抗血小板薬間の差異（TRITON-TIMI 38）

TRITON-TIMI 38トライアルの結果、経皮的冠動脈インターベンションを施行される患者に対し、prasugrelはクロピドグレルよりもより有益であることが示された

TRITON-TIMI 38 trial indicates prasugrel offers more benefit than clopidogrel for patients undergoing percutaneous coronary intervention

経皮的冠動脈インターベンションを施行される中等度－高リスクの急性冠症候群患者に対し、prasugrelはクロピドグレルよりも有益である、とAmerican Heart AssociationのLate-Breaking Clinical Trialセッションで発表された。TRITON-TIMI 38では30ヵ国の患者13,608人を、prasugrel（初回投与量として60mg、維持量として1日10mg）またはクロピドグレル（初回投与量300mg、維持量1日75mg）を施術後最長15ヵ月間内服する群に無作為に割り付けた。その結果、prasugrel群において心血管死または非致死的心筋梗塞または脳卒中の一次エンドポイントが有意に低かった（prasugrel群で9.9%に対しクロピドグレル群で12.1%）。重大な出血はprasugrel群において有意に多かった（2.4%に対しクロピドグレル群1.8%）が、全体的な臨床上の有益性はprasugrelにおいて有意に高かった。今回の投与量において、prasugrelに対する反応が不良であることを予測する因子には、脳卒中の既往、高齢、低体重が挙げられた。

Full Text

Prasugrel appears to offer more benefit than clopidogrel for moderate- to high-risk patients with acute coronary syndrome undergoing percutaneous coronary intervention, according to a late-breaking clinical trial presentation at the annual American Heart Association Scientific Sessions in Orlando, Florida, USA.

TRITON - TIMI 38, a large, international, double-blind phase III trial, compared single dosage regimens of prasugrel, a novel antiplatelet drug, and clopidogrel. Both medications are in the same drug class, thienopyridines.

At the doses tested, "Prasugrel was shown to be more potent, work more quickly and have more consistent antiplatelet effects than standard, approved doses of clopidogrel," said Elliott M. Antman, MD, professor of medicine at Harvard Medical School and director of the Samuel A. Levine Cardiac Unit at Brigham and Women's Hospital in Boston, Mass.

The study enrolled 13,608 patients with moderate- to high-risk acute coronary syndrome who were scheduled to undergo percutaneous coronary intervention. Patients were randomized at 707 sites in 30 countries to prasugrel (60 mg as a loading dose followed by a daily 10 mg dose) or clopidogrel (300 mg loading dose followed by daily 75 mg dose) for up to 15 months following their procedure.

The primary efficacy endpoint (death from cardiovascular causes, myocardial infarction, or stroke) was significantly lower on prasugrel (12.1 percent for clopidogrel versus 9.9 percent of patients for prasugrel, meeting the primary hypothesis of superiority.

In addition to superior efficacy, prasugrel was associated with a significantly lower incidence of stent thrombosis, urgent target vessel revascularization, and myocardial infarction. Although major bleeds were also significantly higher with prasugrel (2.4 percent versus 1.8 percent for clopidogrel, net clinical benefit (all cause mortality, nonfatal infarction, nonfatal stroke, or nonfatal major bleed) was significantly higher for prasugrel.

"Although clopidogrel is a highly effective antiplatelet drug, many patients who receive it still have serious ischemic events despite reliably taking the drug," said Antman. "The benefits of the higher degrees of inhibition of platelet aggregation achieved with the doses of prasugrel that we tested in TRITON-TIMI 38 represent the latest advance in antiplatelet therapy for patients with an acute coronary syndrome."

Antman said there were some patients who did not do as well with this dosage of prasugrel, such as patients who had a history of prior stroke, were elderly or had a low body weight. Potential modifications of the maintenance dose will be guided by ongoing analyses of a pharmacokinetic substudy in TRITON-TIMI 38.