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Impact of age on clinical outcomes after PCI in patients with ACS and stable CAD treated with 23-month ticagrelor monotherapy following 1-month DAPT in the randomized GLOBAL LEADERS study

M. Tomaniak[1], P. Chichareon[2], R. Modolo[2], P. Buszman[3], M. Sabate[4], T. Geisler[5], C. Hamm[6], P.G. Steg[7], Y. Onuma[8], P. Vranckx[9], M. Valgimigli[10], S. Windecker[10], R. Anderson[11], M. Dominici[12], P.W. Serruys[13]

[1]*Erasmus Medical Centre, ThoraxCenter, Warsaw Medical University, Rotterdam, Netherlands (The);* [2]*Academic Medical Center of Amsterdam, Amsterdam, Netherlands (The);* [3]*Medical University of Silesia, Katowice, Poland;* [4]*Clinic Hospital Barcelona, Barcelona, Spain;* [5]*Uniklinikum Tübingen, Tübingen, Germany;* [6]*University of Giessen, Giessen, Germany;* [7]*FACT (French Alliance for Cardiovascular Trials), Université Paris Diderot, Hôpital Bichat, Paris, France;* [8]*Erasmus Medical Centre, Rotterdam, Netherlands (The);* [9]*Hartcentrum Hasselt, Jessa Ziekenhuis, Hasselt, Belgium;* [10]*Bern University Hospital, Inselspital, University of Bern, Bern, Switzerland;* [11]*University Hospital of Wales, Cardiff, United Kingdom;* [12]*Azienda Ospedaliera S. Maria, Terni, Italy;* [13]*NHLI, Imperial College London, London, London, United Kingdom*
On behalf of GLOBAL LEADERS

Background: The efficacy and safety of ticagrelor monotherapy in elderly patients undergoing percutaneous coronary intervention (PCI) for acute coronary syndromes (ACS) or stable coronary artery disease (CAD) has not been evaluated.

Purpose: To evaluate the efficacy and safety of ticagrelor monotherapy following 1-month dual antiplatelet therapy (DAPT) after PCI in relation to age and clinical presentation in the GLOBAL LEADERS study cohort.

Methods: This is a subanalysis of the randomized multicentre GLOBAL LEADERS study, comparing the experimental strategy of 23-month ticagrelor monotherapy after 1 month of ticagrelor and aspirin with the reference strategy of 12-month DAPT followed by 12-month aspirin monotherapy in 15991 patients undergoing PCI. Patients were categorized into elderly and very elderly according to a pre-specified cut-off of 75 years and a post-hoc defined cut-off of 80 years. Impact of age and clinical presentation (ACS versus stable CAD) on clinical outcome at 2 years was evaluated. The primary endpoint was a composite of all-cause mortality or nonfatal, centrally adjudicated, new Q-wave myocardial infarction.

Results: In the overall elderly (>75 years) population (n=2565), primary endpoint occurred in 7.2% of patients in the experimental group and in 9.4% of patients in the reference group (p=0.041) at 2 years (p int =0.23). Elderly patients in the experimental group had a lower rate of definite stent thrombosis (ST) (0.2% vs. 0.9%, p=0.043, p int=0.03), definite or probable ST (0.4 vs. 1.3%, p=0.015, p int=0.01) and a numerically higher rates of BARC 3 or 5 type bleeding (5.0% vs. 3.9%, p=0.192, p int=0.06), when compared to the reference arm.

Among elderly patients presenting with ACS both treatment groups did not differ in the rates of primary endpoint (9.1% vs. 10.8%, p=0.367) and BARC 3 or 5 type bleeding (4.7% vs. 5.7%, p=0.458), whereas among elderly patients with stable CAD the experimental strategy was associated with numerically lower rates of the primary endpoint (5.7% vs. 8.4%, p=0.046) (p int =0.42) and a higher rate of BARC 3 or 5 type bleedings (5.3% vs. 2.6%, p=0.012) (p int =0.02) at 2 years.

Exploratory analyses among very elderly (≥80 years) patients (n=1169) indicated no significant differences between treatment groups in the rates of the primary endpoint (10.2% vs. 11.7% p=0.411, p int=0.940) and BARC 3 or 5 type bleeding (6.0% vs. 5.3%, p=0.630, p int=0.514) at 2 years.

Conclusions: The efficacy and safety of the experimental treatment strategy of 23-month ticagrelor monotherapy after 1-month DAPT following PCI was not identified as age-dependent. Among elderly patients the anti-ischemic benefit was derived at the expense of increased rate of BARC 3 or 5 type bleeding in stable CAD subgroup, but not in ACS subgroup.