Ivabradineによる心拍数低下により冠動脈イベントが減少する

BEAUTIFULトライアル：Ivabradineは安定冠動脈疾患および左室機能低下を有する患者の心筋梗塞および血行再建術施行率を減少させる初めての抗狭心症治療薬である

BEAUTIFUL:Ivabradine is first antianginal treatment to reduce myocardial infarction and revascularization in patients with stable coronary disease and left ventricular dysfunction

BEAUTIFULトライアル：morBidity-mortality EvAlUaTion of the If inhibitor ivabradine in patients with CAD and left ventricULar dysfunction（冠動脈疾患および左室機能不全を有する患者に対するIf電流阻害薬ivabradineの有病率と死亡率に対する効果の評価）の結果、ivabradineを用いて心拍数を低下させることにより、洞調律患者の心筋梗塞、心筋梗塞による左室収縮不全および血行再建術施行率を減少させる、とミュンヘンで開催された2008年European Society of Cardiology学会で発表された。左室駆出率40%未満の安定した患者10,917人を、5mgのivabradine（目標用量の7.5mgを1日2回投与まで増量）またはプラセボを投与する群に無作為に割り付けた。患者らは心血管系治療薬による至適治療を継続して受けた。スタディの対象全体で一次複合エンドポイント（心血管死、心筋梗塞による入院、心不全の新規発症または増悪による入院の合計）においてivabradineの有効性は認められなかった（p=0.94）。しかし、事前に定義されたサブグループの患者（心拍数70bpm以上）において、ivabradineは致死性および非致死性心筋梗塞による入院を36%（p=0.001）、冠動脈血行再建術施行を30%（p=0.016）減少させた。またこの試験の結果、ivabradineは安全で忍容性が高く、ルーチンに処方される全ての心血管治療薬と併用可能であることも確認された。

Full Text

The landmark BEAUTIFUL (morBidity-mortality EvAlUaTion of the If inhibitor ivabradine in patients with CAD and left ventricULar dysfunction) trial shows that heart rate reduction with ivabradine reduces myocardial infarction, associated left ventricular systolic dysfunction and revascularization in patients who are in normal sinus rhythm according to a featured presentation at the European Society of Cardiology Congress 2008 in Munich.

Commenting after the results presentation, the Chairman of the BEAUTIFUL Executive Committee, Professor Kim Fox said, "Ivabradine was always known to relieve ischemia. With the BEAUTIFUL results, ivabradine is the first antianginal treatment shown to reduce myocardial infarction (MI) and revascularization and to have a good tolerability profile even when used with other drugs. This is the gold standard for any antianginal, anti-ischemic drug".

The BEAUTIFUL trial was initiated in December 2004, under the guidance of an independent Executive Committee with the first patient being enrolled in early 2005. 10,917 patients with left ventricular ejection fractions less than 40% were recruited in 781 centers in 33 countries across 4 continents. The mean heart rate in these patients was 71 bpm and half of the patients had a heart rate more than 70 bpm. The results of the BEAUTIFUL study have shown that these patients with heart rate > 70 bpm are more likely to die or suffer from another cardiovascular event. The increase in risk is 34% for cardiovascular death, 46% for myocardial infarction, 56% for heart failure and 38% for coronary revascularization.

In the overall study population treatment with ivabradine did not result in a significant reduction of the primary composite end point (Cardiovascular death, admission to hospital for acute MI and admission to hospital for heart failure). However in patients with baseline heart rate more than 70 bpm, ivabradine significantly reduced the risk of hospitalization for fatal and non-fatal myocardial infarction by 36% (p=0.001) and the risk of coronary revascularization by 30% (p=0.016). What is important to note is that most of these patients were already receiving the guidelines-recommended cardiovascular therapy: antiplatelet agents (94%), angiotensin-converting enzyme inhibitors or angiotensin receptor blockers (91%), ƒÀ-blockers (87%), as well as lipid-lowering agents (76%). Hence the results of BEAUTIFUL constitute a step further in the management of these coronary patients with heart rate above 70 bpm because, for the first time it has been shown that pure heart rate reduction with ivabradine further reduces coronary events even in patients receiving the current optimal cardiovascular therapy. This study also confirms that ivabradine is safe and well tolerated and can be used with all routinely prescribed cardiovascular drugs.

Commenting on the results the Chairman of the Steering Committee, Prof Roberto Ferrari said, "Often a lot of investigations are performed in coronary patients but a simple heart rate measurement is not done. BEAUTIFUL has reinforced the need to measure heart rate in all CAD patients and if the heart rate is more than 70 bpm to reduce it by using ivabradine on top of background therapy."

BEAUTIFUL results with ivabradine can be explained by its well-documented ability to relieve myocardial ischemia in patients with chronic stable angina. New research has demonstrated that ivabradine improves endothelial dysfunction and prevents the progression of atherosclerosis.

"Half of the CAD patients have a resting heart rate more than 70 bpm. These patients can now benefit from a treatment that will greatly reduce their chances of having another heart attack or needing further surgery", concluded Professor Kim Fox, the Chairman of the BEAUTIFUL Executive Committee.

Conference
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