Meta-analysis of randomized trials on the efficacy of vascular closure devices after diagnostic angiography and angioplasty

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CRD summary
This review concluded that vascular closure devices (VCDs) were associated with shorter time to haemostasis after diagnostic angiography and/or endovascular procedures and may shorten recovery. VCDs were also associated with increased risk of infection, lower limb ischaemia/arterial stenosis/device entrapment and vascular surgery. Data limitations mean that the conclusions on increased risk of vascular complications/surgery should be viewed cautiously.

Authors' objectives
To evaluate the safety and efficacy of vascular closure devices (VCDs) for avoiding puncture site complications after diagnostic angiography and/or endovascular procedures.

Searching
PubMed and The Cochrane Library were searched to May 2009. Search terms were reported. Books and journals of cardiology, interventional radiology and vascular surgery were searched for additional studies. ClinicalTrials.gov was searched for ongoing and completed studies. Only articles published in English were eligible for inclusion.

Study selection
Prospective randomised controlled trials that compared use of VCDs against a control group that included only manual and/or mechanical compression methods with FemoStop (Radi Medical Systems, Uppsala, Sweden) and C-Clamp in adult patients who underwent any type of angiography and endovascular procedure were eligible for inclusion. Trials were required to report at least one of the outcome measures: groin haematoma; bleeding; pseudoaneurysm; blood transfusion; and vascular surgery for femoral artery complications.

All studies involved patients in whom vascular access was achieved through the common femoral artery; patients underwent diagnostic angiography, percutaneous coronary intervention, peripheral vascular angiography or peripheral vascular intervention. VCDs assessed were VasoSeal, Angio-Seal, Techstar, Prostar, Duett, Perclose, X-Press, EVS and StarClose. Most studies excluded patients who were at high risk of puncture site complications.

The authors did not state how many reviewers selected studies for inclusion.

Assessment of study quality
Three authors independently applied Cochrane Risk of Bias criteria (generation of random allocation sequence, allocation concealment, blinding of intervention, incomplete outcome data, freedom from selective reporting and freedom from other biases) to the included studies. Each "yes" scored zero, "unclear" scored 1 and "no" scored 2. The sum of these scores was used to quantify the risk of bias of each study. Missing data were evaluated and a drop-out rate of less than 5% was considered acceptable.

Data extraction
Data were extracted on the incidence of adverse events in VCD and control groups. Data were used to calculate risk ratios (RRs) with 95% confidence intervals (CIs). Continuous variables were extracted as reported. Mean differences between VCD and control groups, with 95% CI, was calculated.

All six authors independently extracted data from all included studies using a standardized form.

Methods of synthesis
Where significant heterogeneity was identified, random-effects models were used to calculate overall risk ratios with 95% CIs (for discrete adverse events) and weighted mean differences with 95% CIs (for continuous variables). Separate
analyses were conducted for patients who underwent diagnostic coronary angiography and for patients who underwent percutaneous coronary interventions. Analyses of all patients who underwent diagnostic angiography and/or endovascular procedure were stratified by VCD type.

Between-study heterogeneity was assessed using $\chi^2$ and $I^2$ tests ($I^2 < 40\%$ was considered to indicate non-significant heterogeneity). Available data were considered insufficient to support the exploration of heterogeneity using meta-regression analysis.

Results of the review

Thirty-one studies (n=7,528 patients) were included in the review. The mean risk of bias score was 5.3±1.8. Random sequence generation was adequate in seven studies. Allocation concealment was adequate in six studies. Incomplete outcome data were addressed in 28 studies. Twenty-four studies were free of selective reporting. Sixteen studies were free of other biases.

No intervention-related death was reported in any study. The mean rate of successful deployment of VCDs was 96.4±3.8% (19 studies).

Meta-analyses indicated a significantly increased risk of groin infection associated with use of VCDs in patients who underwent percutaneous coronary intervention (RR 2.49, 95% CI 1.06 to 5.88; 12 studies), but not in patients who underwent diagnostic coronary angiography.

Use of VCDs was associated with a significantly shorter time to haemostasis in both patient groups: weighted mean differences of -16.64 (95% CI -21.96 to -11.32; five studies) for patients who underwent diagnostic coronary angiography and -37.67 (95% CI -47.94 to -27.40; eight studies) for those who underwent percutaneous coronary interventions.

There were no statistically significant differences between VCD and control groups in terms of groin haematoma, bleeding, pseudoaneurysm and blood transfusion, lower limb ischaemia and other arterial ischaemic complications and surgery for vascular complications. Uncommon (0.3%) lower limb ischaemia and other arterial ischaemic complications occurred only after VCD use.

Authors' conclusions

Use of VCDs was associated with a significantly shorter time to haemostasis, which may shorten recovery time. But use of VCDs was associated with an increased risk of infection, lower limb ischaemia/arterial stenosis/device entrapment in the artery and need of vascular surgery for arterial complications.

CRD commentary

The review was generally well conducted. The research objective was clearly stated and appropriate inclusion criteria were defined. Searches were restricted to published English-language studies, which raised possibilities of language and publication biases. The methodological quality of included studies was assessed. Measures were taken to minimise the potential for error and bias during data extraction and quality assessment; it was unclear whether similar measures were applied to study selection. The meta-analyses undertaken were appropriate and the authors' conclusions were broadly supported by the data presented. However, these data appear insufficient to support an association of VCDs with increased risk of lower limb ischaemia/arterial stenosis/device entrapment in the artery and of vascular surgery.

Implications of the review for practice and research

Practice: The authors made no recommendations for practice.

Research: The authors stated that further studies were needed, particularly in patients at high risk of femoral artery puncture-related complications. Costs analyses were needed to estimate whether VCDs had potential to reduce costs of angiography and endovascular procedures.

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