Aspirin for Primary Prevention of Cardiovascular Disease: Harms Outweigh Benefits

September 30, 2014

Why is this important?

Aspirin has long been used for primary prevention of cardiovascular disease (CVD) and is available over the counter. On May 5, 2014, the Food and Drug Administration made a public statement that aspirin is not recommended for primary prevention, and can cause significant harm. The United States Preventive Services Task Force recommends aspirin in men ages 45-79 and women ages 55-79 for prevention of CVD only when reduction in myocardial infarction or stroke, respectively, exceeds the harm from bleeding.

Facts:

- A systematic review identified 9 randomized trials with 102,621 participants randomized to either aspirin or placebo for primary prevention of cardiovascular events.
- Participants had an average age of 57 and were followed for a mean of 6 years.
- Aspirin led to a small reduction in the risk of total cardiovascular events, mainly driven by a lower risk of non-fatal myocardial infarction (See figure).
- Non-trivial bleeding events (fatal bleeding, retinal or cerebrovascular bleeding, bleeding from a hollow viscus, bleeding requiring hospitalization or transfusion, or study-defined major bleeding) were increased in the aspirin group.
- These findings corroborate those of an earlier meta-analysis.

For patients at low to moderate risk of cardiovascular events, aspirin causes more harm (non-trivial bleeding) than benefit (reduced cardiovascular events) when used for primary prevention. Mortality is not reduced by aspirin over an average of 6 years.
Strength of Evidence

(Adapted from Guyatt G BMJ, 26 April 2008, Volume 336)

This refers to the degree to which the findings of this study are likely to be free of bias.

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Tips for Discussion of Results with Patients

Explore patient concerns, preferences, and values.

- Aspirin is known to benefit patients who have already had a heart attack, stroke or other vascular event. In patients at low or moderate risk for cardiovascular events, the risk of harm from bleeding exceeds the benefits gained.
- It is unknown if longer follow up may show more of a benefit in cardiovascular outcomes.
- When considering the initiation of aspirin for primary prevention, specific benefits to the patient’s risk of cardiovascular disease should be assessed, and compared to the risk of bleeding.

References


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The Bottom Line summaries reflect the expertise and opinions of the SGIM EBM Task Force as of the date of release of this summary.