高齢者においてアスピリンは一次予防に役立たなかった (Abstract 20753)

JPPP：複数の動脈硬化リスクファクターを有する高齢者において低用量アスピリンは心血管イベントを低下させない

JPPP: Low-dose aspirin does not reduce cardiovascular events in elderly patients with multiple atherosclerotic risk factors

複数の心血管リスクファクターを有する高齢患者において低用量アスピリンは総心血管イベントを有意に低下させなかった、とのlate-breaking clinical trialの結果が2014年American Heart Association年次集会で発表された。Japanese Primary Prevention Project（JPPP）スタディでは、高血圧、脂質異常症および／または糖尿病を有し心血管疾患歴のない60～85歳の患者14,466人を組み入れ、アスピリン腸溶錠1日100mgを内服する群またはアスピリンを内服しない群にランダムに割り付け、リスクファクターのコントロールは継続した。一次エンドポイントは、心血管系の原因による死亡、非致死性脳卒中および非致死性MIの合計であった。追跡期間中央値5.02年の時点で、一次エンドポイント数またはイベントリスクは2群間で差がなかった。TIA率はアスピリン群において有意に少なかった（43%低下、p=0.044）。逆に、アスピリン群では重篤な頭蓋外出血が有意に多かった—ハザード比からそれらのイベントが85%高いことが示された（p=0.004）。TIA減少に関するアスピリンのいかなる有益性も重篤な頭蓋外出血リスクの有意な上昇を考慮しバランスをとるべきである、と筆者らは警告している。

Full Text

Low-dose aspirin was not associated with significant reduction in total cardiovascular events in elderly patients with multiple cardiovascular risk factors according to late-breaking clinical trial research presented at the American Heart Association's Scientific Sessions 2014.

The role of aspirin in the primary prevention of cardiovascular (CV) disease has been hotly debated for several years. Meta-analyses indicate benefits as well as risks. Recently, the US Food and Drug Administration cautioned against the general use of aspirin for the primary prevention of heart attacks and strokes. The Japanese Primary Prevention Project (JPPP) study, prospectively evaluated daily, low-dose aspirin in the primary prevention of cardiovascular events in elderly Japanese patients with one or more risk factors for cardiovascular events but no history of atherosclerotic disease.

A total of 14,466 individuals aged 60 to 85 years with hypertension, dyslipidemia and/or diabetes mellitus who did not have a history of CV disease were randomly assigned to receive enteric-coated aspirin, 100 mg/day or no aspirin, while continuing treatment to control their risk factors. Patients were enrolled from 1007 clinics in Japan between March 20115 and June 2007. Throughout the study, 10.5% of the study population was lost to follow-up.

At a median follow-up of 5.02 years, there was no significant difference between the two groups in the number of primary events or the risk of event. The 5-year cumulative event rates were 2.772 percent for the aspirin treated group compared to 2.960 percent, for the no-aspirin group.

The primary endpoint was a composite of death from CV causes, non-fatal stroke and non-fatal MI. At 5 years there was an insignificant 6% reduction in the risk of a primary endpoint event in the aspirin group vs. the no aspirin group (p = 0.544). No statistically significant interaction between any risk factor and treatment was observed.

When evaluating secondary endpoints, the researchers found that the rate of TIA was significantly reduced in the aspirin group (a 43% reduction, p=0.044). Conversely, there was a significant increase in serious extracranial hemorrhage in the aspirin group − the hazard ratio indicates an 85% increase in such events (p=0.004). Therefore, the authors caution that any benefits of aspirin in terms of the reduced risk of TIA must be counterbalanced with consideration of the significantly increased risk of serious extracranial hemorrhage.

The authors conclude that aspirin was not associated with significant reduction in total cardiovascular events in elderly patients with multiple cardiovascular risk factors.

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