Commentary

To plug or not to plug?

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Abstract

Coronary artery disease remains a common problem in industrialized countries. Percutaneous coronary interventions are usually performed utilizing the femoral approach. Arterial puncture-closing devices have been developed in hope to avoid manual compression and shortening the period of rest. In a recent meta-analysis in the *Journal of the American Medical Association* these devices have shown only marginal benefits over manual compression. Further, well designed studies are necessary to document the comparative effects of these devices versus manual compression.

Keywords arterial puncture, coronary artery disease, hemostasis, percutaneous coronary angioplasty

Coronary artery disease is a common malady in Western civilizations [1]. Coronary interventions have increased in frequency, improving the quality of life for many coronary artery disease patients. In fact, it is estimated that more than one million procedures occur each year [2]. Although complications in the coronary artery can be devastating, peripheral complications are also of concern. These procedures involve arterial puncture with a relatively large bore cannula, and hematoma formation, pseudoaneurysms and other local complications are not infrequent [3,4].

Following percutaneous coronary interventions for acute and chronic coronary syndromes, manual compression of the femoral access site has been standard management. Arterial puncture-closing devices (APCDs) have been developed over the past three decades with the hope of avoiding manual compression and of shortening the period of bed rest prescribed after a percutaneous coronary intervention.

In a recent publication in the *Journal of the American Medical Association*, Koreny and colleagues present a systematic review and meta-analysis of APCDs compared with standard manual compression [5]. They searched several literature databases and queried experts and manufacturers for clinical trials comparing these methods of maintaining hemostasis. Thirty randomized trials eventually met the authors' selection criteria. The reviewers then abstracted the data, and random effects models were constructed to pool the data for meta-analysis. Koreny and colleagues report relative risks for growing hematoma, bleeding, development of arteriovenous fistula and psudoaneurysm at the puncture site, which were not significantly different between APCDs and manual compression. However, the confidence intervals for these relative risks were quite wide in their meta-analysis.

A meta-analysis is an attempt to combine data from several separate primary data sources to increase the power for the study for the outcome variable. Meta-analyses are dependent on the quality of the original studies and on the reports of those studies. As Koreny and colleagues note, the quality of the reports for the studies included in their systematic review was generally only fair. Blinded outcome assessment, allocation concealment and explicit intention-to-treat reporting were not common among these selected studies. It is also important to note that 12 of the 30 selected reports were only in abstract form. These studies reported both diagnostic and therapeutic procedures, and they used several different APCDs. The definitions of the outcome variables are also an important consideration in a meta-analysis and, in fact, some of the studies included in this systematic analysis do not even define some of the outcome variables.

APCD = arterial puncture-closing device.

The conclusions of Koreny and colleagues is that there is only marginal evidence that APCDs are effective. Given the poor quality of the reported clinical data and the heterogeneity evident in the data, one cannot make any other conclusion. The question to us remains 'to plug or not to plug?', and the answer requires well-designed, randomized, blinded clinical trials.

Hemostatic occlusion of a puncture vessel is an important issue for clinicians caring for patients that have undergone any kind of large-caliber arterial puncture, including interventional radiologists, diagnostic cardiologists and critical care practitioners. Before adopting new hemostatic techniques or devices, should not solid evidence of comparative efficacy be available? At the current time, the clinician faced with the question of APCDs or not has little information with which to guide a rationale decision. As Koreny and colleagues noted, if one limits the analysis to clinical trials in which explicit intention-to-treat approaches were used, APCDs appeared to increase the risk of hematoma and psudoaneurysm, with 95% confidence limits that do not include unity. We must agree with the authors of this meta-analysis that further study is necessary documenting the comparative efficacy of APCDs.

Competing interests

None declared.

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