GISSI-HF心不全トライアルの総合結果

GISSI-HFトライアル：ロスバスタチンは原因に関係なく慢性心不全患者の臨床転帰に影響しなかったが魚油単独のサプリメントは有益であった

GISSI-HF: Rosuvastatin did not affect clinical outcomes in patients with chronic heart failure of any cause but a simple fish oil supplement showed benefit

ロスバスタチンは原因に関係なく慢性心不全患者の臨床転帰に影響しなかった（ロスバスタチンは安全な様であった）が魚油単独のサプリメントは有益であったとのGISSI-HFトライアルの結果が、2008年European Society of Cardiology学会で発表されLancetオンライン版に掲載された。New York Heart Associationクラス II～IVの慢性心不全患者4,574人（平均年齢68±11歳）を、心不全の原因または左室駆出率を問わず、ロスバスタチン1日10mg（2,285人）とプラセボ（2,289人）を比較する二重盲検無作為化トライアルに組み入れた。患者らは中央値で3.9年間追跡調査された。一次エンドポイント（死亡までの期間、または死亡および心血管疾患による入院までの期間の合計）は両群間で差がなかった。同じトライアルの別の群における結果では、魚油単独のサプリメントは心不全患者に有益である可能性が示唆された。n-3多価不飽和脂肪酸（n-3 PUFA、1日1g）の投与を受けた患者においては、死亡および心血管系が原因の入院の相対リスクが8%低下した（p=0.009）。

Full Text

Rosuvastatin (10 mg daily) did not affect clinical outcomes in patients with chronic heart failure of any cause, in whom the drug seemed to be safe, but a simple fish oil supplement benefitted these patients according to results from the GISSI-HF trial presented at the European Society of Cardiology Congress 2008.

Large observational studies, small prospective studies and post-hoc analyses of randomized clinical trials have suggested that statins could be beneficial in patients with chronic heart failure. However, previous randomized controlled trials have been methodologically weak. This trial investigated the efficacy and safety of the statin rosuvastatin in patients with heart failure.

4,574 patients (mean age 68±11 yr) with chronic heart failure of New York Heart Association class II--IV, irrespective of cause and left ventricular ejection fraction, were included in a double-blind randomized trial testing rosuvastatin 10 mg daily (n=2,285) against placebo (n=2,289). Patients were followed-up for a median of 3.9 years. Primary endpoints were time to death, and time to death or admission to hospital for cardiovascular reasons.

According to the intention to treat analysis, 657 (29%) patients died from any cause in the rosuvastatin group (28.8%) and 644 (28%) in the placebo group (adjusted hazard ratio [HR] 1.00, [95.5% CI 0.898--1.122], p=0.943). No differences were found also with respect to the other primary end-point: 1305 (57%) patients in the rosuvastatin group died or were admitted to hospital for cardiovascular reasons and 1283 (56%) in the placebo group (adjusted HR 1.01, [99% CI [0.908--1.112], p=0.903).

A separate arm of the same study found that a simple fish oil supplement (n-3 PUFA) can benefit patients with heart failure. Several epidemiological and experimental studies suggested that n-3 PUFA could exert favorable effects on the atherotrombotic cardiovascular disease including arrhythmias.

The GISSI researchers enrolled 6,975 patients with chronic heart failure of New York Heart Association class II-IV, assigned to n-3 PUFA 1 g daily or placebo. Patients were followed up for a median of 3.9 years. Primary end-points were time to death and time to death or admission to hospital for cardiovascular reasons. Analysis was by intention-to-treat population.

Among the GISSI findings: 955 (27%) patients died from any cause in the n-3 PUFA group and 1014 (29%) in the placebo group (relative risk reduction 9%, p=0.041). 1981 (57%) patients in the n-3 PUFA group and 2053 (59%) in the placebo group died or were admitted to hospital for cardiovascular reasons (relative risk reduction 8%, p=0.009). In absolute terms, 56 patients needed to be treated for 3.9 years to avoid one death or 44 to avoid one event like death or admission to hospital for cardiovascular reasons. In a per-protocol analysis performed in about 5000 full complier patients, the relative risk of death was reduced by 14% (p=0.004). Safety was excellent.

GISSI is endorsed by the Associazione Nazionale Medici Cardiologi Ospedalieri (ANMCO), Firenze, Italy; Ist.Ricerche Farmacologiche Mario Negri, Milan, Italy and the Consorzio Mario Negri Sud, Santa Maria Imbaro, Italy. The GISSI-HF trial was planned, conducted and analyzed by the GISSI group, which has full ownership of the dat

Conference
News

[News Flash 01]
Ivabradineによる心拍数低下により冠動脈イベントが減少する

[News Flash 02]
PCIとCABGの相対的なメリットは未だに解決されていない

[News Flash 03]
GISSI-HF心不全トライアルの総合結果

[News Flash 04]
新世代の薬剤溶出ステントの有効性が示された

[News Flash 05]
テルミサルタンは心保護作用を有する

[News Flash 06]
血管手術におけるフルバスタチンの心保護作用

[News Flash 07]
大動脈弁狭窄は脂質低下では改善しない

[News Flash 08]
FX06は心再灌流傷害を軽減する可能性がある

[News Flash 09]
高齢者に対する集中治療は有益でない

[News Flash 10]
ペリンドプリルとカルシウム拮抗薬併用により予後が改善する

[News Flash 11]
Prasugrelは糖尿病患者に臨床上有益である

[News Flash 12]
Dronedaroneは心房細動の患者を脳卒中から保護する

[News Flash 13]
若年アスリートに心臓超音波検査のスクリーニングは不要

[News Flash 14]
新たな治療により動脈硬化性プラークが予防される