CRD summary
This review, of largely retrospective data, concluded that the optimal regimen for antithrombotic therapy in the first 90 days after tissue aortic valve replacement remained unclear because of methodological limitations in the included studies. Due to methodological flaws in the review process, the authors' conclusion may not be reliable.

Authors' objectives
To review the effectiveness of anticoagulant/antithrombotic therapy in the first 90 days following bioprosthetic aortic valve replacement.

Searching
The following electronic databases were searched from 1966 to 2006: MEDLINE, EMBASE, CINAHL and the Cochrane Library. Search terms were reported. The search was restricted to English language publications. Reference lists of included studies were also searched.

Study selection
Studies in adults (aged 18 or over) who had undergone tissue aortic valve replacement were eligible for inclusion. Included studies had to contain for five or more participants. Studies of aortic mechanical valve, mitral or tricuspid valve replacement were excluded, as were studies published in abstract form only.

Included studies were carried out in populations ranging in age from six to 95 years. Many studies combined the results of aortic and mitral valve replacements. A wide variety of antithrombotic and anticoagulation regimens were used. These were categorised by the authors as aspirin, vitamin K antagonist or no treatment. Outcomes reported were death, stroke, transient ischaemic attack or thromboembolism. Factors associated with increased risk of thromboembolism and bleeding complications were also recorded.

Two reviewers independently assessed studies for inclusion in the review. The authors did not state how discrepancies were resolved.

Assessment of study quality
The authors did not state what criteria were used to assess validity, other than whether the study was prospective, and whether participants were recruited consecutively. If it was not stated, the reviewers assumed the study was retrospective or non-consecutive.

Two reviewers independently assessed validity using a standardised form. The authors did not state how discrepancies were resolved.

Data extraction
Where studies reported data for tissue aortic valve replacement patients and other patients, the data for the tissue aortic valve replacement patients was separated where possible.

The authors did not state how many reviewers performed the data extraction, although it was implied that two reviewers extracted data independently using a standardised form.

Methods of synthesis
The authors synthesised evidence from the included studies narratively, grouped as evidence for and against early anticoagulation.
Results of the review
Twenty eight studies were included in the review (n=11,667 patients who had tissue aortic valve replacement only). Sample size of included studies ranged from 121 to 2,943 patients. Three were prospective randomised controlled trials (RCTs, n=640 patients) and the rest were prospective or retrospective case series, although the design of some included studies was unclear.

Three studies provided evidence in favour of early anticoagulation; one prospective study (n=209 patients) and two retrospective studies (n=985 patients). The prospective study found that ticlopidine statistically significantly reduced the risk of thromboembolic events compared to oral anticoagulant (p=0.002) but bleeding related episodes were not statistically significantly reduced.

Five studies provided evidence against early anticoagulation: one prospective (n=249) and four retrospective (n=1,218). The prospective study found no statistically significant difference between warfarin and low dose aspirin in frequency of cerebral ischaemic events or in rates of bleeding.

Risk factors associated with bioprosthetic aortic valve replacement, incidence of thromboembolism and bleeding complications due to anticoagulation were reported in the review.

Authors' conclusions
The optimal regimen for antithrombotic or anticoagulation following tissue aortic valve replacement remained unclear, due to a lack of prospective randomised controlled trial data.

CRD commentary
The review specified inclusion and exclusion criteria for participants and interventions, but not for study design or outcomes, to select studies from a comprehensive literature search. The search was restricted to English language publications and no attempts were made to locate unpublished material, so it is possible that some relevant studies may have been missed. The procedures for study selection were reported, but the procedures for validity assessment and data extraction were not clear. Criteria used for validity assessment were not listed by the authors, so there was potential for reviewer error and bias. The validity assessment seemed very limited and, as most of the studies were retrospective, their reliability may have been poor. The authors stated that it was difficult to identify the effect of treatment in the different study populations due to lack of details of treatment regimens, use of combination therapies and different risk factors between study populations. Many included studies did not specify the treatment regimen and many combined results of aortic and mitral valve replacements. Clinical and methodological heterogeneity between included studies led the authors appropriately to conduct a narrative synthesis of evidence. However, data from included studies did not seem to have been summarised in a systematic way in the tables. Data on participant characteristics were also very limited. Only results from eight of the 28 included studies were reported in the text. The authors did acknowledge certain limitations with the included studies. However, due to the sometimes unclear reporting of review procedures, the considerations with validity, and the reporting of results for only a small proportion of the included studies, the authors' conclusion may not be reliable.

Implications of the review for practice and research
Practice: The authors did not state any implications for practice.

Research: The authors called for further large prospective randomised controlled trials.

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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.