Low-Dose Aspirin for Primary Prevention of Cardiovascular Events in Elderly Patients With Multiple Atherosclerotic Risk Factors: A Randomized Controlled Trial

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Background:
Prevention of atherosclerotic cardiovascular diseases (ASCVD) has been an important public health priority due to the aging of the population and changes of lifestyle. We aimed to examine the efficacy of low-dose aspirin for primary prevention of cardiovascular events in Japanese elderly patients with multiple atherosclerotic risk factors who have no previous history of ASCVD.

Methods:
The Japanese Primary Prevention Projects (JPPP) is a multicenter, open-labelled, randomized, parallel-group trial which evaluates primary prevention with low-dose aspirin in Japanese patients aged 60 to 85 years with hypertension, dyslipidemia, or diabetes mellitus. Enrollment began in March 2005 and was completed in June 2007. A total of 14,466 individuals were randomly allocated to receive enteric-coated aspirin, 100mg/day or no aspirin. At randomization, study cohort had a mean age of 70.6 years. 57.8 % of the patients were women, 85.0% had hypertension, 71.7% had dyslipidemia, and 33.9% had diabetes. 80.4% of enrolled patients had = 3 conventional risk factors. The primary endpoints were atherosclerotic events including fatal or nonfatal myocardial infarction, fatal or nonfatal stroke and other cardiovascular death. Secondary endpoints included each and combinations of primary and other cardiovascular endpoints as well as death from any cause. Endpoint assessment was done by a central adjudication committee blinded to treatment assignments.

Results:
The final analysis was done at a median follow-up time of 5.02 years (Quartiles: 4.55-5.33) according to the recommendation in Data Safety Monitoring Board. The number of eligible patients in aspirin and non-aspirin group was 7,220 and 7,244, respectively. There was no significant difference between two groups (P=0.544) while we observed
193 and 207 primary events in each group and the estimated hazard ratio was 0.941 (95%CI 0.774-1.145). The 5 year cumulative event rates were also 2.772% (95%CI 2.400%-3.201%) and 2.960% (95%CI 2.575%-3.402%), respectively, although we assumed annual event rate would be 1.5% or 2.0% in non-aspirin group.

Conclusion:

Aspirin was not associated with significant reduction in total cardiovascular events in elderly patients with multiple cardiovascular risk factors.

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