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Evidence Updated: New
Bottom Line: Slight correction
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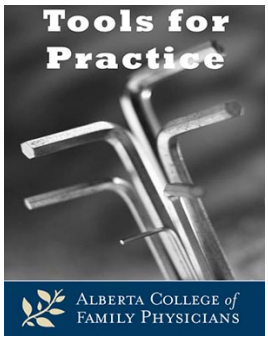

ASA in Primary Prevention: Do the Benefits Outweigh Risks?

Clinical Question: Are the benefits worth the risks of ASA in primary prevention (patients with no history of cardiovascular disease (CVD))?

Bottom-line: The majority of primary prevention patients will not benefit from daily ASA therapy. It is possible that there is net benefit in higher-risk primary prevention patients. Although the best risk level to initiate ASA is uncertain, it may be those with a ≥15-20% risk of CVD over 10 years.

Evidence:

- An individual patient-level meta-analysis[1] of six randomized controlled trials with 95,000 patients taking ASA 75-500mg/day followed for ~6.5 years:
  - No effect on mortality (all-cause or vascular).
  - 12% relative risk reduction in CVD.
    - ASA 0.51% per year vs. 0.57% per year without ASA.
    - Number Needed to Treat (NNT) ~1,400 to prevent one serious vascular event per year.
  - 50% relative risk increase in major gastrointestinal and other extracranial bleeds (transfusion or death).
    - ASA 0.1% per year vs. 0.07% per year without ASA, Number Needed to Harm (NNH) ~2,800 per year.
  - Risk factors that increased CVD risk also proportionately increased the risk of hemorrhagic stroke and extracranial bleeds.
- Results of newer meta-analyses[2-4] including three additional trials (total 102,621 patients) are consistent with the above.
  - Of interest, in one meta-analysis,[2] a more inclusive definition of "non-trivial bleeding" occurred in:
    - ASA 12% vs. 9.6% without ASA, NNH 42.

Context:

- Few studied patients were at "high" risk (only 2% had five-year risk of coronary heart disease of ≥10%).[1]

- In secondary prevention (patients with established CVD), ASA benefits do outweigh risks.[1,5,6]
  - Over approximately 24-33 months, the outcomes in patients with established CVD taking 75-325mg/day are:
    - NNT 30 for CVD.
    - NNT 72 for mortality.
    - NNH 112 for major GI bleeds.
- Cost-effectiveness analysis[7] estimates a patient's 10-year risk of CVD would have to be 15-20% for ASA in primary prevention to be cost-effective.

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