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Effect of ticagrelor monotherapy for 23 months following 1-month DAPT vs. standard DAPT for 12 months followed by 12 months of aspirin monotherapy in patients undergoing complex PCI

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On behalf of the Global Leaders investigators

*Steering committee of the Global Leaders study

Study design of the Global Leaders trial

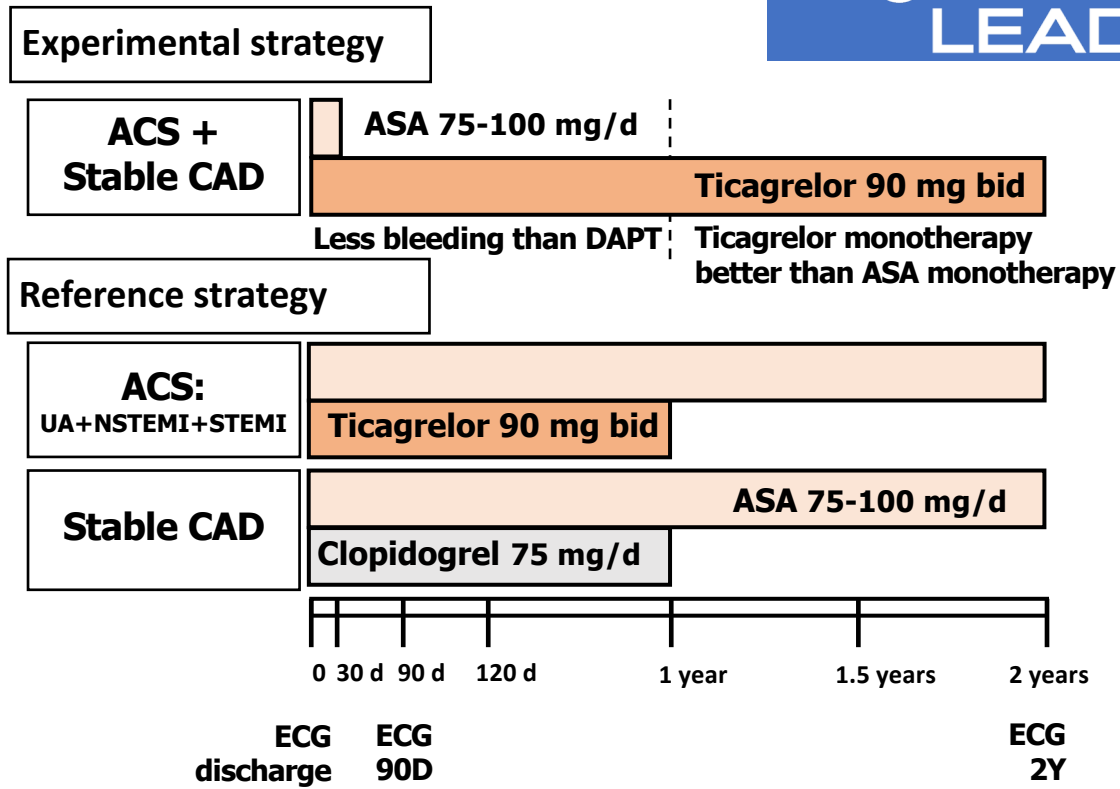
GLOBAL LEADERS

"All-comers" PCI population
N = 15,991
1:1 Randomisation, open-label design, 130 centers worldwide

- Any type of lesions: Left main, SVG, CTO bifurcation, ISR, etc.
- Unrestricted use of DES (number, length)

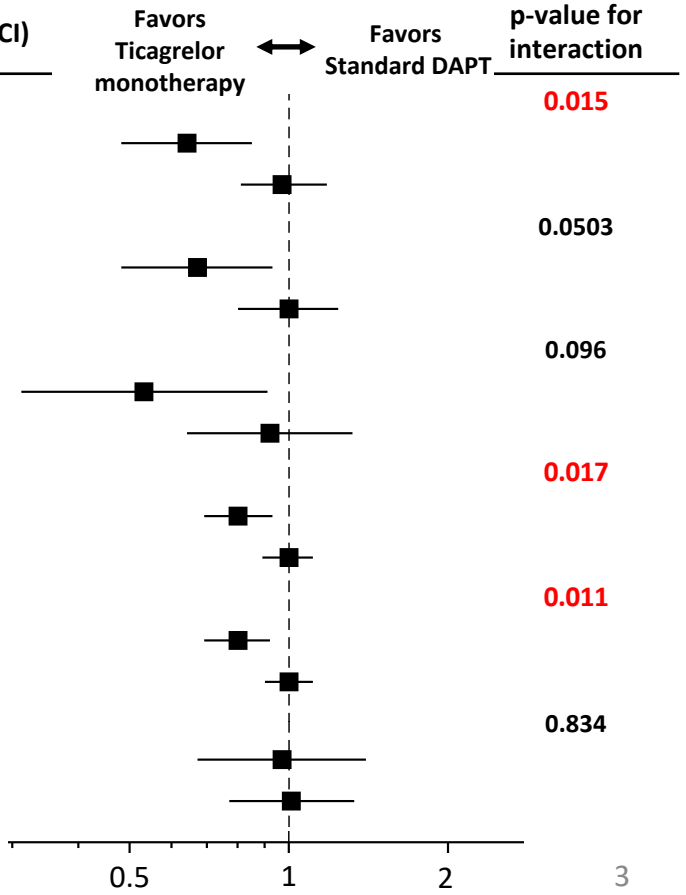
Bivalirudin-supported

BioMatrix DES by default



Treatment effect of the ticagrelor monotherapy vs. the standard DAPT according to complex PCI

	Ticagrelor monotherapy	Standard DAPT	Hazard Ratio (95% CI)	p-value for interaction
Primary endpoint				0.015
Complex PCI	80/2283	124/2287	0.64 (0.48-0.85)	
Noncomplex PCI	211/5434	217/5446	0.97 (0.81-1.18)	
All-cause mortality				0.0503
Complex PCI	60/2283	89/2287	0.67 (0.48-0.93)	
Noncomplex PCI	156/5434	157/5446	1.00 (0.80-1.24)	
New Q-wave MI				0.096
Complex PCI	21/2283	39/2287	0.53 (0.31-0.91)	
Noncomplex PCI	57/5434	62/5446	0.92 (0.64-1.32)	
POCE				0.017
Complex PCI	316/2283	391/2287	0.80 (0.69-0.93)	
Noncomplex PCI	665/5434	672/5446	1.00 (0.89-1.11)	
NACE				0.011
Complex PCI	345/2283	427/2287	0.80 (0.69-0.92)	
Noncomplex PCI	730/5434	736/5446	1.00 (0.90-1.11)	
BARC type 3 or 5 bleeding				0.834
Complex PCI	55/2283	57/2287	0.97 (0.67-1.40)	
Noncomplex PCI	105/5434	104/5446	1.01 (0.77-1.33)	



Why this study?

ESC European Society of Cardiology
European Heart Journal (2019) 40, 87–165
doi:10.1093/eurheartj/ehy394

ESC/EACTS GUIDELINES

2018 ESC/EACTS Guidelines on myocardial revascularization

The Task Force on myocardial revascularization of the European Society of Cardiology (ESC) and European Association for Cardio-Thoracic Surgery (EACTS)

Developed with the special contribution of the European Association for Percutaneous Cardiovascular Interventions (EAPCI)

Authors/Task Force Members: Franz-Josef Neumann* (ESC Chairperson) (Germany), Miguel Sousa-Uva*[1] (EACTS Chairperson) (Portugal), Anders Ahlsson[1] (Sweden), Fernando Alfonso (Spain), Adrian P. Banning (UK), Umberto Benedetto[1] (UK), Robert A. Byrne (Germany), Jean-Philippe Collet (France), Volkmar Falk[1] (Germany), Stuart J. Head[1] (The Netherlands), Peter Jüni (Canada), Adnan Kastrati (Germany), Akos Koller (Hungary), Steen D. Kristensen (Denmark), Josef Niebauer (Austria), Dimitrios J. Richter (Greece), Petar M. Seferović (Serbia), Dirk Sibbing (Germany), Giulio G. Stefanini (Italy), Stephan Windecker (Switzerland), Rashmi Yadav[1] (UK), Michael O. Zembala[1] (Poland)

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Table 9. High-risk features for ischaemic events

Prior stent thrombosis on adequate antiplatelet therapy
Stenting of the last remaining patent coronary artery
Diffuse multivessel disease, especially in diabetic patients
Chronic kidney disease
At least three stents implanted
At least three lesions treated
Bifurcation with two stents implanted
Total stented length >60 mm
Treatment of a chronic total occlusion
History of STEMI

Neumann et al. Eur Heart J. 2019 Jan 7;40(2):87-165.

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Table 9. High-risk features for ischaemic events

One of the exclusion criteria in the trial
Technically not an exclusion criteria
Diffuse multivessel disease, Diabetes (patient related)
Chronic kidney disease (patient related)
At least three stents implanted
At least three lesions treated
Bifurcation with two stents implanted
Total stented length >60 mm
Duration of occlusion was not captured in the eCRF
History of STEMI (patient related)

Neumann et al. Eur Heart J. 2019 Jan 7;40(2):87-165.

Why is this important?

- Patients who underwent complex PCI had a higher risk of ischemic and bleeding events at two years, as compared to the non-complex PCI group.
- Ticagrelor monotherapy following 1-month DAPT was associated with a significantly lower risk of death/Q-wave MI (primary endpoint) and POCE, with a similar risk of BARC type 3 or 5 bleeding, thereby achieving a significant net clinical benefit, NACE in patients with complex PCI, but not in those with non-complex PCI.
- Importantly, the benefit of long-term ticagrelor monotherapy was greater as the number of high-risk features increased.
- Thus, ticagrelor monotherapy following 1-month ticagrelor and aspirin may be a better alternative to the standard DAPT in patients who underwent complex PCI.

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ECRI/Cardialysis - THANK YOU