Meta-analysis of randomized trials of percutaneous transluminal coronary angioplasty versus atherectomy, cutting balloon atherotomy, or laser angioplasty


CRD summary
This review concluded that ablation during percutaneous coronary intervention did not improve clinical outcomes, or lower restenosis rates, compared with balloon angioplasty. The review found higher risks of heart attack and major coronary events in patients treated with ablative procedures. A lack of some methodological details means that it is difficult to comment on the quality of this review.

Authors' objectives
To determine the effects on clinical outcomes of plaque modification (ablative therapy) during percutaneous coronary interventions, compared with balloon angioplasty.

Searching
PubMed was searched from 1993 to 2002. The search strategy was not presented, and there was no mention of whether any language restrictions were applied to the search. Proceedings of Scientific Sessions of the American Heart Association, American College of Cardiology and Transcatheter Therapeutics were also searched for relevant studies, though the unpublished data included in the review was restricted to multicentre studies.

Study selection
Study designs of evaluations included in the review
The study designs included published randomised controlled trials (RCTs) and unpublished multicentre RCTs.

Specific interventions included in the review
Studies assessing any ablative therapy (i.e. coronary atherectomy, laser angioplasty, or cutting balloon atherotomy) in comparison with balloon angioplasty were eligible for inclusion. In some studies, coronary stents were used.

Participants included in the review
The review included participants undergoing percutaneous coronary intervention; no further participant inclusion or exclusion criteria were given. The basic demographic characteristics of the participants were not described, nor was the severity of disease.

Outcomes assessed in the review
The following outcomes were assessed in the review: 30-day mortality, 30-day myocardial infarction (MI), 30-day major adverse cardiac event (MACE), angiographic restenosis (90 to 360 days), revascularisation at less than 31 days and at 180 to 365 days, and total revascularisation rates (up to 360 days). None of these outcomes was identified as a primary outcome of the review. The original definition of MACE from each study was used for the analysis.

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

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

Data extraction
The authors stated that data were extracted in duplicate from original studies. The source of the number of events and
rates were carefully documented for individual studies in the review. Odds ratios (ORs) for outcome effects were calculated for individual studies using the Woolf method. Events were calculated from the total number of participants given for each time point in follow-up. If total numbers were not given, values were calculated on an intention-to-treat basis. The authors stated that all calculations accounted for the duplicate control group (222 patients) in one of the included studies.

Methods of synthesis
How were the studies combined?
Pooled ORs and 95% confidence intervals (CIs) were calculated for each outcome, comparing ablative therapies (overall and individually) with coronary angioplasty using an empirical Bayes (random-effects) model.

How were differences between studies investigated?
Differences between the studies were investigated using the Q statistic method of DerSimonian and Laird and the Peto-modified Mantel-Haenszel method. Subgroup analyses were performed according to different ablative procedures.

Results of the review
The review included 16 studies (9,222 patients), although not all studies provided information for each outcome.

Thirty-day mortality (16 trials, 8,487 patients): the use of ablative procedures did not affect short-term death rates (OR 0.94, 95% CI: 0.46, 1.92).

Thirty-day MI (15 trials, 8,255 patients): the use of ablative procedures was associated with an increased risk of MI (OR 1.83, 95% CI: 1.43, 2.34). This association was also present when each of the ablative procedures was studied individually, but only reached the 5% significance level for directional coronary atherectomy and percutaneous transluminal rotational atherectomy.

Thirty-day MACE (16 trials, 8,990 patients): the use of ablative procedures was associated with an increased risk of MACE (OR 1.54, 95% CI: 1.25, 1.89).

Angiographic restenosis in 90 to 360 days (16 trials, 6,958 patients): the use of ablative procedures slightly increased angiographic restenosis rates, but this association was not significant at the 5% level (OR 1.06, 95% CI: 0.97, 1.17).

Total revascularisation rates up to 360 days (15 studies, 8,176 patients): these did not differ between the two intervention types (OR 1.04, 95% CI: 0.94, 1.14).

MACE at 360 days (16 trials, 8,311 patients): there was an increased risk of MACE with ablative procedures (OR 1.09, 95% CI: 0.99, 1.20), although this was only marginally statistically significant at the 5% level.

No significant heterogeneity between studies was found (0.75 > P > 0.50).

Subgroup analyses showed that there were some differences between the different ablative procedures for some outcomes.

Authors' conclusions
Ablative therapies are not associated with improved clinical outcomes or lower restenosis rates.

CRD commentary
This review addressed whether being treated with ablative procedures during percutaneous angioplasty affects clinical and angiographic outcomes.

The database search was limited to PubMed. Some unpublished multicentre trials were included in the review, but it was unclear why unpublished single-centre RCTs were excluded. These limitations could have resulted in studies having
been missed or excluded from the review. The review was reported thoroughly in some aspects (e.g. the detailed account of how the outcome data for individual studies were derived), but there were important details missing which make it hard to evaluate the quality of the review. These omissions include the lack of information about any assessment of validity assessment or methods used to select the individual studies. There were inconsistencies between some of the text and figures. In addition, it was unclear how the control group for one trial with three arms was dealt with in the meta-analysis. These observations place some doubt on the statistical interpretation of the results.

No details on the basic demographic characteristics of the participants in the studies were provided. The authors noted that the results are generalisable across the several centres from which the studies were drawn, but the wider external validity of the review is unclear.

The authors’ conclusions were too conservative. They found a higher rate of short-term MI and MACE in the patients treated with ablative procedures, suggesting that these procedures are not as safe or efficacious as balloon angioplasty.

Implications of the review for practice and research
Practice: The authors stated that their results do not support the use of routine ablation or sectioning of atheromatous tissue during percutaneous coronary interventions.

Research: The authors recommended that new innovations in tissue ablation should be identified before any new clinical trials are planned.

Bibliographic details

PubMedID
15028347

DOI
10.1016/j.jacc.2003.10.039

Original Paper URL
http://content.onlinejacc.org/cgi/content/full/43/6/936

Indexing Status
Subject indexing assigned by NLM

MeSH
Angioplasty, Balloon, Coronary /methods; Angioplasty, Laser /methods; Atherectomy, Coronary /methods; Coronary Artery Disease /mortality /surgery /therapy; Humans; Randomized Controlled Trials as Topic

AccessionNumber
12004000624

Date bibliographic record published
30/06/2005

Date abstract record published
30/06/2005

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.