The effectiveness of mechanical compression devices in attaining hemostasis after removal of a femoral sheath following femoral artery cannulation for cardiac interventional procedures

Authors' objectives
To present the best available information on the effectiveness of mechanical compression devices in achieving haemostasis after removal of the femoral sheath from patients after cardiac interventions, and to review patient tolerability of mechanical compression devices following removal of the femoral sheath.

Searching
MEDLINE, CINAHL, HealthSTAR, Evidence Based Database, Current Contents, EMBASE, DARE and the Cochrane Library were searched for published studies. In addition, searches of Dissertation Abstracts International, Proceedings First, and cardiac conference proceedings were undertaken to identify unpublished research. The searches were conducted from the early 1970s where possible (or the earliest date available) until 1999, and were restricted to studies reported in the English language. Examples of the keywords used are 'hemostasis', 'haemostasis', 'femoral', 'femoral and sheath', 'femoral and removal', 'mechanical and compression', 'femostop', 'hemo* and clamp', 'arterial and seal'; further details are provided in the review.

Handsearching was limited to journals and books, which were accessible to the reviewer from the hospital and university libraries. Where possible, manual searches of cardiology journals were extended to a 14-year period from 1985 to 1999, as the reviewers noted that few studies addressing compression procedures were published earlier than this. Further details of the sources searched manually, including conference proceedings, were provided in the review. The reference lists of all retrieved articles were checked.

The author provided no details of how many reviewers undertook the search, but in referring to 'this reviewer' implies that she herself undertook the search procedures.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs), uncontrolled clinical trials and descriptive studies were eligible for inclusion in the review. RCTs were preferred.

Specific interventions included in the review
Comparisons of any form of mechanical compression device with manual compression, another mechanical compression device, or any other form of compression device that was applied to attain haemostasis after removal of the femoral sheath, were included in the review. Also included in the review were studies involving mechanical compression devices used to obtain haemostasis either immediately upon sheath removal in the catheter laboratory, or at a later period (less than or equal to 24 hours) in the cardiac unit after procedures such as percutaneous transluminal coronary angioplasty (PTCA).

Participants included in the review
Adults who underwent cardiac diagnostic or investigational procedures using a femoral sheath approach were included in the review. Participants undergoing specific cardiac interventions in studies with more than one group of patients (e.g. coronary angiography, PTCA, cardiac catheterisation or intracoronary stent deployment) were analysed as separate subgroups. Studies involving persons who had radial or brachial approach procedures, a haematoma prior to femoral sheath removal, or whose oral anticoagulation medications did not cease at least 2 days prior to the procedure, were excluded.

Outcomes assessed in the review
All outcome measures relating to effectiveness were of interest. These included time to achieve haemostasis, and the incidence of bleeding, bruising, haematoma formation, inadequate distal blood flow, arteriovenous fistula and pseudoaneurysm formation after femoral sheath removal. Subjective outcome measures, which described the level of patient satisfaction or discomfort with the mechanical device employed, were also included.

How were decisions on the relevance of primary studies made?
The author does not state explicitly how the papers were selected for the review, but it is implicit in the review text that she herself made decisions on the relevance of the primary studies.

Assessment of study quality
The author states that a checklist designed by the Joanna Briggs Institute for Evidence Based Nursing and Midwifery (JBIEBNM), based upon work of the Cochrane Collaboration and the NHS Centre for Reviews and Dissemination (see Other Publications of Related Interest nos.1-2), was used to assess the validity of the primary studies, both RCTs and non-randomised controlled trials. The studies included in the review were further categorised according to the strength of the evidence reported, using a scale published by the Quality of Care and Health Outcomes Committee (see Other Publications of Related Interest no.3). The author states that one reviewer undertook most of the validity assessment, but that a small number of studies were assessed by two reviewers independently.

Data extraction
Data meeting the outcome inclusion criteria were extracted from each study using a data extraction tool, similar to those developed and pilot-tested by the JBIEBNM. Further details of the tool were provided in an appendix to the review. The author states that the data were independently extracted by another reviewer in a small sample of studies, to allow the primary reviewer to seek feedback and to assess their method of data extraction against a more experienced reviewer. The author states that this process demonstrated a high degree of agreement between the reviewers.

Data were extracted on the following: the general demographic details of study participants; a description of the study institution(s); data related to specific diagnostic and interventional treatment groups; the specific mechanical device being compared and its method of application; and all outcome measures employed to determine the effectiveness of the device. Details on study design were also collected. Narrative data that were judged to be important or relevant were also extracted. A brief summary of the major findings and other relevant results was also noted on the data extraction sheet.

Methods of synthesis
How were the studies combined?
Four comparisons were evaluated: mechanical versus manual compression; two different forms of mechanical compression; mechanical compression versus other compression techniques (not simply manual); and mechanical compression versus no compression.

Where sufficient data were available, the Peto odds ratios (ORs) for categorical outcome data or standardised mean differences for continuous outcome data were calculated for each study, along with the 95% confidence intervals (CIs). Where statistical pooling was not possible or was inappropriate, the data were combined narratively. For ORs, CIs that did not include 1 were deemed statistically significant; for mean differences, CIs that did not include 0 were statistically significant.

How were differences between studies investigated?
The author reports that the meta-analysis was limited owing to differences between the study participants, intervention details, and the timing and method of assessing clinical outcome measures. No formal test of heterogeneity was reported, but where the data were pooled, the results of the chi-squared test for heterogeneity were reported in figures.

Results of the review
A total of 12 studies were included: 8 RCTs (n=2,998), 2 non-randomised controlled trials (n=3,975) and 2 descriptive
studies (n=299). Details of the range of different interventions compared in the different studies were provided in the review.

The incidence of bleeding after femoral sheath removal did not demonstrate a statistically-significant difference between any study interventions.

Overall, the incidence of haematoma formation was low and occurred significantly more often in the manual compression groups than in the mechanical compression groups (OR 7.26, 95% CI: 1.62, 32.45).

No statistically-significant differences were found between study interventions (2 studies) in the incidence of bruising (ecchymosis).

No statistically-significant differences were found between interventions (one study) in the incidence of pulsatile mass.

One study found a statistically-significant difference in the incidence of pseudoaneurysm between manual compression (19%) and the FemoStop group mechanical compression group (2%; p=0.01). No statistically-significant differences were found for the two studies assessing arteriovenous fistula formation.

The time taken to attain haemostasis with either a manual or a mechanical device differed between the studies. Insufficient information was reported in some of these studies, and thus it was not possible to make statistical comparisons in a meta-analysis. One study reported a statistically-significant difference between ClampEase (29.20 plus or minus 14.9) and FemoStop (188.80 plus or minus 60.4), favouring ClampEase.

Two studies found no statistically-significant differences between interventions (ClampEase versus FemoStop; HOLD versus sandbag pressure, pressure dressing or no compression) during or after compression for patient comfort or discomfort. However, a statistically-significant difference was reported by another study comparing manual and mechanical compression; patient discomfort was greater after 30 minutes of manual compression, compared with 30 minutes of mechanical compression using the Compressar device (p=0.05).

Many levels of findings, sometimes on a study by study basis, were reported in the review.

**Authors’ conclusions**

No formal conclusions were presented. However, in the 'Implications for Practice' section, the author asserts that there is no difference in the effectiveness of mechanical compression devices in attaining haemostasis after femoral sheath removal, compared with manual compression or any other compression techniques.

**CRD commentary**

The review question and the study selection criteria were stated clearly. The literature search seemed reasonably comprehensive, although English language restrictions were applied; the author noted that these might have restricted the scope of the review and strength of the findings. The study selection, validation and data extraction processes were apparently undertaken by the author herself, although some attempt was made to corroborate the accuracy of the processes by employing a second independent reviewer for a small sample of publications and articles. The author noted the methodological limitations of relying principally upon one non-independent reviewer. The statistical methods employed seem appropriate, although where the data were pooled, the results of the formal heterogeneity test were not reported. However, the author noted that many of the studies were too heterogeneous to pool statistically. Where a meta-analysis was undertaken, ample details of the findings were tabulated. The 'Results' section was long and divided into subsections according to the different groups and subgroups of different interventions; it would have been useful to have had a short summary of the main findings for appropriate subsections.

The author provided details of the quality of the included studies according to the specified subgroup interventions. However, the findings from poorly controlled or methodologically weak non-randomised controlled studies and descriptive studies were included with those from RCTs; this makes for confusing reading, particularly given the lack of summary or concluding sections to highlight the findings that the author interprets as key or creditable. There were discrepancies between the findings reported in the 'Discussion' section and those in the main 'Results' section: e.g.
regarding pseudoaneurysm, the study by Sjoberg et al. was of ClampEase, not Compressar versus FemoStop, and the findings were not statistically significant, rather than significant (p=0.09), as reported in the discussion.

A major limitation of the review was that there was no executive summary section or abstract, and therefore, the reader is left to form views upon the main findings from the 'Discussion' and the 'Implications for Practice' sections. Similarly, in the absence of formal conclusions, the reader is left to interpret these from the 'Discussion' and the 'Implications for Practice' sections of the review.

The author is appropriately cautious in making recommendations for practice given the limitations of the review material discussed and the findings presented.

Implications of the review for practice and research
Practice: The author states that it is not possible to make clear recommendations that a particular mechanical device is more effective than another, or any other compression technique.

Research: The author states that more well-designed RCTs with larger participant populations are required to establish the effectiveness of the interventions assessed in this review

Bibliographic details

Other publications of related interest

Indexing Status
Subject indexing assigned by CRD

MeSH
Angina, Unstable; Angioplasty; Catheterization, Peripheral; Constriction; Coronary Artery Bypass; Coronary Disease; Equipment and Supplies; Equipment Design; Femoral Artery; Heart Diseases; Hemodynamics; Hemostasis; Stents; Treatment Outcome

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Record Status
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.