心室性不整脈の軽減

MERLIN TIMI-36トライアルの結果、ranolazineは急性非ST上昇心筋梗塞患者の心室性および心房性不整脈を減少させることが示された

MERLIN TIMI-36 Trial shows ranolazine reduces ventricular and atrial arrhythmias in patients with acute non-ST elevation infarctions

MERLIN TIMI-36トライアルの結果、標準的な治療を受けている急性非ST上昇心筋梗塞または不安定狭心症の患者にranolazineを投与することにより、心室性および心房性不整脈が減少することが示された、とESCで発表された。このトライアルでは6,560人の患者を、実薬またはプラセボを静脈内投与しその後外来で徐放性薬剤またはプラセボを長期投与する群に無作為に割り付けた（ranolazine 3,279人，プラセボ3,281人）。全ての患者は入院中および外来で、アスピリン、β遮断薬、およびスタチンなどの標準治療も受けた。その結果、ranolazineはプラセボと比較し、8連発以上の心室頻拍の相対リスクを37%低下させ、心臓突然死を減少させた（56対65）。組み入れ後最初の7日間にホルター心電図を施行し、患者全員で計100万拍以上の解析用のデータが得られた。この数はクリニカルトライアルの一部として得られた中で最も多いと考えられた。

Full Text

MERLIN TIMI-36 data show that extended-release ranolazine reduces ventricular and atrial arrhythmias in patients with acute non-ST elevation myocardial infarctions or unstable angina who are already receiving standard therapy, according to a presentation at the annual meeting of the European Society of Cardiology.

MERLIN TIMI-36 (Metabolic Efficiency with Ranolazine for Less Ischemia in Non-ST Elevation Acute Coronary Syndromes) was a multi-national, double-blind, randomized, placebo-controlled, parallel-group clinical trial designed to evaluate the efficacy and safety of the extended-release drug formulation during acute and long-term treatment in 6,560 patients (3,279 received ranolazine, 3,281 received placebo) with non-ST elevation acute coronary syndrome treated with standard therapy.

Within 48 hours of onset of angina, eligible hospitalized patients were enrolled in the study and randomized to intravenous drug or placebo, followed by long-term outpatient treatment with extended-release drug or placebo. All patients also received standard therapy during both hospital-based and outpatient treatment. The doses of ranolazine extended-release tablets used in MERLIN TIMI-36 have been studied in previous Phase III clinical trials.

Participants in the MERLIN TIMI-36 study received modern therapy, with approximately 96 percent of patients on aspirin, approximately 89 percent on beta blockers and approximately 82 percent on statins. Approximately 59 percent of study participants received coronary angiography during their initial hospitalization.

The ranolazine group had a 37-percent reduction in relative risk of ventricular tachycardia lasting eight beats or more and fewer episodes of sudden cardiac death (56 deaths) compared with placebo patients (65 deaths).

As part of the MERLIN TIMI-36 safety assessment, Holter monitors recorded continuous electrocardiographic (ECG) recordings for the first seven days after patients were admitted to the study with an episode of non-ST elevation myocardial infarction or unstable angina. The more than 1,000,000 hours of Holter monitor data from 6,351 study participants are believed to represent the largest Holter monitor database ever collected in a clinical trial.

"The significant reductions in ventricular arrhythmias observed in ranolazine patients in the MERLIN TIMI-36 study provide important and reassuring data regarding the long-term safety of ranolazine and suggest that ranolazine could have potential as a new anti-arrhythmic agent in treating ventricular arrhythmias," said Benjamin Scirica, a cardiologist at Brigham and Women's hospital, an investigator at the TIMI Study group and lead author of the study.

These data represent the first clinical report of the effect of ranolazine to reduce the incidence of cardiac arrhythmias and support the findings of many prior preclinical studies that suggested ranolazine has potential anti-arrhythmic properties due to its action as an inhibitor of the late sodium current.

Extended release ranolazine is currently indicated in the USA for treatment of chronic angina in patients who have not achieved an adequate response with other antianginal drugs, and should be used in combination with amlodipine, beta-blockers or nitrates.

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