

Statement on Use of Aspirin

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Plain English Summary

Aspirin can help to reduce heart attacks and strokes, but this must be balanced against the risk of bleeding from the stomach or intestines.

For people already diagnosed with a heart attack or stroke, who have not previously suffered from bleeding from the stomach or intestines, the reduced level of risk for future heart attack or stroke usually outweighs the increased risk of bleeding. For these people a low dose of aspirin (defined as 75 mg/day) is recommended unless they are known to be unable to take aspirin.

For people without a previous diagnosis of heart attack or stroke, the balance of benefits against harms from aspirin is small. For these people, therefore, daily aspirin is not generally advised. Aspirin *may* be considered beneficial if an individual's future risk of stroke or heart attack is higher than average, however aspirin should only be considered *after* an accurate assessment of that individual's risk by his or her doctor and *after* blood pressure has been controlled to target, if hypertensive..

Scientific Summary

The use of aspirin to prevent future cardiovascular events in those with a prior history of cardiovascular disease (CVD) is recommended by all relevant guidelines and is supported by a strong evidence base. However, there has been much publicity and debate resulting from reports questioning the benefits of aspirin use in those with no history of prior CVD, including those with diabetes,^{1,2,3} particularly in the context of the known increase in risk of gastrointestinal bleeding. People with atrial fibrillation are a special category and the BIHS endorses the current National Institute for health and Clinical Excellence (NICE) recommendation for these individuals.

Most guidelines recommend that all patients suitable for secondary prevention strategies (those with prior history of CVD), including those with type 2 diabetes of greater than 10 years duration or over 50 years of age, have a sufficient level of CVD risk to benefit from aspirin therapy, and should be considered for low -dose aspirin (75mg daily) unless they have specific contraindications to aspirin use.

For primary prevention, the balance of benefits vs harm mandate that patients need to be at higher CVD risk to shift the balance in favour of benefit. For example, the use of low-dose aspirin, in well treated hypertensive subjects at different levels of baseline CVD risk, was neutral at a 10 year CVD risk of about 10%, but favoured benefit at higher levels of risk.⁴

The Lancet meta-analysis,¹ using individual participant data from the original trials of the use of aspirin in primary prevention, reported an overall proportional risk reduction in serious vascular events of 12% (0.51% aspirin vs 0.57% control per year, $p=0.0001$) due mainly to a reduction of about one fifth in non-fatal myocardial infarction (0.18% vs 0.23% per year, $p<0.0001$). However, this benefit was offset by an increase in major gastrointestinal and extracranial bleeds (0.10% vs 0.07% per year, $p<0.0001$). In this analysis, the absolute reduction in the risk of vascular events was only about twice as large as the absolute increase in bleeding and, as the authors of the meta analysis pointed out, most of the patients recruited into the primary prevention trials were not taking statins, which would have reduced their absolute risk of vascular events without any increase in harm. Even in those patients at higher risk the number of vascular events was too few to allow any reliable conclusions to be drawn.

In a further report of a meta analysis of trials of aspirin use in the primary prevention of cardiovascular events in people with diabetes,² there was a non significant trend for benefit on all cardiovascular events (Hazard Ratio (HR) 0.90, 95% Confidence Interval (CI) 0.81-1.00), but a significant reduction in the risk of myocardial infarction in men (HR 0.57, CI 0.34-0.94) but not women (HR 1.08, CI 0.71-1.65). The evidence from these trials for harm associated with aspirin was inconsistent.

The most recent meta-analysis, involving over 100,000 subjects in a prospective follow up study of the effect of aspirin on vascular and non-vascular outcomes⁵ concluded that aspirin in primary prevention significantly reduces the risk of total CVD events (Number need to treat (NNT) 120 over 6 years), largely through its effect on nonfatal myocardial infarction (NNT 162 over 6 years). There was no benefit on CV death or on cancer deaths or on all-cause mortality. From these analyses, aspirin increased harm (H) through the risk of bleeding (NNH for non-trivial bleeds 73 over 6 years).

The authors of these analyses also emphasise that in current practice, where risk factor control with statins and other agents effectively reduces atherosclerotic CVD events, any additional potential benefits of aspirin in primary prevention are small. The Medicines and Healthcare Products Regulatory Agency (MHRA) remind physicians and the public that aspirin is only licensed for the secondary prevention of CVD, and that if aspirin is used in primary prevention, the balance of benefits and risks should be considered for each individual, particularly the presence of risk factors for CVD and the risk of gastrointestinal bleeding.

On the basis of these findings and reports, the BIHS Working Party reaffirms its earlier recommendations that aspirin use in the prevention of cardiovascular disease in hypertensive people should, in general, be restricted to patients with a prior history of CVD. As advocated by MHRA, physicians should weigh up the benefits and risks of low dose aspirin in all individuals. An accurate quantitative assessment of CVD risk is essential before prescribing aspirin for individuals in the primary prevention of CVD where the evidence for benefit versus harm is very limited.

References

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