

ASPIRIN AND PRIMARY PREVENTION

There is a fine balance between benefits and risks of aspirin in primary prevention. These should be considered for each individual patient. New evidence is continually emerging and not yet conclusive.¹

Local advice

- Low-dose aspirin is **recommended** for the prevention of thrombotic cerebrovascular disease and cardiovascular disease events in those **with established atherosclerotic disease (secondary prevention)**.
- Low-dose aspirin is **not recommended to be routinely initiated** for primary prevention of thrombotic cerebrovascular or cardiovascular disease in patients with diabetes who do not have other cardiovascular risk factors.
- Low-dose aspirin is **not recommended to be routinely initiated** for primary prevention of thrombotic cerebrovascular or cardiovascular disease in individuals **who are apparently healthy** (asymptomatic individuals without established atherosclerotic disease but with a calculated cardiovascular risk of $\geq 20\%$ over 10 years).
- In patients with hypertension and a 10 year cardiovascular disease risk exceeding 20%, once blood pressure is treated to $< 150/90\text{mmHg}$, prescribers must **weigh up the balance of risks and benefits for individual patients** including the risk of bleeding with aspirin.
- In patients already taking low-dose aspirin for primary prevention, the decision on whether to continue with treatment should be taken by **both the patient and prescriber** in light of available evidence and by **weighing up the balance of risks and benefits for the individual patient. This should be done at the next routine review.**

Background

Advice from the Medicines and Healthcare products Regulatory Agency (MHRA)

The MHRA has recently issued advice to healthcare professionals on the unlicensed use of low-dose aspirin in primary prevention (i.e. the prevention of cerebrovascular disease and cardiovascular disease events in those without a history of vascular disease). The MHRA has advised that results of recent studies lend support to the licensed indications for aspirin in secondary prevention of vascular events, however if aspirin is used in primary prevention, the balance of benefits and risks should be considered for each individual, particularly in the presence of risk factors for vascular disease and the risk of gastrointestinal bleeding.² See [MHRA Drug Safety Update, October 2009](#) for further information.

Aspirin for primary prevention in diabetes

Increasing evidence indicates that the expected benefit of aspirin in the primary prevention of major cardiovascular events or death in people with diabetes may not exceed the risk of major bleedings, particularly among those at low cardiovascular risk ($<20\%$ over 10 years), or among older patients (>70 years) at high risk of bleeding.^{3,4} A meta-analysis of randomised controlled trials⁴ of aspirin compared with placebo or no aspirin in people with diabetes and no pre-existing cardiovascular disease, found no significant reduction in the risk of major cardiac events or all cause mortality. However a subgroup analysis by sex found that aspirin

significantly reduced the risk of MI in men by 43% with no benefit found in women.⁴ A randomised placebo controlled trial including patients with diabetes who were determined as having asymptomatic peripheral arterial disease, found aspirin was not effective in the primary prevention of cardiovascular events.³ Evidence from ongoing trials, A Study of Cardiovascular Events in Diabetes (ASCEND) and the Aspirin and Simvastatin Combination for Cardiovascular Events Prevention Trial in Diabetes (ACCEPT-D) are awaited.

- Locally, diabetologists do not routinely recommend low-dose aspirin for primary prevention in diabetic patients without additional risk factors or diabetic complications such as hypertension or evidence of target organ damage e.g. renal impairment.

National Guidance

Recommendations from the Scottish Intercollegiate Guidelines Network (SIGN),⁵ are outlined in [SIGN guideline no. 97, Risk estimation and the prevention of cardiovascular disease](#). With regard to use of aspirin in primary prevention these recommendations have now been superseded by our local advice as detailed above.

References

1. Aspirin for primary prevention of cardiovascular disease? *DTB* 2009; 47 (11): 122-125 [online]. Available from: <http://dtb.bmj.com> (subscription only) [Accessed 6 November 2009]
2. MHRA. *Drug Safety Update* 2009, October; 3 (3) [online]. Available from: <http://www.mhra.gov.uk/Publications/Safetyguidance/DrugSafetyUpdate/CON059804> [Accessed 6 November 2009].
3. Belch, J. et al. The prevention of progression of arterial disease and diabetes (POPADAD) trial: factorial randomised placebo controlled trial of aspirin and antioxidants in patients with diabetes and asymptomatic peripheral arterial disease. *BMJ* 2008; 337: a1840
4. De Berardis, G. et al. Aspirin for primary prevention of cardiovascular events in people with diabetes: meta-analysis of randomised controlled trials. *BMJ* 2009; 339: b4531
5. Scottish Intercollegiate Guidelines Network, 2007. Risk estimation and the prevention of cardiovascular disease. A national clinical guideline. 97 [online]. Available from: <http://www.sign.ac.uk/pdf/sign97.pdf> [Accessed 1 December 2009].

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