Prognosis in patients with prior myocardial infarction and PEGASUS-TIMI 54 criteria in the CLARIFY registry

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Background/Introduction: The PEGASUS-TIMI 54 trial showed that prolonged treatment with ticagrelor reduces the cumulative occurrence of ischemic adverse events. CLARIFY is the biggest real life registry on chronic coronary syndrome.

Purpose: - To evaluate the percentage of patients eligible for long-term ticagrelor therapy in the CLARIFY registry.

– To compare the outcome of this subgroup of patients with those with PEGASUS exclusion criteria or without PEGASUS inclusion criteria.

Methods: Within the CLARIFY population, we selected post MI patients and we excluded those with missing info (post MI evaluable population). Then, we divided patients into 3 groups: excluded (meeting PEGASUS exclusion criteria, namely use of P2Y12 receptor antagonists or chronic oral anticoagulant, any stroke, coronary-artery bypass grafting in the past 5 years); eligible (meeting PEGASUS high-risk inclusion criteria, namely age≥65 years; diabetes; multivessel disease; creatinine clearance <60 ml/min) and ineligible (not meeting PEGASUS high-risk inclusion criteria). We therefore compared the ischemic (CV death, MI and stroke) and bleeding (major bleeding) outcome of the 3 groups adjusting for age, sex, smoking and geographical region.

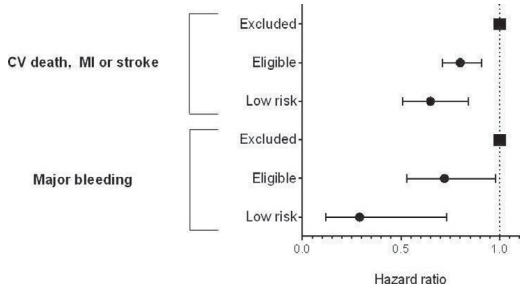
Results: Among the 11811 post-MI evaluable patients, 4706 (39.8%) were included in the eligible group, 5715 (48.4%) in the excluded group, and 1390 in the ineligible group (11.8%). Both the ischemic and bleeding endpoints were significantly different among the 3 groups with the excluded patients with the worst and ineligible patients with the best outcome (see table). The same trend was shown for CV death, while the occurrence of MI was not significantly different among the 3 groups. In the eligible group, the ratio between ischemic and bleeding events was 6:1, whereas between CV death and major bleeding was 3.5:1.

Conclusions: Around 40% of CLARIFY post-MI patients could benefit from prolonged ticagrelor therapy. In this group of patients, ischemic risk seems to be higher than the bleeding one.

Ischemic and Bleeding Outcome

Outcome	Level	No. with event/No. in group	HR (95% CI)	Individual p-values	Overall p-value
CV death, MI or Stroke	1: Excluded group	595/5715 (10.41%)	1.00 (–)		<0.0001
	2. Eligible group	455/4706 (9.67%)	0.80 (0.71, 0.91)	0.0005	
	3: Low risk	73/1390 (5.25%)	0.65 (0.51, 0.84)	0.0010	
Major Bleeding	1: Excluded group	101/5520 (1.83%)	1.00 (–)		0.0064
	2: Eligible group	72/4591 (1.57%)	0.72 (0.53, 0.98)	0.0349	
	3: Low risk	5/1352 (0.37%)	0.29 (0.12, 0.73)	0.0086	

CV: cardiovascular; MI: myocardial infarction; No.: number; HR: hazard ratio; CI: confidence interval.



Ischemic & bleeding risk in the 3 groups