

2型糖尿病患者に対する低用量アスピリンに関するトライアル(LBCT, abstract # 163)

JAPDトライアル：低用量アスピリンは2型糖尿病患者の動脈硬化性イベントを有意に減少させなかった

JAPD Trial: Low-dose aspirin did not significantly lower atherosclerotic events in type 2 diabetics

糖尿病患者に対する低用量アスピリン投与の有効性を評価した大規模一次予防トライアルにおいて日本の研究者らは、毎日のアスピリン内服は、致死性心筋梗塞および脳卒中は予防するが、一次エンドポイントとしての全ての動脈硬化性イベントに関しては有意な有益性が認められなかったとのLate-Breaking Clinical Trialの結果を、2008年American Heart Associationで報告した。しかし、サブグループ解析の結果、65歳を超えた人々においては、アスピリンによる致死性および非致死性動脈硬化性イベントの有意な減少、および脳心血管死の減少が認められた。この無作為化トライアルには日本の163の病院の2型糖尿病患者2,539人が組み入れられた。患者全体においてアスピリン群で動脈硬化性イベントが少ない傾向が認められた（相対リスクが20%低下）が、統計学的な有意差には達しなかった。研究者らは、致死性冠動脈および脳血管イベントのリスクがアスピリン群においてアスピリン無投与群よりも大きく有意に低下したことを明らかにした（ハザード比0.10）。しかし、この結果の信頼区間は広く（CI=0.01-0.8）、さらなる検討が必要であることが示唆された。Japanese Primary Prevention of Atherosclerosis with Aspirin for Diabetes (JPAD)の結果は、同時にJournal of the American Medical Associationに掲載された。

Full Text

Type 2 diabetics treated with low-dose aspirin did not have a significantly lower incidence of atherosclerotic events than those who received placebo in this primary prevention trial of low-dose aspirin, according to research presented at the American Heart Association's Scientific Sessions 2008. However, sub-group analyses showed a significant reduction with aspirin in both atherosclerotic events in those over 65 years of age, and a reduction in cerebrocardiovascular deaths.

Results from The Japanese Primary Prevention of Atherosclerosis with Aspirin for Diabetes (JPAD) trial were presented as a late-breaking clinical trial. The study was simultaneously published in the Journal of the American Medical Association.

"Our results indicate that aspirin is effective and safe for primary prevention of cardiac and cerebrocardiovascular death in diabetics," said Hisao Ogawa, M.D., Ph.D., lead investigator of the study and a professor of cardiovascular medicine at Kumamoto University, Kumamoto, Japan, and chief of the division of cardiology at the Kumamoto University Hospital. "In addition, it offers a low-cost approach."

The randomized trial included 2,539 type 2 diabetics at 163 Japanese medical centers.

Researchers observed a positive trend for a reduction in all atherosclerotic events in the aspirin group (20 percent relative risk reduction) for the entire population, but it did not reach statistical significance. Atherosclerotic events include coronary heart disease death, fatal stroke, non-fatal myocardial infarction, unstable angina, exertional angina, non-fatal stroke including transient ischemic attack, and peripheral arterial disease.

In a subgroup analysis, the researchers found an association between daily low-dose aspirin use and a 32 percent reduced relative risk for all atherosclerotic events, both fatal and non-fatal, but only for diabetics over age 65. In other words, individuals over age 65 who took aspirin had a hazard ratio of 0.68 compared to those who did not take aspirin.

During an average of 4.4 years of follow-up, 154 atherosclerotic events occurred, both fatal and non-fatal (68 in the aspirin group, 86 in the non-aspirin group.) Those events included one fatal cardiovascular event (a hemorrhagic stroke) in the aspirin group and 10 fatal strokes or heart attacks in the non-aspirin group, Ogawa said.

Researchers found a large, statistically significant risk reduction for fatal coronary and cerebrovascular events in the aspirin group vs. the non-aspirin group (hazard ratio of 0.10.) But the confidence interval on that finding was wide (CI=0.01 to 0.8), indicating a need for further study, he said.

Aspirin therapy is commonly used for primary prevention in diabetic patients in the United States and Canada, but not in Japan, Ogawa said.

Several earlier studies have established the benefits of aspirin therapy in preventing second cardiac events. However, its use for primary prevention in diabetics has been controversial because of the lack of data indicating benefits and because aspirin carries a risk of gastric bleeding, Ogawa said.

He said aspirin was well tolerated as demonstrated by the comparable number of the combined endpoint of serious hemorrhagic events (hemorrhagic strokes and major gastrointestinal bleeds).

In comparing bleeding events, the researchers reported 13 hemorrhagic strokes, with no statistically significant difference between aspirin takers and non-takers (six such strokes in the aspirin group; seven in the non-aspirin group).

On the other hand, the total number of all hemorrhagic events was greater in the aspirin group compared to the non-aspirin group (34 vs. 10 such events). Four patients in the aspirin group had bleeding events that required transfusion. Furthermore, those in the aspirin group had more gastrointestinal symptoms (55 cases vs. eight cases), but all cases were resolved without surgery and no fatalities occurred, he said.

"Our findings need to be interpreted in the context of the low incidence of atherosclerotic disease in Japan," Ogawa said. "We conclude that aspirin as primary prevention is beneficial at least for fatal heart attack and fatal stroke in our entire study group and for all atherosclerotic disease among those age 65 or over."

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Cardiology特集

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