

心房細動においてdabigatranはワルファリン よりもより有効である

RE-LY: 心房細動患者の脳卒中予防において経口抗凝固薬dabigatranは ワルファリンよりも有効である

RE-LY: Oral antithrombin dabigatran more effective than warfarin in preventing stroke in patients with atrial fibrillation

抗凝固薬dabigatranはワルファリンと比較し、心房細動(AF)患者の脳卒中および末 梢塞栓イベント予防効果が高かったとのRE-LY(Randomized Evaluation of Long-term anticoagulant therapY:長期抗凝固療法無作為評価)スタディの結果が、バルセロナ で開催されたESC 2009ホットラインセッションで発表された。RE-LYスタディでは、 脳卒中リスクの高い心房細動患者18,113人において、2つの用量のdabigatran(150mg および110mgを1日2回)と現在の標準療法であるワルファリンを比較した。このスタ ディには44ヵ国951以上の施設が参加した。患者は2年以上にわたり組み入れられ、 さらに1年間追跡された。高用量のdabigatranにより、ワルファリンと比較し、年間 の一次エンドポイント (脳卒中および末梢塞栓イベント) が34%減少し (p<0.001) 出血性脳卒中イベントが74%(p<0.001)減少した。低用量のdabigatranの脳卒中予防 効果はワルファリンと同様であったが、重大な出血は有意に少なかった。高用量の dabigatranにより二次エンドポイントであるMIのリスクは増加した(p=0.048)。

Full Text

The anticoagulant dabigatran is more effective than warfarin in the prevention of stroke in patients with atrial fibrillation, according to results from the RE-LY study (Randomized Evaluation of Long-term anticoagulant therapY).

"Although researchers have been looking for a replacement for warfarin for several decades, nothing has been successful as an oral blood thinner," says Professor Stuart Connolly, Director of the Division of Cardiology at McMaster University, Canada, and one of the leading investigators of the study.

The RE-LY study compared two doses of dabigatran with the current standard therapy, warfarin, in 18,113 patients with atrial fibrillation at increased risk of stroke. The study included more than 951 centers in 44 countries. Patients were enrolled over a two-year period and then followed for one further year. The study was designed to evaluate whether either of two doses of dabigatran were non-inferior to warfarin (i.e., at least as good as warfarin). The results show, however that the higher dose of dabigatran 150 mg twice daily, significantly reduces the risk of stroke by 34% compared to warfarin. The lower dose, 110 mg twice daily, had a similar effect to warfarin in the prevention of stroke, but with significantly less major bleeding.

According to Professor Connolly, although warfarin has been the gold standard for reducing stroke in atrial fibrillation for more than 20 years, it has many problems; these include a need for monitoring by blood test measurement, and a significant risk of increased bleeding, which makes it unsuitable for many patients. "Several new drugs have been recently studied to see if they could replace warfarin," says Professor Connolly. "None, however, has been satisfactory. Either they were not effective enough, they had too many side effects or they caused too much bleeding. This is the first time in more than 50 years that a new oral blood thinner has been developed which has been found to be both safer and more effective than existing therapy."

The RE-LY study was coordinated by the Population Health Research Institute of McMaster University and sponsored by Boehringer-Ingelheim.

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