Original Investigation

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Frequency of Intracranial Hemorrhage With Low-Dose Aspirin in Individuals Without Symptomatic Cardiovascular Disease

A Systematic Review and Meta-analysis

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Key Points

Question Does preventive, low-dose aspirin increase the frequency of intracranial hemorrhage in the general population?

Findings In this systematic review and meta-analysis that included 13 randomized clinical trials, low-dose aspirin was associated with an increased risk of any intracranial bleeding.

Meaning Use of low-dose aspirin was associated with an overall increased risk of intracranial hemorrhage among people without symptomatic cardiovascular disease.

Abstract

Importance Use of low-dose aspirin for the primary prevention of cardiovascular events remains controversial because increased risk of bleeding may offset the overall benefit. Among major bleeding events, intracranial hemorrhage is associated with high mortality rates and functional dependency.

Objective To assess the risk of intracranial hemorrhage associated with low-dose aspirin among individuals without symptomatic cardiovascular disease.

Data Sources PubMed, Embase, the Cochrane Central Register of Controlled Trials, and ClinicalTrials.gov were searched from January 1966 to October 30, 2018.

Study Selection Randomized clinical trials that compared low-dose aspirin (daily dose ≤100 mg) vs control and recorded the end points of intracranial hemorrhage separately for active treatment and control groups were included.

Data Extraction and Synthesis A random-effect estimate was computed based on the Mantel-Haenszel method. Relative risk with 95% CI was used as a measure of aspirin vs control on risk of intracranial hemorrhage.

Main Outcomes and Measures The main outcomes were any intracranial hemorrhage, intracerebral hemorrhage, subdural or extradural hemorrhage, and subarachnoid hemorrhage, for aspirin vs control.

Results The search identified 13 randomized clinical trials of low-dose aspirin use for primary prevention, enrolling 134 446 patients. Pooling the results from the random-effects model showed that low-dose aspirin, compared with control, was associated with an increased risk of any intracranial bleeding (8 trials; relative risk, 1.37; 95% CI, 1.13-1.66; 2 additional intracranial hemorrhages in 1000 people), with potentially the greatest relative risk increase for subdural or extradural hemorrhage (4 trials; relative risk, 1.53; 95% CI, 1.08-2.18) and less for intracerebral hemorrhage and subarachnoid hemorrhage. Patient baseline features associated with heightened risk of intracerebral hemorrhage with low-dose aspirin, compared with control, were Asian race/ethnicity and low body mass index.

Conclusions and Relevance Among people without symptomatic cardiovascular disease, use of low-dose aspirin was associated with an overall increased risk of intracranial hemorrhage, and heightened risk of intracerebral hemorrhage for those of Asian race/ethnicity or people with a low body mass index.

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