Arterial puncture closing devices compared with standard manual compression after cardiac catheterization: systematic review and meta-analysis

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CRD summary
This review aimed to compare the effects of arterial puncture closing devices (APCDs) against compression after the insertion of a catheter into an artery. The authors concluded that APCDs reduce the time taken to stop bleeding, but may increase the risk of certain adverse effects. A lack of study details makes it difficult to determine the reliability of these conclusions.

Authors' objectives
To evaluate the safety and efficacy of arterial puncture closing devices (APCDs) for use after percutaneous vascular interventions or coronary angiography.

Searching
The following electronic databases were searched for studies in any language: MEDLINE (1966 to January 2003), EMBASE (1989 to January 2003), Pascal (1996 to January 2003), BIOSIS Previews (1990 to January 2003), CINAHL (1982 to January 2003) and the Cochrane CENTRAL Register. The authors stated that the search terms used were available on request. To identify further studies, including unpublished research, the reviewers contacted experts in the field and distributors of APCDs. They also examined the reference lists of included studies.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) were eligible for inclusion.

Specific interventions included in the review
Studies comparing APCDs with manual compression of the femoral artery were eligible for inclusion. Manual compression could either be used alone or with additional mechanical compression devices. The specific APCDs used in the included studies were Vasoseal, Angioseal, Duett and Perclose (including Techstar, Prostar and Prostar Plus).

Participants included in the review
Studies conducted in patients who had undergone coronary angiography or percutaneous vascular interventions were eligible for inclusion. The studies in the review contained either one or both of these patient groups. The vascular interventions included percutaneous transluminal coronary angioplasty and stenting.

Outcomes assessed in the review
No inclusion criteria relating to the outcomes were specified. The outcomes of interest, which were defined in advance, were complications at the puncture site (haematoma, bleeding, arteriovenous fistula and pseudoaneurysm), time to haemostasis, duration of bed rest and length of hospital stay. Other outcomes assessed in the studies included the need for surgical intervention at the puncture site, blood transfusion and leg ischaemia. The definitions of the outcomes varied between studies.

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 studies were assessed on the basis of allocation concealment, whether analysis was by intention-to-treat, and blinding of the outcome assessment. The studies were awarded a quality score ranging from 0 if none of the criteria
were fulfilled, to 3 if all were fulfilled. Two reviewers independently assessed validity. Discussion among at least three reviewers was used to resolve any disagreements.

Data extraction
Two reviewers independently extracted the data. Discussion among at least three reviewers was used to resolve any disagreements. The reviewers extracted data on the type of APCD used, the comparison group (manual compression alone, or with additional mechanical compression), and the type of procedure (diagnostic or intervention).

Safety outcomes were extracted as defined by the trial authors. For each safety outcome, the reviewers extracted the number of events in the APCD and manual compression groups, along with the total number of patients in each group. These were then used to calculate the relative risk (RR) and 95% confidence interval (CI). If patients with the outcome were divided into several categories, e.g. different grades of haematoma, these were added together to produce a binary outcome.

For efficacy outcomes, the difference between the means of the APCD and manual compression groups was used in the review. Trials that did not report the standard deviation, standard error or 95% CI, or that only reported the median, were excluded from the analysis of efficacy outcomes.

Methods of synthesis
How were the studies combined?
RRs or differences between means were combined using random-effects meta-analyses. For each outcome, studies of different types of APCD were combined in the meta-analysis. Publication bias was assessed using funnel plots and a regression method.

How were differences between studies investigated?
The authors assessed the proportion of variation between studies that was due to heterogeneity using the I-squared statistic. A random-effects meta-regression analysis was used to investigate the effect of several patient and intervention variables on the results. The variables, specified in advance, were the type of APCD, comparison group and procedure. Sensitivity analyses were used to assess the effects of allocation concealment, blinding and intention-to-treat analysis. Each quality item was assessed separately, grouping the studies according to whether the criterion was fulfilled.

Results of the review
Thirty RCTs were included in the review. The number of patients was not reported for all trials, but the total number of patients in the review was over 5,000. Nineteen trials compared APCDs with manual compression alone, while in 11 trials the comparison group received additional mechanical compression.

The quality scores for the studies ranged from 0 (21 studies) to 3 (2 studies). Allocation concealment was reported in 6 studies, blinding of the outcome assessment in 3 studies and intention-to-treat analysis in 4 studies.

Safety.

When APCDs were compared with manual compression, there were no statistically significant differences in the risk of groin haematoma (19 RCTs; RR 1.14, 95% CI: 0.86, 1.51, P=0.35), groin bleeding (12 RCTs; RR 1.48, 95% CI: 0.88, 2.48, P=0.14), arteriovenous fistula (6 RCTs; RR 0.83, 95% CI: 0.23, 2.94, P=0.77) and pseudoaneurysm (16 RCTs; RR 1.19, 95% CI: 0.75, 1.88, P=0.46). There was some evidence of statistical heterogeneity in the outcomes of haematoma (I-squared 33%) and bleeding (I-squared 38%), but none for arteriovenous fistula and pseudoaneurysm.

There were also no statistically significant differences between the APCD and manual compression groups in the risk of surgical intervention at the puncture site, blood transfusion or arterial leg ischaemia.

Efficacy.

APCDs were associated with a shorter time to haemostasis (16 RCTs; mean difference 17 minutes, range: 14 to 19) and duration of bed rest (10 RCTs; mean difference 10.8 hours, 95% CI: 8.5, 13.1) than manual compression. There was
strong evidence of statistical heterogeneity for both these outcomes (I-squared 96% and 98%, respectively). The length of hospital stay was also shorter in the APCD group (4 RCTs; mean difference 0.6 days, 95% CI: 0.1, 1.1) with evidence of statistical heterogeneity (I-squared 58%).

There was evidence of publication bias or heterogeneity in trials assessing the time to haemostasis and the duration of bed rest. The meta-regression analysis showed that the type of comparison group, APCD and procedure did not influence the effect size. In sensitivity analyses, trials that reported intention-to-treat analysis showed a statistically significant increased risk of haematoma (RR 1.89, 95% CI: 1.13, 3.15) and pseudoaneurysm (RR 5.40, 95% CI: 1.21, 24.5) associated with APCDs. In trials with adequate allocation concealment, there was no significant difference in the risk of bleeding between the APCD and manual compression groups (RR 0.97, 95% CI: 0.33, 2.83). The authors stated that other main outcomes were not affected by study quality.

**Authors' conclusions**

APCDs appeared to reduce the time to haemostasis, but there was insufficient evidence to determine whether clinically relevant outcomes, such as the length of hospital stay, were affected. In higher quality studies, the use of APCDs was associated with an increased risk of haematoma and pseudoaneurysm formation.

**CRD commentary**

The review question was clear in terms of the intervention, participants and study design of interest. Several electronic databases were searched, the search dates were reported and the search terms were available from the authors on request. The reviewers included papers in any language, which minimised the potential for language bias. Although the reviewers attempted to locate unpublished research, there was evidence of possible publication bias. Two reviewers assessed validity and extracted the data independently, thus the potential for errors and bias in the review was reduced. However, bias in the selection of papers for the review could not be assessed, as details of this process were not reported.

The characteristics of the studies were not reported in full, and this made it difficult to assess the comparability of the included studies. The reviewers indicated that there were differences between the studies, and used meta-regression to investigate some sources of heterogeneity. They also used sensitivity analyses to assess how individual quality items affected the results. Owing to the lack of study details, it was not possible to judge whether pooling the studies in a meta-analysis was appropriate. Therefore, it was not possible to determine whether the authors' conclusions, which were based on this meta-analysis, were reliable.

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

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

Research: The authors stated that the safety and efficacy of APCDs need further assessment. Large, high-quality RCTs are required. Additional information may be provided by individual patient data meta-analyses, and by the use of data on device use and patient safety from registries and other sources.

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