A meta-analysis of 17 randomized trials of a percutaneous coronary intervention-based strategy in patients with stable coronary artery disease

Schomig A, Mehilli J, de Waha A, Seyfarth M, Pache J, Kastrati A

CRD summary
This review evaluated the impact on long term mortality of percutaneous coronary intervention (PCI) of patients with stable coronary disease. The authors concluded that PCI-based invasive strategy may improve long-term survival compared with medical treatment only strategy. The authors’ conclusions reflected the evidence presented, but due to a lack of reporting on review processes their reliability was unclear.

Authors’ objectives
To assess the impact on long-term mortality of percutaneous coronary intervention (PCI) of patients with stable coronary disease.

Searching
PubMed, the United States' National Institute of Health and the Cochrane Central Register of Controlled Trials databases were searched between January 1980 to August 2007. Proceedings of the American Heart Association, American College of Cardiology and the European Society of Cardiology, pertinent reviews and editorials from leading journals, reference lists from retrieved articles and unspecified internet sources of results of clinical trials in cardiology were searched to identify further studies.

Study selection
Studies eligible for inclusion in the review were all randomised trials comparing PCI based invasive treatment and medical treatment strategy with a medical treatment-only strategy in patients with coronary artery disease or signs of ischaemia. Trials that included patients with acute coronary syndromes (with or without ST-segment elevation on electrocardiogram and with or without troponin or cardiac enzyme elevations) within the first week of presentation were excluded. Although not specified in the inclusion criteria, the primary outcome of interest was all cause death. Secondary outcomes of interest were cardiac death and non-fatal myocardial infarction. Demographic characteristics and previous history of myocardial infarction (MI) varied between studies. Patient enrollment period spanned from 1987 to 2004. The authors stated neither how the papers were selected for the review nor how many reviewers performed the selection.

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

Data extraction
Data was extracted in order to calculate odds ratios (OR) and 95% confidence intervals (CI), and to perform a meta-regression analysis. The authors did not state how many reviewers performed the data extraction.

Methods of synthesis
ORs were combined in a meta-analysis using both the fixed-effects Mantel-Haenszel model and the random-effects DerSimonian and Laird model. Heterogeneity was assessed using the Cochran Q statistic and I^2 test. Random-effects meta-regression analysis was used to estimate the influence of covariates (such as proportion of people with previous MI and enrollment period) on treatment effect. Publication bias was assessed using a funnel plot and the Egger test. Sensitivity analysis was performed by comparing the treatment effects obtained when each trial was consecutively removed from the analysis. Subgroup analysis was performed for trials that examined mortality where: all patients had a recent (less than four weeks) MI; coronary angiography was required before randomisation; or coronary artery bypass grafting (CABG) was not allowed as a treatment option.

Results of the review
Seventeen RCTs (n=7,513) were included in the meta-analysis for all cause mortality. Sample sizes ranged from 44 to 2,287. Follow up ranged from 12 months to 122 months. There was no evidence of statistically significant publication
PCI was associated with a statistically significant reduction in all cause death compared to medical treatment. Both the fixed-effects (95% CI: 0.68, 0.95, p-value not given) and random-effects model (95% CI: 0.64, 0.99, p-value not given) reported an OR of 0.80. There was no evidence of statistically significant heterogeneity. In the meta-regression analysis none of the covariates had a statistically significant influence on treatment effect.

Thirteen RCTs (n= 5,619) were included in the meta-analysis for cardiac death. PCI was associated with a statistically significant reduction in cardiac death using the fixed-effects model (OR 0.74, 95% CI: 0.57, 0.96) and a non-statistically significant reduction in cardiac death using the random-effects model (OR 0.74, 95% CI: 0.51, 1.06). There was no evidence of statistically significant heterogeneity.

Results of subgroup analyses were also reported (see full article for details).

**Authors' conclusions**

PCI-based invasive strategy may improve long-term survival compared with medical treatment only strategy in patients with stable coronary artery disease.

**CRD commentary**

The review addressed a clear research question and was supported by detailed inclusion criteria. The search strategy was adequate, but it was unclear whether language restrictions were applied. Publication bias was assessed and reported to be absent. However, the methods used to select studies and extract data were not reported, therefore, it was not known what efforts were made to minimise reviewer error and bias. The authors did not state whether study validity was assessed, so the reliability of data from the included studies could not be fully determined. Adequate details of primary studies were provided and the synthesis methods were appropriate. The authors' conclusions appeared to be supported by the evidence presented. But, the lack of reporting on methods of study selection, data extraction and validity assessment meant that the reliability of the authors' conclusions was unclear.

**Implications of the review for practice and research**

**Practice:** The authors did not state any implications for practice.

**Research:** A new randomised clinical trial sufficiently powered for evaluating the impact of PCI on long-term mortality should be performed.

**Funding**

Unrestricted grant from Department of Cardiology, Technische Universität, Munich, Germany, from Amersham/General Electric, Bayerische Forschungsstiftung, Bristol-Myers Squibb, Cordis, Cryocath, GlaxoSmithKline, Guidant, Lilly, Medtronic, Novartis, Nycomed, Sanofi-Aventis and Schering.

**Bibliographic details**


**PubMedID**

18772058

**DOI**

10.1016/j.jacc.2008.05.051

**Indexing Status**

Subject indexing assigned by NLM
MeSH
Angioplasty, Balloon, Coronary; Coronary Artery Disease /mortality /therapy; Humans; Randomized Controlled Trials as Topic; Treatment Outcome

AccessionNumber
12008106285

Date bibliographic record published
23/12/2008

Date abstract record published
20/05/2009

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.