

Effect of once-daily, low-dose aspirin on CV death and other outcomes

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Yasuo Ikeda, M.D., of Waseda University, Tokyo, Japan, and colleagues examined whether once-daily, low-dose aspirin would reduce the total number of cardiovascular (CV) events (death from CV causes, nonfatal heart attack or stroke) compared with no aspirin in Japanese patients 60 years or older with hypertension, diabetes, or poor cholesterol or triglyceride levels. The study appears in *JAMA* and is being released to coincide with its presentation at the American Heart Association's Scientific Sessions 2014.

The World Health Organization estimates that annual global mortality due to cardiovascular diseases (including heart attack and stroke) will approach 25 million by 2030. A recent study of trends in cardiovascular disease in Japan indicated that there has been, from 1960 to 2000, a steep increase in the prevalence of glucose intolerance, hypercholesterolemia, and obesity, probably due to the adoption of Western diets and lifestyles. By 2030, it is estimated that 32 percent of the Japanese population will be 65 years or older. Prevention of atherosclerotic cardiovascular diseases is an important public health priority in Japan due to an aging population, according to background information in the article.

This study included 14,464 patients (60 to 85 years of age) with hypertension, dyslipidemia (poor cholesterol or <u>triglyceride levels</u>), or diabetes mellitus who were randomized to aspirin (100 mg/d) or no aspirin in addition to ongoing medications. The patients were recruited by primary care physicians at 1,007 clinics in Japan. The study was



terminated early by the data monitoring committee after a median followup of 5.02 years based on likely futility.

The researchers found that there was no statistically significant difference between the two groups in time to the primary end point (a composite of death from cardiovascular causes, nonfatal stroke, and nonfatal heart attack). At 5 years after randomization, the cumulative primary event rate was similar in participants in the aspirin group (2.77 percent) and those in the no aspirin group (2.96 percent).

Aspirin significantly reduced incidence of nonfatal heart attack and transient ischemic attack, and significantly increased the risk of extracranial hemorrhage requiring transfusion or hospitalization.

The authors write that despite inconsistent evidence for the benefit of aspirin in primary prevention of <u>cardiovascular events</u>, the benefits in secondary prevention are well documented, including in Japanese patients. "There is also a growing body of evidence to suggest benefits for aspirin in the prevention of colorectal and other cancers, and the prevention of cancer recurrence, including in the Japanese population. Reduction in the incidence of colorectal cancer may influence the overall benefitrisk profile of aspirin. Further analyses of [this] study data are planned, including analysis of deaths associated with cancers, to allow more precise identification of the patients for whom aspirin treatment may be most beneficial."

J. Michael Gaziano, M.D., M.P.H., of the Veterans Affairs Boston Healthcare System, Brigham and Women's Hospital, Harvard Medical School, Boston, and Associate Editor, *JAMA*, and Philip Greenland, M.D., of the Northwestern University Feinberg School of Medicine, Chicago, and Senior Editor, *JAMA*, write in an accompanying editorial that the findings from this study adds to the body of evidence that helps refine the answer to the question of when aspirin should be used to



prevent vascular events.

"Decision making involves an assessment of individual risk-to-benefit that should be discussed between clinician and patient. However, at present the choice of aspirin remains clear in several situations. Aspirin is indicated for patients at high short-term risk due to an acute vascular event and those undergoing certain vascular procedures; patients with any evidence of vascular disease should be given daily aspirin. On the other hand, patients at very low risk of vascular events should not take aspirin for prevention of vascular events, even at low dose."

"However, some individuals who do not have overt vascular disease will have risk levels that approach those of patients with CVD (such as <u>patients</u> with multiple risk factors). It remains likely that there is some level of risk of CVD events that would result in a positive trade-off of benefit and risk for the use of <u>aspirin</u>, but the precise level of risk is uncertain."

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