CRD summary
This review concluded that, compared with transfemoral percutaneous coronary intervention, transradial percutaneous coronary intervention reduced major bleeding and major adverse events in people with acute ST-segment-elevation myocardial infarction. Data came from both randomised controlled trials (RCTs) and observational studies. Based on subgroup analyses of RCT data, the authors' overall conclusions appear to be unreliable.

Authors’ objectives
To compare the safety and efficacy of transradial versus transfemoral percutaneous coronary intervention in people with acute ST segment elevation myocardial infarction.

Searching
The Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, SCOPUS and Web of Science with Conference Proceedings were searched, from January 1993 to August 2009, without restriction by language. Search terms were reported. Bibliographies of included studies and relevant reviews were checked. Abstracts from meetings of four relevant associations were checked.

Study selection
Controlled studies that compared the radial with the femoral approach for percutaneous coronary intervention patients with acute myocardial infarction were eligible for inclusion. Eligible studies had to have data available for analysis on an intention-to-treat basis. Both primary and rescue percutaneous coronary interventions were eligible.

The primary outcomes of interest were mortality, major adverse cardiovascular and cerebrovascular events (including death, recurrent myocardial infarction, emergency percutaneous coronary intervention, coronary artery bypass graft and stroke) and major bleeding (defined as fatal bleeding, intracranial haemorrhage, 3g/dL or more haemoglobin drop, or requirement for transfusion or surgery).

The mean age of participants in the included studies ranged from 55 to 71 years; the proportion of men ranged from 68 to 88%. Two studies were solely on people undergoing rescue percutaneous coronary intervention: seven studies were on primary percutaneous coronary intervention; and in three other studies between 18 to 66% had rescue percutaneous coronary intervention. Where stated, most studies used the Allen test to assess eligibility; some also used pulse oxymetry. The majority of studies excluded people with cardiogenic shock. Glycoprotein IIb/IIIa inhibitors were not used in one study; they were used in all participants in four studies; they were used in 21 to 94% of participants in other studies. All studies used unfractionated heparin and, with the exception of one study where antiplatelets were used, either ticlopidine or clopidogrel were also used.

The authors did not report how many reviewers performed the study selection.

Assessment of study quality
Study quality was assessed using a scale modified from Jadad and Biondi-Zoccai. Points were awarded for items such as: statement of objectives; explicit inclusion and exclusion criteria; description of intervention; objective means of follow-up; description of adverse events; power analysis; description of statistical methods; multi-centre design; discussion of withdrawals; and details of medical therapy during and after procedure. The maximum score was 10 points.

One reviewer assessed quality.
Data extraction
Odds ratio (OR) and 95% confidence intervals (CI) were calculated for dichotomous outcomes. Mean differences (MD) with 95% confidence intervals were calculated for continuous variables. Study authors were contacted for missing information.

Data were extracted independently by two reviewers. Disagreements were resolved by consensus and discussion with a third reviewer.

Methods of synthesis
A fixed-effect model was used to calculate pooled odds ratios and 95% confidence intervals for dichotomous variables. Mean differences with 95% confidence intervals were calculated for continuous variables. Heterogeneity was assessed using the $I^2$ statistic.

Subgroup analyses were performed based on study design (randomised versus observational) and quality score (up to 7 versus more than 7 points), and sensitivity analyses using a random-effects model and according to risk (less than 30% rescue percutaneous coronary intervention versus over 30% rescue percutaneous coronary intervention), use of glycoprotein IIb/IIIa inhibitors (less than 90% versus over 90%).

Results of the review
Twelve studies were included, of these five were randomised controlled trials (RCT; 516 participants) and seven (2,808 participants) were registry (observational) studies. One study scored 9 points for quality and one scored 5; the remaining scored between 6 and 8 (out of a possible 10 points). Follow-up was in-hospital or at 30 days in the majority of studies; one study followed up at nine months.

Compared with transfemoral percutaneous coronary intervention, the radial approach reduced the risk of death (OR 0.54, 95% CI 0.33 to 0.86), major bleeding (OR 0.30, 95% CI 0.16 to 0.55), and major adverse cardiovascular and cerebrovascular events (OR 0.56, 95% CI 0.39 to 0.79). There were no differences in procedural time or time to reperfusion. Fluoroscopy time was higher with radial percutaneous coronary intervention, but there was significant heterogeneity between studies. Radial percutaneous coronary intervention was associated with more frequent access site crossover and shorter hospital stay.

When analysed by study design, the results remained unchanged for non-randomised studies. However, pooling only RCTs resulted in no significant differences between radial and transfemoral approach for major adverse cardiovascular and cerebrovascular events (OR 0.65, 95% CI 0.32 to 1.30), death (OR 0.63, 95% CI 0.25 to 1.58), or major bleeding (OR 0.49, 95% CI 0.18 to 1.31). This conflicted with the summary given in the text of the paper. which stated that subgroup analyses continued to show benefits in favour of the radial approach.

When pooled according to risk, in those studies with more than 30% of participants having rescue percutaneous coronary intervention there was no difference in outcomes between the two groups, but in those with less than 30% rescue percutaneous coronary intervention results were similar to the main analyses.

Authors’ conclusions
Transradial percutaneous coronary intervention reduced the risk of peri-procedural major bleeding and of major adverse events in people with acute ST segment elevation myocardial infarction.

CRD commentary
The inclusion criteria with regard to participants, intervention and outcomes were clearly stated. The search covered a number of relevant sources including unpublished and non-English language material, which was likely to have reduced any possible effect of publication or language bias. The methods of data extraction were those aimed at reducing reviewer bias or error, but those for study selection were not described.

The quality of the included studies was assessed, but the use of summary scores may have obscured important
differences between the quality of studies. The authors pooled results from RCTs and observational studies; this may have appeared appropriate, given that there was little statistical heterogeneity. However, the authors did not acknowledge the very different results produced when studies were analysed according to study design. Results for RCTs, which showed no difference for mortality, major bleeding or major adverse cardiac events between the radial and femoral approaches, largely invalidated the authors’ overall findings. There were also discrepancies between information reported in the text and that given in the tables (the data reported in this review was taken from the tables).

The data presented suggest that the authors’ conclusions are likely to be unreliable.

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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.