Authors' objectives
To obtain reliable estimates of the risks of thromboembolic and bleeding complications in patients with mechanical heart valves.

Searching
MEDLINE and Current Contents were searched from 1985 to 1992 for studies published in the English language. Cross-references were also checked, and the search was extended back to 1970 for studies where no anticoagulation or only antiplatelet therapy was given.

Study selection
Study designs of evaluations included in the review
Reports with data on the incidence of thromboembolic and/or bleeding complications in a non-selective patient population, which stated the duration of follow-up, type of anticoagulation and the number treated, and which were able to discriminate between thrombosis, major and minor embolism, and major and minor bleeding. Only studies which reported results separately by model and position of the valve, and type and intensity of anticoagulation therapy, were included.

Specific interventions included in the review
Mechanical heart valve prostheses.

Participants included in the review
General population of patients with a mechanical heart prosthesis.

Outcomes assessed in the review
Thromboembolic and bleeding complications of the heart valve, major thromboemboli and all emboli.

How were decisions on the relevance of primary studies made?
The authors do not state how the papers were selected for the review, or how many of the authors performed the selection.

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

Data extraction
A standardised data form was used.

Methods of synthesis
How were the studies combined?
Averages of the results of individual series were calculated by weighting each study for sample size and using a multivariate poisson regression. This was only repeated for studies published after 1980.

How were differences between studies investigated?
Differences between studies were investigated by using multivariate poisson regression to estimate the rate of complications by type and position of valve and anticoagulation.
Results of the review
Forty-six studies (53,647 patient years), of which 7 investigated the absence of antithrombotic treatment, and 10 studied the effect of antiplatelet treatment alone; 6 reports described more than one regimen.

With cumarin therapy (the most commonly used), the incidence of valve embolism was 0.2 per 100 patient years (95% confidence interval, CI: 0.2, 0.2); major embolism was 1.0 (95% CI: 1.0, 1.1) and total embolism 1.8 (95% CI: 1.7, 1.9). In series with no anticoagulation the rates were at least 4 times higher. Antiplatelet therapy did not reduce these rates. These rates were similar to those found in the multivariate regression analysis. Antiplatelet therapy combined with cumarin did not reduce thrombotic complications more than cumarin alone, but increased the incidence of major bleeding. Mitral valve position was associated with a higher risk of thromboembolic complications, whilst caged-ball types of valves were associated with a higher risk of embolism. These results were stable over time.

Authors' conclusions
Cumarin treatment reduces the incidence of major embolism in patients with mechanical heart valves by approximately 75%, from about 4 to 1% per year. This offsets the incidence of major bleeding, 1.4% per year, induced by cumarin therapy. These data provide a reference for future studies and risk estimates for clinical decision making.

CRD commentary
A well-documented review of case series. It is difficult to assess the reliability of the relative risk of complications from pooling case series patients receiving different valves and treatments differing in other respects. It is not possible to assess the degree to which the regression analysis has adequately adjusted for these factors.

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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.