MI後のチカグレロル使用の安全性はクロピドグレルと同等である(Abstract 18-LB-17918-ACC)

TREAT：効果的で即効性のある抗血小板薬は線溶療法を施行された患者の出血リスクを上昇させない

TREAT: Potent, fast acting anticoagulant does not raise risk of bleeding in those taking fibrinolytic therapy

心筋梗塞治療目的で線溶療法を施行された75歳未満の患者において、より効果的な抗血小板薬チカグレロルは標準的な抗血小板薬クロピドグレルと比較し、大出血（主要評価項目）のリスクを上昇させなかった、とAmerican College of Cardiology's 67th Annual Scientific Sessionで発表され、同時に*JAMA Cardiology* オンライン版に掲載された。TIMI出血基準の大出血は両群ともに約0.7% の患者に発現し、二群間に統計学的有意差はなかった。今回の新たなスタディと過去のスタディとの大きな違いは、患者が線溶療法を受けていたことである。

Full Text

Among people younger than 75 years who were given fibrinolytic agents to treat a myocardial infarction (MI), taking the more potent blood thinner ticagrelor did not increase the risk of major bleeding (the primary endpoint) compared with the standard blood thinner clopidogrel, in a trial presented at the American College of Cardiology's 67th Annual Scientific Session and simultaneously published online in *JAMA Cardiology*.

The results align with those of previous studies assessing ticagrelor's safety. However, a key difference between the new study and earlier ones is that participants were taking fibrinolytic therapy. These new findings suggest ticagrelor, which reduces clotting by preventing platelet aggregation, is safe to use in combination with fibrinolytics, at least in patients younger than 75, researchers said.

The trial was conducted in 10 countries on five continents: Australia, New Zealand, Argentina, Russia, China, Canada, Peru, Brazil, Colombia and Ukraine.

"This is the first large, international trial of ticagrelor in STEMI patients taking fibrinolytic therapy," said Otavio Berwanger, MD, PhD, cardiologist and clinical epidemiologist at Brazilian Clinical Research Institute, Sao Paulo, and the study's lead author. "I think doctors, some of whom are already using ticagrelor off-label, will find the results reassuring because they suggest that you can use ticagrelor in this population without causing more major bleeding or fatal bleeding than clopidogrel."

The trial enrolled 3,800 patients treated for STEMI at more than 180 centers. All patients had received fibrinolytic therapy within 24 hours of their MI. Half of the participants were randomly assigned to take ticagrelor and half took clopidogrel. Patients were given an initial loading dose of their assigned drug and then continued taking the drug for 12 months. After 30 days, the researchers assessed rates of major bleeding events in both study groups using the criteria defined by the Thrombolysis in Myocardial Infarction (TIMI) score, the standard tool used to score bleeding severity.

TIMI-scored major bleeding occurred in roughly 0.7 percent of patients in each group, with no statistically significant difference between the two groups. Thus, the trial met its primary endpoint indicating that ticagrelor is not inferior to clopidogrel in terms of major bleeding at 30 days.

The researchers also found no difference between the study groups in terms of rates of major bleeding according to two other sets of criteria, BARC (Bleeding Academic Research Consortium) and PLATO (Study of Platelet Inhibition and Platelet Outcomes), as well as rates of fatal bleeding and bleeding in the brain. They did observe a significantly higher rate of minor bleeding among patients receiving ticagrelor, which was expected because ticagrelor is a more potent blood thinner.

Researchers will track cardiovascular outcomes for 12 months and plan to report in 2019 on how well each drug performs in preventing major adverse cardiovascular outcomes.

"For patients who may be resistant to clopidogrel, or for those in whom it may be desirable to use the more potent drug, at least from our results doctors can know it is safe to do so," Berwanger said. "However, we will have to wait until next year to assess efficacy."

The risk of bleeding increases with age. Because the new trial was restricted to patients younger than 75 years, Berwanger noted that the findings may not apply to older adults.

The trial was funded by AstraZeneca, maker of ticagrelor.

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