Vascular complications associated with arteriotomy closure devices in patients undergoing percutaneous coronary procedures: a meta-analysis

CRD summary
This review investigated the safety of arteriotomy closure devices (ACDs) versus mechanical compression in patients undergoing percutaneous transfemoral coronary procedures. The vascular complication rates were similar in diagnostic settings. In intervention settings, two ACDs had similar complication rates to mechanical compression, whereas one had higher rates. The lack of a validity assessment of the included studies limits the results.

Authors' objectives
To assess the safety of arteriotomy closure devices (ACDs) versus mechanical compression in patients undergoing percutaneous transfemoral coronary surgery.

Searching
The Cochrane Library, MEDLINE, CINAHL and EMBASE were searched from 1991 to April 2003 for published studies; the keywords were listed. The reference lists of identified articles were also checked.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs), cohort and case-control studies were eligible for inclusion. Some studies were excluded because they used historical controls or because there was a risk of bias in patient selection.

Specific interventions included in the review
Studies comparing ACD with mechanical compression (manual, by means of hand compression, sandbag, C-clamp, or Femostop) were eligible for inclusion. The authors stated that the included studies had to have a well-described protocol of intervention, but this was not defined further. The included studies assessed Angio-Seal, VasoSeal and Perclose ACDs.

Participants included in the review
Studies of patients undergoing percutaneous coronary intervention (PCI) with transfemoral access were eligible for inclusion. The authors stated that the included studies had to have a precise report on each of the major vascular complications, but this was not defined further.

The included studies were conducted in diagnostic settings and/or PCI settings. In the included studies the proportion of men ranged from 56 to 94% and the proportion of patients with diabetes from 8 to 43%. Seventy-three per cent of studies used a ≥8-F device sheath.

Outcomes assessed in the review
Studies that compared access-related complications were eligible for inclusion. The primary outcome measure was the cumulative incidence of major vascular complications. This was defined as: pseudo-aneurysm requiring ultrasound-guided compression or surgical repair; arterio-venous fistula; retro-peritoneal haematoma causing haemodynamic compromise, surgery, blood transfusion, prolonged hospitalisation and/or death; femoral artery thrombosis (vessel occlusion requiring surgery or thrombolysis); surgical vascular repair; access-site infection necessitating treatment with antibiotics and/or surgical drainage; and blood transfusion.

How were decisions on the relevance of primary studies made?
Two authors independently searched the literature and assessed the relevance of studies. Any disagreements were resolved by consensus, with arbitration by a third reviewer.
Assessment of study quality
The authors did not state that they assessed validity.

Data extraction
The pooled average rate of complications was extracted from each study. The authors did not state how many reviewers performed the data extraction.

Methods of synthesis
How were the studies combined?
Combined odds ratios (ORs) and 95% confidence intervals (CIs) were calculated using fixed-effect models (or random-effects models if there was statistical heterogeneity).

How were differences between studies investigated?
Heterogeneity across the studies was assessed using the Q statistic. Subgroup analyses based on different devices, different study designs (randomised versus non-randomised) and different settings (diagnostic, PCI, mixed, or all settings) were performed.

Results of the review
Thirty studies involving 37,066 participants were included: 18 RCTs (4,536 participants) and 12 non-randomised studies (32,530 participants).

Any ACD versus mechanical compression (30 studies).
There was a higher complication rate in ACD compared with control patients when all studies were pooled (OR 1.34, 95% CI: 1.01, 1.79), although there was significant heterogeneity between studies (P<0.001). When only randomised studies were included, there was no difference in complication rate between patients receiving ACD or control (OR 1.30, 95% CI: 0.90, 1.87), with no statistical heterogeneity (P=0.19).

Angio-Seal versus mechanical compression (12 studies).
There was no statistical difference in complication rate between the two methods when all studies were pooled (OR 1.14, 95% CI: 0.72, 1.81). There was significant heterogeneity between studies (P<0.001). The findings were similar when Angio-Seal was compared with mechanical compression for complication rate in randomised trials, or in PCI or diagnostic settings. The subgroup analysis of randomised trials in PCI settings suggested that Angio-Seal was associated with fewer complications, although this was not of statistical significance (OR 0.46, 95% CI: 0.20, 1.04, P=0.062). There was no evidence of statistical heterogeneity in these subgroup analyses.

VasoSeal versus mechanical compression (10 studies).
There was a higher complication rate among patients treated with VasoSeal compared with controls (OR 2.27, 95% CI: 1.35, 3.80), with no significant heterogeneity between studies (P=0.65). This risk was similar among randomised studies only (OR 2.78, 95% CI: 1.51, 5.13), with no significant heterogeneity between studies (P=0.73). This increased risk was seen in PCI settings (OR 2.52, 95% CI: 1.36, 4.65), but not in diagnostic or mixed settings.

Perclose versus mechanical compression (15 studies).
There was no statistically significant difference in complication rates among patients treated with Perclose compared with control, either in any setting or in any one particular setting. Restricting the analysis to only randomised studies, there remained no evidence of benefit or harm from Perclose.

Other subgroup analyses found similar complication rates between ACDs and control among patients treated with glycoprotein IIb/IIIa inhibitors, patients treated with smaller and larger sheath size, or Perclose in the PCI setting.
Authors' conclusions
ACDs and mechanical compression have similar vascular complication rates in diagnostic settings. In PCI settings, Angio-Seal and Perclose have similar complication rates to mechanical compression, whereas VasoSeal has higher complication rates.

CRD commentary
Despite a clear research question, some inclusion criteria were not clearly defined. This might have led to subjective decisions regarding the inclusion or exclusion of studies. In addition, potentially relevant studies were excluded on the basis of using historical controls or because of a risk of bias in participant selection, though these were not part of the original inclusion criteria. The authors acknowledged that the search for only published studies might have biased the included studies. Two reviewers selected the studies, but it is unclear what attempts were made to reduce error and bias in the data extraction process. Sufficient details of the primary studies were provided in the review. The results presented may not be reliable since there was no validity assessment.

The authors' conclusions should be viewed with some caution because of the lack of a validity assessment and the poorly defined inclusion criteria.

Implications of the review for practice and research
Practice: The authors did not state any implications for practice.

Research: The authors stated that additional studies are required to examine the safety of ACDs and the impact of generational advances of these devices on outcomes.

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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.