, 95% confidence interval [CI]: 0.58-0.99, p=0.041; pint=0.23); BARC-defined bleeding type 3/5 occurred in 5.2% and 4.1%, respectively (HR 1.29, 95% CI: 0.89-1.86; p=0.180; pint=0.06). The elderly with stable CAD had a higher rate of BARC 3/5 type bleeding (HR 2.05, 95% CI: 1.18-3.55) with ticagrelor monotherapy versus the reference treatment (pint=0.02). Elderly patients had a lower rate of definite or probable stent thrombosis (ST) with ticagrelor monotherapy (0.4% vs 1.4%, p=0.015, pint=0.01), compared with the reference group. CONCLUSIONS In this pre-specified, exploratory analysis of the overall neutral trial, there was no differential treatment effect of ticagrelor monotherapy (after one-month dual therapy with aspirin) found in elderly patients undergoing PCI with respect to the rate of the primary endpoint of all-cause death or new Q-wave MI. The lower rate of ST in the elderly with ticagrelor monotherapy is hypothesis-generating. ClinicalTrials.gov identifier: NCT01813435.

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CORONARY INTERVENTIONS

Ticagrelor monotherapy beyond one month after PCI in ACS or stable CAD in elderly patients: a pre-specified analysis of the GLOBAL LEADERS trial

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Aims: Antiplatelet treatment in the elderly post percutaneous coronary interventions (PCI) remains a complex issue. Here we report the results of the pre-specified subgroup analysis of the GLOBAL LEADERS trial evaluating the long-term safety and cardiovascular efficacy of ticagrelor monotherapy among patients categorised according to the pre-specified cut-off value of 75 years of age.

Methods and results: This was a pre-specified analysis of the randomised GLOBAL LEADERS trial (n=15,991), comparing 23-month ticagrelor monotherapy (after one month of DAPT) with the reference treatment (12-month DAPT followed by 12 months of aspirin). Among elderly patients (>75 years; n=2,565), the primary endpoint (two-year all-cause mortality or new Q-wave core lab-adjudicated myocardial infarction [MI]) occurred in 7.2% and 9.4% of patients in the ticagrelor monotherapy and the reference group, respectively (hazard ratio [HR] 0.75, 95% confidence interval [CI]: 0.58-0.99, p=0.041; p_{int}=0.23);

p_{int}=0.06). The elderly with stable CAD had a higher rate of BARC 3/5 type bleeding (HR 2.05, 95% CI: 1.16-3.55) with ticagrelor monotherapy versus the reference treatment (p_{int}=0.02). Elderly patients had a lower rate of definite or probable stent thrombosis (ST) with ticagrelor monotherapy (0.4% vs 1.4%, p=0.015, p_{int}=0.01), compared with the reference group.

Conclusions: In this pre-specified, exploratory analysis of the overall neutral trial, there was no differential treatment effect of ticagrelor monotherapy (after one-month dual therapy with aspirin) found in elderly patients undergoing PCI with respect to the rate of the primary endpoint of all-cause death or new Q-wave MI. The lower rate of ST in the elderly with ticagrelor monotherapy is hypothesis-generating. ClinicalTrials.gov identifier: NCT01813435

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