TITLE: Mechanical Hemostasis Devices for Use in Adult Patients Undergoing Arterial Sheath Removal Procedures: Clinical Effectiveness, Safety, and Guidelines

DATE: 29 September 2011

RESEARCH QUESTIONS

1. What is the clinical effectiveness of mechanical hemostasis devices in adult patients post cardiac procedure requiring arterial sheath removal?

2. What is the clinical safety of mechanical hemostasis devices in adult patients post cardiac procedure requiring arterial sheath removal?

3. What are the evidence-based guidelines regarding the use of mechanical hemostasis devices in adult patients post cardiac procedure requiring arterial sheath removal?

KEY MESSAGE

Overall, evidence suggests that mechanical compression devices are effective and a safe alternative to manual compression in adult patients post cardiac procedure requiring arterial sheath removal. It is not recommended for patients undergoing higher dose heparin anticoagulation.

METHODS

A limited literature search was conducted on key resources including PubMed, The Cochrane Library (2011, Issue 9), University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2003 and September 14, 2011. Internet links were provided, where available.
The summary of findings was prepared from the abstracts of the relevant information. Please note that data contained in abstracts may not always be an accurate reflection of the data contained within the full article.

RESULTS

Rapid Response reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by randomized controlled trials, non-randomized studies, and evidence-based guidelines.

Three randomized controlled trials and one non-randomized study were identified pertaining to the use of mechanical hemostasis devices in adult patients post cardiac procedure requiring arterial sheath removal. No relevant health technology assessment reports, systematic reviews or evidence-based guidelines were identified. Additional information that may be of interest is included in the appendix.

OVERALL SUMMARY OF FINDINGS

In a randomized trial that compared the Femostop mechanical compression device with c-clamp compression, or manual compression, no differences were found in measures of discomfort, patient distress, or vascular complications in patients undergoing percutaneous coronary intervention (PCI). In a non-randomized trial of patients undergoing PCI, the Femostop device was found to result in reduced immobilization time and reduced time to hemostasis. Most patients (85%) suffered no device-related discomfort and the most common complications were bruising-related.

In patients post-elective percutaneous transluminal coronary angioplasty (PCTA), the Femostop mechanical device was associated with longer time of compression, a greater number of vagal reactions, and hemorrhage at the puncture site in patients with high versus low heparin anticoagulation treatment. Authors recommended against using the Femostop device in patients with high heparin anticoagulation levels.

In a randomized trial of patients undergoing coronary angiography, the QuicKlamp mechanical compression device was compared with manual compression. Authors found that time to hemostasis and time to mobilization following surgery were slower in the QuicKlamp group. At the five-day follow-up, the QuicKlamp device was associated with more swelling in female patients and more bruising in all patients whereas manual compression was associated with more episodes of chest pain.

No evidence-based guidelines and no information specific to the CompressAR device were identified.
REFERENCES SUMMARIZED

Health Technology Assessments
No literature identified.

Systematic Reviews and Meta-analyses
No literature identified.

Randomized Controlled Trials

   PubMed: PM16317360

   PubMed: PM15152127

   PubMed: PM12590890

Non-Randomized Studies

   PubMed: PM14713179

Guidelines and Recommendations
No literature identified.
APPENDIX – FURTHER INFORMATION:

Review Articles


Additional References