**Effectiveness of Mechanical Compression Devices in Attaining Hemostasis After Femoral Sheath Removal**

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**Background** Cardiac interventions are widely accepted as a practical treatment option for coronary artery disease. However, few changes have occurred in the techniques used for percutaneous arterial cannulation and for attaining hemostasis after cardiac interventions. To date, researchers have focused on techniques to achieve optimal hemostasis at the time of removal of the arterial catheter and to minimize the impact and complications of arterial puncture.

**Objective** To summarize the best available evidence on the effectiveness of mechanical compression devices used to obtain hemostasis following femoral sheath removal after cardiac interventional procedures.

**Method** An attempt was made to detect both published and unpublished reports of research evaluations of mechanical compression techniques used to attain hemostasis after femoral sheath removal. Methodological quality was assessed by using predesigned criteria. Data were extracted from information on randomized controlled trials and were statistically combined in meta-analysis where possible. Evidence was also synthesized by using narrative summaries.

**Results** Twelve studies met the inclusion criteria; however, only 3 were included in the meta-analysis. The results of meta-analysis indicated that the mechanical compression technique was the most effective for preventing formation of hematomas. The prevalence of bleeding did not differ significantly for different methods of compression.

**Conclusion** A gap exists in the literature on quality randomized controlled trials of various devices used to attain hemostasis after femoral sheath removal. (American Journal of Critical Care. 2002;11:155-162)

Cardiac interventions are widely accepted as a practical treatment option for coronary artery disease. Femoral artery puncture and cardiac catheterization are widely used diagnostic and interventional procedures, and, increasingly, cardiac catheterization and related procedures are performed safely in an outpatient setting.

Although formerly removal of femoral sheaths after cardiac interventional procedures was done by physicians, more recently removal of the sheaths has become a component of the expanding role of cardiac nurses. Nurses need information on the effectiveness and reliability of various techniques used to achieve hemostasis after femoral sheath removal. This information will enable cardiac nurses to choose the appropriate technique to facilitate a reduction in groin complications after femoral sheath removal.

**Background**

Despite major advances in coronary revascularization techniques in recent years, few changes have
occurred in the techniques used for percutaneous arterial cannulation and for attaining hemostasis after cardiac interventions.5,6 The use of larger cannulation devices and the need for more aggressive anticoagulation have increased the prevalence of peripheral vascular complications.7 Complications that may occur after cardiac interventions are costly, increase patients’ length of stay in the hospital, and affect morbidity.8 Inadequate hemostasis can lead to one or all of the following: significant blood loss, patient’s discomfort, vessel occlusion, thrombosis, formation of arteriovenous fistula, and pseudoaneurysm requiring surgical intervention.9,10 Complications at the access site due to arterial cannulation occur in 1% to 5% of cases but may be as high as 14% with some cardiac interventional procedures.9 The potential high prevalence of complications has stimulated investigation of techniques that achieve optimal hemostasis at the time of removal of the arterial catheter and minimize the impact and complications of arterial puncture.

The femoral sheath provides support at the puncture site and reduces potential arterial trauma if multiple catheter exchanges are required.11 At the end of the cardiac procedure, the femoral sheath is removed, and the femoral artery is compressed to control bleeding until hemostasis occurs. Although manual compression is commonly used to attain hemostasis, this technique has limitations. Application of manual compression may be required for up to 20 minutes or longer in order to control bleeding and allow coagulation to occur,12 and inconsistent pressure due to hand and arm fatigue can lead to the formation of hematoma and/or thrombus.10,11

The increase in catheterizations in outpatient settings, the desire for earlier mobilization of patients, and an effort to decrease vascular injury and complications led to the development and use of alternative hemostatic devices such as mechanical clamps, inflatable pressure devices, implantable collagen plugs, and manual pressure aids.9 These devices can be used as an adjunct to or can provide an alternative to manual compression to attain hemostasis. Some devices have transparent domes that provide direct visualization of the puncture site during compression. Others that use pneumatic or clamp pressure to compress the femoral artery may be considered less labor-intensive than is manual compression.12 As with manual compression, use of mechanical devices may have limitations, including patients’ discomfort and prolonged immobilization.

More recently, collagen vascular hemostatic sealing devices were developed to attain hemostasis after femoral sheath removal. With these devices, an absorbable bovine collagen plug is instilled into the tract from the femoral artery to the skin’s surface. Hemostasis occurs after formation of a fibrin clot within this tract, sealing the puncture site. In preliminary clinical trials, these devices were effective in achieving hemostasis with significantly reduced groin compression time,13–15 but their use in routine procedures such as coronary angiography may be limited because of the associated costs.

Methods

In a systematic review, a concise methodical investigation of a subject is done by using a predetermined plan that includes the summary, appraisal, and synthesis of multiple primary studies.16,17 The findings of well-conducted systematic reviews can help define the evidence on a topic through the assessment and integration of large volumes of relevant information. In addition, the findings may explain variations in practice and resolve conflicting evidence on a topic, thereby assisting health professionals in making rational decisions about healthcare practices.18 The aim of this systematic review was to determine the best available evidence on the effectiveness of mechanical compression devices in achieving hemostasis and reducing hematoma formation after removal of femoral artery sheaths.

Selection and Search Strategies

We examined primary research studies in which the investigators compared any mechanical compression device with (1) manual compression, (2) another mechanical compression device, or (3) any other form of compression device used to attain hemostasis in adult patients after cardiac investigational procedures in which a femoral sheath approach was used. Outcomes included the time to achieve hemostasis and the prevalence of bleeding, bruising, hematoma formation, inadequate distal blood flow, arteriovenous fistula, and pseudoaneurysm formation. Bleeding was defined as any ooze, leaking, or frank blood drainage from the puncture site. A bruise was defined as any discoloration of the subcutaneous tissue around the puncture site. A hematoma was defined as any swelling, palpable mass, or newly formed bruit, a sound heard during auscultation suggesting nonlaminar flow through the femoral artery.19 Inadequate distal blood flow was defined as the absence of distal foot pulses.

Randomized controlled trials were of primary interest because these studies provide the highest level of recognized evidence.20 For other studies, such as uncontrolled clinical trials and descriptive studies, that met the inclusion criteria, we incorporated the results
of the studies in a narrative review. Although the level of evidence in these studies is considered less rigorous than that of randomized clinical trials,\(^{20}\) the inclusion of the narrative summary will help identify current approaches used to attain hemostasis after femoral sheath removal.

In the literature search, we sought to detect both published and unpublished studies. Although the unpublished studies we selected may not have been peer reviewed, the rigorous requirements for data inclusion should have reduced the possible negative effects of the inclusion of unpublished work. Databases searched for published studies included MEDLINE (1966 through June 1999), CINAHL (1982 through January 1999), HEALTHSTAR (1975-1999), EBM Reviews-Evidence Based Database (1991 through June 1999), Current Contents (1998-1999), EMBASE, DARE, and the Cochrane Library (1999, issue 1). Dissertation Abstracts International database (1992-1999), Proceedings First Database (1992-1999), and hand searching of cardiac conference proceedings were used to detect unpublished research. A search of MEDLINE, CINAHL, Current Contents, and the Cochrane Library for the period June 1999, when the systematic review was done, through September 2001 did not reveal any other published studies comparing manual and mechanical compression techniques.

A 2-step search process based on the searching strategy outlined by Dickersin et al\(^{19}\) was used. Key terms used to frame the search process were cardiac catheterization, femoral sheath removal, mechanical compression, manual compression, device, pneumatic clamp, hemostatic techniques, hemostasis, and bleeding. The reference lists and/or bibliographies of all retrieved articles were checked for additional studies.

### Assessment of Methodological Quality

The methodological quality of studies that satisfied the inclusion criteria were critically appraised. A checklist based on the work of the Cochrane Collaboration\(^{21}\) and the Centre for Reviews and Dissemination at the University of York\(^ {17}\) was developed to critically appraise the research (Table 1). The checklist was pilot tested on 5 research articles by one of us (T.J.), who had no previous experience in the critical appraisal used in systematic reviews, and by another person who did have such experience. The findings of the 2 reviewers were identical for all 5 articles.

Randomized controlled studies were assessed for inclusion in a meta-analysis. The narrative summary included research in which other methods, such as uncontrolled clinical trials and descriptive studies, were used. Studies were categorized according to the strength of their evidence by using a scale published by the Australian Quality of Care and Health Outcomes Committee\(^ {20}\) (Table 2). The quality of each study varied with respect to bias and error. Studies were excluded from meta-analysis if they had

- an inadequately defined randomization technique (selection bias);
- apart from the study intervention, had a difference in care within the study groups (performance bias);
- had different treatment groups because participants withdrew or dropped out from the study (attrition bias); or
- had different outcome assessment measures (detection bias).

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### Table 1 Randomized controlled trial critical appraisal form

<table>
<thead>
<tr>
<th>Author _______</th>
<th>Year _____</th>
<th>Record number ______</th>
</tr>
</thead>
<tbody>
<tr>
<td>Questions 1 to 5 must be answered yes for the study to be included in the meta-analysis. If any questions are answered no, the study may then be considered in the systematic review as a narrative summary.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Were the participants randomly allocated to the study groups?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Other than the research intervention, were participants in each group treated the same?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Were the study outcomes measured in the same manner for all participants, regardless of the treatment groups?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Were the study groups comparable at entry?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Was there adequate follow-up of participants? (ie, was the attrition rate explained?)</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>(&gt;20% not followed up)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Was allocation of participants to the treatment groups concealed from the allocator?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Were those assessing the objective study outcomes blinded to treatment allocation?</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

**SUMMARY**

**Decision**

Use in the meta-analysis

Include as a narrative summary

Reject from the systematic review

**Level of evidence**

**Comments**
The components of data extracted from each study included in the meta-analysis are listed in Table 3. Data were extracted by using a data extraction tool. The tool was developed and tested for reliability by the Joanna Briggs Institute for Evidence-Based Nursing and Midwifery (Adelaide, Australia). The tool consists of 3 sections; each section pertains to a specific area of research: methodology, methods, and analysis. In order to add rigor to the data extraction, data were extracted independently by one of us (T. J.) and by another reviewer in a small sample of studies. When the data were compared between the 2 reviewers for 5 articles that met the inclusion criteria, the findings were identical.

**Data Analysis**

When sufficient data were available, the Peto odds ratio (for categorical outcome data) or standardized mean differences (continuous data), CIs that did not cross zero were statistically significant.

**Results**

A total of 53 articles met the initial inclusion criteria. Of these, 12 were randomized controlled trials or descriptive cohort studies and were of acceptable methodological quality for inclusion in the systematic review. These 12 studies are listed chronologically in Table 4, which outlines the study design, study interventions, and outcome measures. A total of 41 articles were excluded from the systematic review because they were overviews or reports of various hemostatic techniques, did not evaluate mechanical compression devices, were single or case series reports, had deficiencies in study design, or had insufficient reporting of the details of the study design.

Although meta-analysis was initially confined to studies of the same intervention that measured conceptually similar outcomes, if sufficient data had been available from studies of different types of mechanical devices, the data would have been synthesized in a meta-analysis. Consequently, meta-analysis was limited because of inadequate reporting of results or missing data. For this reason, much of our results are in narrative form. We acknowledge that for the purpose of meta-analysis, a reviewer would typically contact the investigator of the original study if data were insufficiently reported or missing; however, financial and time constraints meant that this step was not possible.

**Table 2** Randomized categories used to determine levels of evidence20

<table>
<thead>
<tr>
<th>Level</th>
<th>Description of category</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Evidence obtained from a systematic review of all relevant randomized controlled trials</td>
</tr>
<tr>
<td>II</td>
<td>Evidence obtained from at least one properly designed randomized controlled trial.</td>
</tr>
<tr>
<td>III.1</td>
<td>Evidence obtained from well-designed controlled trials without randomization</td>
</tr>
<tr>
<td>III.2</td>
<td>Evidence obtained from well-designed cohort or case control analytic studies, preferably from more than a single center or research group</td>
</tr>
<tr>
<td>III.3</td>
<td>Evidence obtained from multiple time series with or without the intervention Dramatic results in uncontrolled experiments</td>
</tr>
<tr>
<td>IV</td>
<td>Opinion of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees</td>
</tr>
</tbody>
</table>

**Table 3** Components of data extraction

<table>
<thead>
<tr>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>General demographic details of the study participants</td>
</tr>
<tr>
<td>A description of the study institution(s)</td>
</tr>
<tr>
<td>Diagnostic and/or interventional treatment group(s)</td>
</tr>
<tr>
<td>The mechanical device being compared and its method of application</td>
</tr>
<tr>
<td>Outcome measures such as</td>
</tr>
<tr>
<td>Bleeding</td>
</tr>
<tr>
<td>Hematoma formation</td>
</tr>
<tr>
<td>Ecchymosis</td>
</tr>
<tr>
<td>Pseudoaneurysm</td>
</tr>
<tr>
<td>Arteriovenous fistula formation</td>
</tr>
<tr>
<td>Patients’ discomfort associated with the compression technique</td>
</tr>
<tr>
<td>Time to effect hemostasis</td>
</tr>
<tr>
<td>Study design, including method of randomization, allocation, and blinding</td>
</tr>
<tr>
<td>Sample size</td>
</tr>
<tr>
<td>Results: dichotomous (numbers of patients in treatment and control groups) and continuous (mean and SD) data</td>
</tr>
<tr>
<td>Narrative data, such as expert opinion or anecdotal evidence</td>
</tr>
</tbody>
</table>

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Bleeding

Data on bleeding could be synthesized from the studies by Nordrehaug et al.¹² and Pracyk et al.¹ because the outcome measures in these studies were homogeneous. The meta-analysis of data collected from these studies (Figure 1) indicated that bleeding from the femoral puncture site after femoral sheath removal did not differ significantly when either a mechanical compression device or manual compression was used to attain hemostasis. Other studies²²⁻²⁴,²⁶ included bleeding as an outcome measure. The prevalence of bleeding after femoral sheath removal did not differ significantly between any interventions in these studies.

Hematoma Formation

Outcome data on hematoma formation after femoral sheath removal were extracted from the randomized controlled trials reported by Pracyk et al.¹ and Homuth.²⁴ When the data were pooled from these studies, the meta-analysis for hematoma formation indicated that the mechanical compression technique was the most effective; no incidents of hematoma formation occurred in either study (Figure 2).

<table>
<thead>
<tr>
<th>Reference</th>
<th>Study design</th>
<th>Sample</th>
<th>Interventions</th>
<th>Outcome(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bogart²²</td>
<td>RCT</td>
<td>503 patients: 332 men, 171 women; Group A: n=173; group B: n=168; group C: n=162</td>
<td>Group A: manual compression with a pressure dressing (a roll of 4 x 4 gauze sponges)</td>
<td>Time to effect hemostasis, bleeding</td>
</tr>
<tr>
<td>Gibson²³</td>
<td>RCT</td>
<td>45 patients: 31 men; 14 women; Group A: n=23; group B: n=22</td>
<td>Mechanical compression clamp for at least 20 minutes</td>
<td>Mechanical compression with the FemoStop device for at least 20 minutes</td>
</tr>
<tr>
<td>Homuth²⁴</td>
<td>RCT</td>
<td>51 patients: 40 men, 11 women; Group A: n=26; group B: n=25</td>
<td>Manual compression</td>
<td>Mechanical compression with the Compressar clamp</td>
</tr>
<tr>
<td>Janerot-Sjoberg et al.²⁵</td>
<td>RCT</td>
<td>979 patients; Group A: n=433, 75% men; group B: n=546, 71% men</td>
<td>Mechanical compression with the ClampEase device for at least 15 minutes</td>
<td>Mechanical compression with the FemoStop device for at least 2 hours</td>
</tr>
<tr>
<td>Lehmann et al.²⁶</td>
<td>RCT</td>
<td>397 patients: 389 men, 8 women; Group A: n=107; group B: n=105; group C: n=96; group D: n=107</td>
<td>Mechanical compression with the ClampEase device for at least 2 hours</td>
<td>Mechanical compression with the Compressar clamp</td>
</tr>
<tr>
<td>Nordrehaug et al.¹²</td>
<td>Multicenter RCT</td>
<td>213 patients: 167 men, 46 women; Group A: n=109; group B: n=104</td>
<td>Mechanical compression for at least 8 minutes</td>
<td>Mechanical compression with the FemoStop device for at least 1 hour</td>
</tr>
<tr>
<td>Pracyk¹</td>
<td>RCT</td>
<td>778 patients: 516 men, 262 women; Group A: n=396; group B: n=382</td>
<td>Mechanical compression with the ClampEase device for at least 15 minutes</td>
<td>Mechanical compression with the FemoStop device for at least 15 minutes</td>
</tr>
</tbody>
</table>

Continues

Table 4: Studies included in the systematic review
As with bleeding, hematoma formation was a widely reported clinical outcome. We did find some variation in the prevalence of hematoma formation, but the prevalence was low, and in one study, formation of hematoma occurred significantly more often in the manual compression group than in the group in which a mechanical device was used.

Complications of Femoral Artery Sheath Removal

Ecchymosis was reported as a clinical outcome in only 2 studies. The prevalence of ecchymosis did not differ between study groups. The femoral puncture site was assessed for clinical evidence of a pulsatile mass in only 1 study. The prevalence varied between the studies.

Pseudoaneurysm is a more serious vascular complication; it is often difficult to recognize and may be masked by the presence of a hematoma. Pseudoaneurysm was a clinical outcome in 4 studies. Although the prevalence of pseudoaneurysm formation varied between studies, when manual compression was compared with the FemoStop mechanical device, the prevalence was significantly higher with manual compression. However, data were collected from the manual compression intervention group retrospectively in this study and were accumulated during an unknown period; we therefore considered the study poorly controlled.

When 2 mechanical compression devices were compared by Janerot-Sjoberg et al, pseudoaneurysm, detected by Doppler examination, occurred in the ClampEase compression group significantly more often than in the FemoStop compression group.

PTCA indicates transluminal percutaneous angioplasty; RCT, randomized controlled trial.
The prevalence of arteriovenous fistula formation after femoral sheath removal was reported in only 2 studies.\textsuperscript{4,28} The prevalence was not significantly different in either study.

**Time to Effect Hemostasis**

Factors differed between studies for the time required to attain hemostasis after application of the hemostatic technique. In 3 studies,\textsuperscript{22,24,27} the Compressar device took significantly longer to effect hemostasis than did manual compression. Only Semler\textsuperscript{10} found that manual compression required more time than did the Compressar device. Meta-analysis was not possible because of insufficient data. Gibson\textsuperscript{23} reported that significantly more time was required to attain hemostasis with the FemoStop than with the ClampEase device. However, in this small sample, a few patients might have skewed the data in favor of the ClampEase device, and so this finding should be interpreted with caution. No significant difference was found in the time required to effect hemostasis after sandbag pressure, pressure dressing, or no compression when these 3 methods were compared with the HOLD compression device.\textsuperscript{2}

**Implications for Nursing Practice and Research**

Removal of the femoral sheath after cardiac interventional procedures can be a time-consuming procedure. Although manual compression has been the favored method of attaining hemostasis after removal of the sheath, alternative techniques, such as mechanical compression devices, are being used more often in clinical practice.

From a clinical point of view, the development of protocols and procedures for femoral sheath removal must be based on evidence that indicates which practices are the most efficient. Although we found articles on primary research related to attaining hemostasis after femoral sheath removal, several of the articles did not address mechanical compression techniques specifically...
or contained insufficient primary research data for inclusion. The limited depth and breadth of our review are due to the quality of the research findings available.

Although Sridhar et al reported a significant difference between manual compression and a mechanical device in the prevalence of hematoma and pseudoaneurysm formation, their findings should be cautiously interpreted because of the poorly controlled retrospective study design. In the study by Janerot-Sjöberg et al, the prevalence of pseudoaneurysm formation was lower with the FemoStop device than with the ClampEase device. This finding is important, because this large randomized controlled trial was well designed, and the formation of pseudoaneurysms was detected by using Doppler examination. In those studies in which the time required to effect hemostasis was measured, some significant differences between study interventions occurred, but the conflicting findings make it difficult to draw clear conclusions about this clinical outcome. When these findings are considered, it is not possible to make clear recommendations that a particular mechanical device is more effective than another mechanical device. However, the meta-analysis that indicated no difference between techniques in regard to bleeding and a statistically reduced prevalence of hematoma formation after mechanical compression make it possible to make a clinical recommendation for the use of mechanical devices.

The few nursing studies related to techniques used to attain hemostasis after femoral sheath removal highlight the need for further studies on this topic. We recommend that more benchmark randomized controlled trials be undertaken. The protocols for these trials should include a rigorous randomization process, inclusion criteria, and establishment of the power of the sample. These requirements may be challenging because the low frequency of complications may necessitate trials with large numbers of participants and careful control strategies to accommodate the variability between manual compression skills and application techniques for various compression devices.

Conclusion

In this systematic review, we used a rigorous pre-planned process to detect primary research on mechanical compression devices used to attain hemostasis after femoral sheath removal after cardiac interventional procedures. Our results highlight the lack of quality research on this topic. Nevertheless, results do highlight particular compression techniques used to attain hemostasis after femoral sheath removal. This information may help cardiac nurses make informed decisions about particular devices and techniques used in clinical practice.

REFERENCES

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Tina Jones and Helen McCutcheon

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