



Effective Health Care

Percutaneous Coronary Intervention and Anticoagulants/Closure Devices

Nomination Summary Document

Results of Topic Selection Process & Next Steps

- Percutaneous coronary intervention (PCI) and anticoagulants was found to be addressed by data from the HORIZONS study, a large randomized controlled trial. Given that the existing research covers this nomination, no further activity will be undertaken on this topic.
 - Stone GW, Witzenbichler B, Guagliumi G, et al. Bivalirudin during primary PCI in acute myocardial infarction. N Engl J Med 2008;358(21):2218-30.
- PCI and closure devices is not feasible for a full systematic review due to the limited data available for a review at this time; however, it could potentially be considered for new research projects within the Effective Health Care (EHC) Program.
- Ongoing research or activities are underway that impact the timing for developing the topic of transradial versus transfemoral access in the treatment of acute myocardial infarction (MI) with primary PCI; therefore, this topic will be revisited in the future when more data becomes available.
- The use of combinations of PCI, anticoagulants, closure devices, and radial versus femoral access is not feasible for a full systematic review due to the limited data available for a review at this time; however, it could potentially be considered for new research projects within the EHC Program.

Topic Description

Nominator: Individual

Nomination Summary: The nominator questions the best combination of treatments for ST segment elevation patients undergoing PCI including anticoagulation, closure devices, and radial or femoral approach to reduce mortality, bleeding, and length of stay.

Staff-Generated PICO (anticoagulants):

Population: ST-elevated myocardial infarction (STEMI) and primary PCI patients

Intervention: Direct thrombin inhibitors (DTI)

Comparator: Glycoprotein inhibitors (GPI)

Outcome: Bleeding/mortality/length of stay

Staff-Generated PICO (closure device):

Population: STEMI and primary PCI patients

Intervention: Arteriotomy Closure Device (ACD)

Comparator: Manual compression
Outcome: Bleeding/mortality/length of stay

Staff-Generated PICO (radial versus femoral approach):

Population: STEMI and primary PCI patients

Intervention: Radial access

Comparator: Femoral access

Outcome: Bleeding/mortality/length of stay

**Key Questions
from Nominator:**

1. For ST segment elevation patients undergoing PCI (percutaneous coronary intervention), what is the best combination with regard to anticoagulation, [closure] device and approach to reduce mortality and length of stay?

Considerations

- The topic meets EHC Program appropriateness and importance criteria. (For more information, see <http://effectivehealthcare.ahrq.gov/index.cfm/submit-a-suggestion-for-research/how-are-research-topics-chosen/>.)
- This topic has four main areas:
 1. Different anticoagulants for PCI
 2. Different closure devices for PCI
 3. Radial versus femoral access for PCI
 4. Combinations of anticoagulants, closure devices, and radial versus femoral access for PCI.
- Questions related to the use of anticoagulants with PCI have been addressed by the HORIZONS trial, which determined that bivalirudin, a direct thrombin inhibitor (DTI), reduces the rates of adverse clinical events and major bleeding at one year compared to the use of heparin plus a glycoprotein inhibitor. There has not been a significant amount of new data beyond this trial.
 - This research article is indexed in Pubmed. The abstract for this article as well as resources to identify full text versions can be found at: <http://www.ncbi.nlm.nih.gov/pubmed/18499566>.
- A scientific statement released in October 2010 by the American Heart Association (AHA) addresses arteriotomy closure devices for cardiovascular procedures and states that there is currently limited comparative evidence for closure devices used for PCI. This was confirmed by a literature search through September 8, 2010. Based on the limited evidence, it appears that a systematic review on this topic would not be feasible; however, this topic may offer an opportunity for new research.
 - Patel MR, Jneid H, Derdeyn CP, et al. Arteriotomy closure devices for cardiovascular procedures. A scientific statement from the American Heart Association. *Circulation* 2010 Oct 4 Epub ahead of print.
- Transradial versus transfemoral access in the treatment of acute MI with primary PCI is an important topic; however, ongoing research activities affect the timing of its development. The International Randomized Trial of Trans-radial Versus Trans-femoral PCI Access Site Approach in Patients with Unstable Angina or Myocardial Infarction Managed with an Invasive Strategy (RIVAL) will study the two

access sites in approximately 7,000 patients at multiple centers. The estimated completion date is January 2011. This topic will be revisited when the results of this trial are available. More details on this trial can be found at: <http://clinicaltrials.gov/ct2/show/NCT01014273>.

- Limited literature was identified that addresses the combination of PCI anticoagulants, closure devices, and radial versus femoral access. Based on the limited evidence, it appears that a systematic review on this topic would not be feasible; however, this topic may offer an opportunity for new research.