

PCI成功後のEPOは有益ではない

HEBE III: 急性心筋梗塞後のボーラスでのエリスロポエチン単回投与は心機能を改善させない

HEBE III: A single bolus of erythropoietin does not improve cardiac function after an acute myocardial infarction

HEBE IIIスタディの結果、過去の小規模のスタディで認められたエリスロポエチン(EPO)の初回ST上昇心筋梗塞(STEMI)患者に対する臨床上の予後改善に関する有望な効果は確認されなかったと、2010年European Society of Cardiology学会のホットラインセッションで発表され同時にEuropean Heart Journalに掲載された。HEBE IIIトライアルは、エポエチン α 60,000IUボーラス単回投与の左室駆出率(LVEF)に対する効果を調査した。EPOは初回STEMIに対するPCI成功後、3時間以内に経静脈的に投与された。計529人の患者がスタディに組み入れられ、うち263人はEPO群、266人はコントロール群に割り付けられた。6週後、EPO群のLVEFは53%でありコントロール群は52%であったが、この1%の差は小さく、統計学的または臨床的に有意ではなかった。さらに、血中蛋白で計測した梗塞サイズも2群間で有意差はなかった。しかし、主要な心血管有害事象が発現したのはEPO群ではわずか8人であったのに対し、コントロール群では19人に認められた。

Full Text

Results from the HEBE III study, a prospective, randomized, multicentre trial performed in seven centers in the Netherlands, suggest that the promising effects of erythropoietin seen in previous smaller studies cannot be confirmed for the improvement of clinical outcome in patients with a first ST-elevation myocardial infarction (STEMI).

Myocardial infarction (MI) remains a major hazard for millions of people. Despite improvements in treatment, the majority still ends up with reduced cardiac function, and strategies to improve post-MI cardiac function are strongly needed. One approach, suggested in experimental and smaller clinical studies, is the administration of erythropoietin (EPO), currently used for the treatment of anemia caused by renal disease. The HEBE III study was designed to study the effects of a single intravenous bolus of EPO on clinical outcome in patients with a first ST-elevation MI. The primary endpoint of the trial - as a measure of cardiac function - was left ventricular ejection fraction (LVEF) after six weeks, with secondary endpoints assessed according to infarct size and major adverse cardiovascular events (MACE).

The trial was conducted in 529 randomized STEMI patients and headline results showed that this single IV bolus of EPO did not improve cardiac function. However, patients who received EPO had fewer major cardiac events, such as heart failure, compared with the control group.

The HEBE III trial studied the effect of a single bolus of 60,000 IU epoetin alfa on LVEF. EPO was administered intravenously within three hours after a successful PCI for a first STEMI. The study aimed to find a 3% increase of LVEF in patients treated with EPO compared to standard care. In total, 529 patients were included in the study, in which 263 patients were assigned to the EPO group and 266 to the control group.

After six weeks, LVEF was 53% in the EPO group and 52% in the control group, but this 1% difference was too small to be statistically or clinically significant. Furthermore, infarct size, measured by proteins in the blood, was also not significantly different between the two groups. However, in the EPO group, only eight patients suffered a major cardiac adverse event, compared to 19 in the control group.

Commenting on the results, principal investigator Dr. Adriaan Voors from the University Medical Center, Groningen, the Netherlands, said: "The promising effects of erythropoietin in previous smaller studies could not be confirmed in this large clinical trial. The reduction of major cardiac effects is of interest, but, since the study was not primarily designed to reduce cardiac effects, and the numbers are small, we should be careful with its interpretation. Larger clinical trials powered to detect a reduction in hard clinical endpoints should be performed before EPO can be routinely used in patients with an acute heart attack."

The HEBE III study was presented at a Hotline session at the ESC Congress 2010 and published concurrently in the European Heart Journal.

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