

# 低用量アスピリンは推奨されない

AAA:無症候性血管イベントを有する患者に対するルーチンのアスピリ ン投与にエビデンスはない

AAA: No evidence for the routine use of aspirin in people with asymptomatic vascular events

無症候性の患者に対する血管イベントー次予防目的のアスピリン投与は支持されな いとのAAA(Aspirin for Asymptomatic Atherosclerosis:無症候性動脈硬化患者に対す るアスピリン) スタディの結果がESC 2009ホットラインセッションで発表された。 このスタディは、足関節上腕血圧比 (ABI) 低値から無症候性動脈硬化症と考えら れた患者に対するアスピリンの効果を評価するためにデザインされた初めてのプラ セボコントロール無作為化試験である。臨床的に明らかな心血管疾患のない、スコ ットランド中部の50~75歳の男女28,980人にABIスクリーニング検査を施行した。 ABI低値(3,350人、ABI≤0.95) の患者がトライアルに組み入れられ、1日100mgの アスピリンまたはプラセボを内服する群に無作為に割り付けられた。平均8.2年後の 一次エンドポイント(致死性または非致死性の初回冠動脈イベントまたは脳卒中の 合計、または血行再建術)はアスピリン群とプラセボ群とで統計学的有意差はなか った(HR 1.03、95%CI 0.84~1.27)。同様に、二次エンドポイント(一次エンドポ イントの合計または狭心症、間欠性跛行または一過性脳虚血発作で定義した初回結 果イベントおよび総死亡率)も両群間で有意差はなかった。

## Full Text

The routine use of aspirin for the primary prevention of vascular events in people with asymptomatic disease cannot be supported, according to results from the Aspirin for Asymptomatic Atherosclerosis (AAA) study. The study is the first placebo-controlled randomized trial designed to determine the effect of aspirin in asymptomatic atherosclerosis as reflected by a low ankle brachial index (ABI). Results found no statistically significant difference in primary endpoint events between those subjects allocated to aspirin or placebo (HR 1.03, 95% CI 0.84-1.27).

Joint first author Professor Gerry Fowkes from the Wolfson Unit for Prevention of Peripheral Vascular Diseases in Edinburgh said: "It is possible that in the general population, aspirin could produce a smaller reduction in vascular events than this trial was designed to detect, but it is questionable whether such an effect, together with aspirin related morbidity, would justify the additional resources and health care requirements of an ABI screening program.'

The benefits of antiplatelet therapy in the prevention of future cardio- and cerebrovascular events is well established in patients with a clinical history of arterial vascular disease. However, evidence in primary prevention is limited with studies suggesting that any benefit of aspirin must be weighed against the risk of bleeding. The aim of the AAA trial was to determine the effectiveness of aspirin in preventing events in people with asymptomatic atherosclerosis detected by ABI screening.

The study recruited 28,980 men and women aged 50 to 75 years who were free of clinically evident cardiovascular disease in central Scotland; all were given an ABI screening test. Those with a low ABI (3350 subjects,≤0.95 ABI) were entered into the trial and randomized to once daily 100 mg aspirin or placebo. Participants were followed for a mean of 8.2 years and outcomes ascertained by annual contact, general practitioner records, linkage to discharges from Scottish hospitals, and death notification. The primary endpoint was a composite of initial fatal or non-fatal coronary event or stroke, or revascularization. There were two secondary endpoints: all initial vascular events defined as a composite of a primary endpoint event or angina, intermittent claudication or transient ischemic attack and all-cause mortality.

Results showed that 357 participants had a primary endpoint event (13.5 per 1000 person years, 95%CI 12.2-15.0), 181 in the aspirin group and 176 in the placebo group. A vascular event comprising the secondary endpoint occurred in 578 participants, but again no statistically significant difference was found between the aspirin and placebo groups (288 vs. 290 events). All-cause mortality was similar in both groups (176 v 186 deaths). An initial event of major bleeding requiring admission to hospital occurred in 34 (2%) of subjects in the aspirin group and 20 (1.2%) in the placebo group.

Commenting on the results (and on the use of ABI as a screening method), Professor Fowkes said: "Although the AAA trial was not of screening per se, the results would suggest that using the ABI as a tool to screen individuals free of cardiovascular disease in the community is unlikely to be beneficial if aspirin is the intervention to be used in those found to be at higher risk. Other more potent antiplatelets might be considered, but only if increased effectiveness in avoiding ischemic events is not matched by increased bleeding.'

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