Role of aspirin in the primary prevention of cardiovascular disease in diabetes mellitus: a meta-analysis
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CRD summary
This review concluded that aspirin for primary prevention of cardiovascular events, in people with diabetes, did not reduce the risk. However, studies were underpowered and further research was needed. There were questions about some review methods, the quality of included data and clear definitions of outcomes, but the authors’ conclusions seem suitably cautious.

Authors' objectives
To assess the effects of aspirin for the primary prevention of cardiovascular events in people with diabetes.

Searching
MEDLINE and The Cochrane Library were searched to December 2009. Search terms were reported. Studies in languages other than English and unpublished studies were excluded.

Study selection
Randomised controlled trials (RCTs) were eligible if they included people with diabetes, and compared aspirin to placebo or no aspirin for primary prevention of cardiovascular disease. Studies of mixed primary and secondary prevention were eligible if data for primary prevention was available separately. The outcomes of interest were major cardiovascular events, myocardial infarction, stroke and all-cause mortality.

In the included studies, some participants also had hypertension or mild peripheral artery disease. Where given, mean ages ranged from 60 to 64 years. Aspirin dosage ranged from 75 to 100mg daily or 100 to 325mg on alternate days. Mean duration of study ranged from 3.7 to 10.1 years.

The authors did not state how many people selected studies for inclusion.

Assessment of study quality
The authors did not state that they assessed study quality.

Data extraction
Data were extracted to calculate relative risk (RR) and 95% confidence intervals (CI).

Two reviewers independently extracted data. Disagreements were resolved by discussion.

Methods of synthesis
Analyses were undertaken on an intention-to-treat basis. Pooled relative risk and 95% confidence intervals were calculated using Mantel-Haenszel random-effects and fixed-effect methods. Cochran Q statistic was used to assess statistical heterogeneity.

Results of the review
Six studies (7,907 participants reported in tables, 7,374 in abstract) were included. Three were RCTs (4,846 participants), and three (3,061 participants) were subgroup analyses of people with diabetes from larger trials. Five were placebo controlled, and one was open label (no comparative treatment).

Compared to controls there was no statistically significant effect of aspirin on cardiovascular events (five studies), myocardial infarction (six studies), ischaemic stroke (three studies) or all-cause mortality (three studies). Three studies reported on bleeding with a total of 50 events in the aspirin groups and 36 in the control groups, there was no statistically significant difference in risk of bleeding between groups.
Authors' conclusions
The evidence showed that aspirin did not reduce the risk of cardiovascular events in people with diabetes. However, the studies were underpowered and additional research was needed.

CRD commentary
The aims of this review were clearly stated in terms of the inclusion criteria. The search was limited to published studies in English. It was possible that studies were missed, so language or publication bias may have affected the review. The methods of data extraction were those aimed at reducing reviewer error or bias, those for study selection weren't clear. Quality of studies was not assessed so it was difficult to comment on the quality of included data. Some data came from subgroups of much larger RCTs and may have been underpowered.

The methods of synthesis were generally appropriate, but there appeared to have been statistical heterogeneity for some outcomes. Little information was presented about the included studies and some definitions weren't clear (such as definitions of cardiovascular events and bleeding). The authors stated that the results could not definitely exclude a potential for benefit of aspirin. There was a possibility of missed studies, questions about some methods of the review, the quality of included data and clear definitions of outcomes. The authors stated in conclusions that results were inconclusive and there was a need for further research, which seemed suitably cautious.

Implications of the review for practice and research
Practice: The authors stated that current evidence did not support the widespread use of aspirin for primary prevention of cardiovascular disease in people with diabetes. If aspirin was used in primary prevention in diabetic patient, this should be based on an individual's cardiovascular risk balanced by the risk of major bleeding.

Research: The authors stated that large adequately powered trials were needed to assess the effects of aspirin for the primary prevention of cardiovascular disease in people with diabetes, in the era of other current drug therapies. Guidelines on this topic need reviewing.

Funding
None.

Bibliographic details

PubMedID
20429671

DOI
10.1517/14656561003792538

Original Paper URL
http://informahealthcare.com/doi/abs/10.1517/14656561003792538

Indexing Status
Subject indexing assigned by NLM

MeSH
Aspirin /therapeutic use; Cardiovascular Diseases /complications /prevention & control; Diabetes Mellitus, Type 2 /complications; Humans; Primary Prevention

AccessionNumber
12010004086

Date bibliographic record published
28/07/2012
Date abstract record published
20/10/2012

Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.