Adjunctive mechanical devices to prevent distal embolization in patients undergoing mechanical revascularization for acute myocardial infarction: a meta-analysis of randomized trials


CRD summary
This review found that adjunctive mechanical devices are safe and associated with better perfusion and decreased embolisation in patients with acute myocardial infarction. Although these conclusions are likely to be reliable, they should be interpreted with some degree of caution as the validity of the primary studies was not assessed and details of the control interventions were not reported.

Authors' objectives
To determine the benefit of adjunctive mechanical devices for the prevention of distal embolisation in patients with acute myocardial infarction (AMI).

Searching
MEDLINE and the Cochrane CENTRAL Register were searched from 1990 to October 2006. Conference abstracts published in relevant journals (1990 to October 2006) or on relevant websites (2002 to October 2005) were screened. The keywords were reported and no language restrictions were applied.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) were eligible for inclusion. Full details of the exclusion criteria used by individual studies were reported in the paper.

Specific interventions included in the review
Studies of mechanical devices to prevent distal embolisation were eligible for inclusion. The specific devices included in the review were thrombectomy devices (x-sizer, angiojet, diver, rescue catheter, pronto catheter, export catheter, thrombus vacuum aspiration catheter) and distal protection devices (GuardWire Plus, FilterWire-EX, AngioGruard, SpideRX and FilterWireEZ). Details of the control interventions were not reported.

Participants included in the review
Studies of patients with AMI were eligible for inclusion.

Outcomes assessed in the review
Studies that reported angiographic or clinical data were eligible for inclusion. Angiographic outcome measures were postprocedural thrombosis in myocardial infarction (TIMI) 3 flow, myocardial blush grade (MBG) 3 and distal embolisation. The primary clinical end point was 30-day mortality, while the primary safety end point was the rate of coronary perforation.

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
Two reviewers independently extracted the data. If data were unclear or incomplete, study authors were contacted for further information. Any disagreements were resolved through consensus. Data were extracted on an intention-to-treat basis. Data were extracted as odds ratios (ORs) together with their 95% confidence intervals (CIs) for a range of postprocedural clinical end points.
Methods of synthesis
How were the studies combined?
Pooled ORs were calculated using the DerSimonian and Laird random-effects model. Publication bias was investigated using a funnel plot, and linear regression analysis to investigate funnel plot asymmetry.

How were differences between studies investigated?
Heterogeneity was assessed using the Breslow-Day test ($p<0.10$ considered as evidence of heterogeneity). Subgroup analyses based on type of device (thrombectomy or distal protection) were performed. A sensitivity analysis was conducted for publication as a full-length article.

Results of the review
Twenty-one RCTs (3,721 patients) were included.

Postprocedural TIMI flow (21 studies, 3,664 patients).
Adjunctive devices showed increased rates compared with controls (OR 1.34, 95% CI: 1.02, 1.76, $p=0.03$). There was moderate evidence of heterogeneity ($p=0.11$). Estimates were similar for thrombectomy and distal protection devices.

There was no evidence of publication bias ($p=0.75$).

Postprocedural MBG 3 perfusion (15 studies, 2,644 patients).
Adjunctive devices showed increased rates compared with controls (OR 2.21, 95% CI: 1.48, 3.32, $p<0.0001$). There was strong evidence of heterogeneity ($p<0.0001$). Estimates were similar for thrombectomy and distal protection devices.

Distal embolisation (14 studies, 3,036 patients).
Adjunctive devices showed decreased embolisation compared with controls (OR 0.58, 95% CI: 0.39, 0.87, $p=0.008$). There was strong evidence of heterogeneity ($p=0.04$). Thrombectomy catheters were more effective than distal protection devices, although this association was not statistically significant.

Mortality at 30 days (18 studies, 3,472 patients).
Adjunctive devices did not affect mortality (OR 0.97, 95% CI: 0.64, 1.46, $p=0.88$). There was no evidence of heterogeneity ($p=0.88$).

Device safety (number of studies not reported, 2,923 patients).
There were no differences in safety (numbers of coronary perforations) between adjunctive devices and control groups (OR 3.05, 95% CI: 0.48, 19.40, $p=0.24$). There was no evidence of heterogeneity ($p=0.63$).

Authors' conclusions
Adjunctive mechanical devices are associated with better epicardial and myocardial perfusion and decreased distal embolisation, but have no apparent effect upon survival; they are also safe.

CRD commentary
The review addressed a focused question that was supported by clearly defined inclusion criteria. The literature search was adequate and included attempts to locate unpublished studies. Steps were taken to minimise bias and errors in the extraction of data, but it is unclear whether such measures were also applied to the selection of studies. A formal quality assessment was not conducted, thus the validity of the included studies remains unclear. Details of the control interventions were not reported: it is difficult to interpret the review findings without knowledge of the comparator interventions.

Methods of analysis were appropriate and included an assessment and investigation of heterogeneity. The results were
clearly presented with the aid of relevant forest plots. The authors' conclusions are likely to be reliable, but should be interpreted with some degree of caution as the validity of the primary studies is unclear and details of the control interventions were not reported.

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

Practice: The authors stated that until more data are available on the effect of adjunctive devices on mortality, their routine use during AMI cannot be recommended.

Research: The authors stated that larger trials in high-risk patients and with longer follow-up are required to investigate the benefit of adjunctive mechanical devices on mortality.

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