High-risk patients with ST-elevation myocardial infarction derive greatest absolute benefit from primary percutaneous coronary intervention: results from the Primary Coronary Angioplasty Trialist versus Thrombolysis (PCAT)-2 Collaboration


CRD summary
This individual patient data review concluded that primary percutaneous coronary intervention was strongly associated with a relative reduction in 30-day mortality irrespective of patient baseline myocardial infarction risk; if access to the procedure was over two hours, fibrinolysis remained a legitimate option in low-risk patients. Despite some potential limitations, the authors' conclusions seem appropriate.

Authors' objectives
To investigate which categories of patients with myocardial infarction would benefit most from the strategy of primary percutaneous coronary intervention (PCI).

Searching
MEDLINE and Web of Science were searched for studies published between January 1990 and December 2002; search terms were reported in a prior paper (see Other Publications of Related Interest). The prior paper stated that articles not in English were eligible for inclusion and that references of identified papers and abstract listings of annual meetings of the American Heart Association, American College of Cardiology, and European Society of Cardiology were searched, but it was unclear if this applied to the current review.

Study selection
Randomised controlled trials (RCTs) that compared fibrinolysis and primary PCI in at least 50 patients with myocardial infarction were eligible for inclusion. The primary outcome was all-cause mortality 30 days post-randomisation.

Over 50% of the participants were over 60 years old; most were male (approximately 75%). Approximately 15% of participants had a prior myocardial infarction, approximately 15% had diabetes, 5% had prior PCI and 2% had prior coronary artery bypass grafting (where reported).

Independent selection of studies for inclusion by three reviewers was reported by the prior related paper.

Assessment of study quality
Completeness and internal consistency of the individual patient data (IPD) used was assessed by comparing with published reports; discrepancies between the IPD and published results were queried and resolved with trialists.

Data extraction
Trialists were contacted to retrieve IPD, including patient characteristics and survival to 30 days post-randomisation.

Methods of synthesis
A model was developed to estimate the probability of 30-day death in individual patients using a random selection of 80% of patients (n=5,421); this was validated on the remaining 20%. A multivariate model was constructed using backward elimination of the least significant variables from the univariate analyses until all variables had p≤0.15 to produce a mortality risk score that included all relevant risk factors. Risk factors were weighted according to the natural logarithm of the corresponding odds ratio (OR). Continuous variables were categorised (details provided in the paper).

The influence of baseline risk was assessed using a multivariate model fitted to the entire data set including: the mortality risk score; allocated treatment (primary PCI versus fibrinolysis); and the interaction term between the risk score and allocated treatment. Relative treatment effects were reported as adjusted odds ratios with 95% confidence intervals (CIs); numbers needed to treat were calculated based on the results of the final model.

Missing data was imputed using mean substitution; sensitivity analyses were conducted using only patients with...
complete data.

Results of the review
Twenty five studies were eligible for inclusion; IPD were unavailable for three trials (980 patients). IPD were obtained from 22 trials (n=6,763 patients; fibrinolysis n=3,452 patients; primary PCI n=3,451 patients), which were included in the analyses.

Overall, 446 patients (6.6%) died within 30 days of randomisation.

Patients who received primary PCI had lower mortality than those who received fibrinolysis (5.3% versus 7.9% events, adjusted OR 0.61, 95% CI 0.49 to 0.77).

Extensive results were reported for the association between a range of variables and mortality used to develop the risk score. Interaction between the risk score and allocated treatment was not statistically significant (p=0.52), which indicated that the relative mortality reduction by primary PCI compared to fibrinolysis was not modified by the baseline mortality risk. However, absolute mortality reduction by primary PCI was strongly and positively associated with the baseline mortality risk.

Analysis of subgroups according to the quartiles of the distribution of the mortality risk score gave a number needed to treat to prevent one death by primary PCI compared with fibrinolysis of 516 patients in the lowest-risk quartile and 17 patients in the highest-risk quartile; intermediate quartiles had numbers needed to treat of 47 and 44 patients.

Authors' conclusions
Primary percutaneous coronary intervention was consistently associated with a strong relative reduction in 30-day mortality, irrespective of patient baseline risk, and should be considered as the first choice reperfusion strategy whenever feasible. If access to primary percutaneous coronary intervention is over two hours, fibrinolysis remained a legitimate option in low-risk patients because of the small absolute risk reduction by primary percutaneous coronary intervention in this particular cohort. Risk scores might be used to select patients who would benefit most from primary percutaneous coronary intervention.

CRD commentary
The review addressed a clear research question supported by appropriate inclusion criteria. Two relevant sources were stated as being searched. A prior paper cited for methods stated that non-English studies were eligible and further sources were searched. However, it was unclear whether this was the case for the current review, so language and publication bias could not be ruled out.

IPD for 22 out of 25 trials was retrieved; no sensitivity analyses using summary results from the three trials were undertaken. Appropriate checking and validation of the data appeared to have been undertaken. The analysis appeared appropriate, but there was a discrepancy in the odds ratio reported for mortality between the main text and the abstract. Sensitivity analysis using aggregate data from the three studies where IPD were not available were not performed, so the potential impact of the omission of these studies on the results was unknown.

Despite some potential limitations of the review, the authors' conclusions seem appropriate.

Implications of the review for practice and research
Practice: The authors stated that this analysis supported the recommendations of the American Heart Association/American College of Cardiology and European Society of Cardiology guidelines. The authors also stated that the risk score might be used to select those higher risk patients who benefit most from primary PCI in regions where hospitals with PCI facilities were rare or where geography did not allow primary PCI in all patients with myocardial infarction.

Research: The authors did not state implications for research.

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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.