Topic Brief: Mechanical Circulatory Support for PCI

Date: 8/29/2022
Nomination Number: 1003

Purpose: This document summarizes the information addressing a nomination submitted on June 3, 2022 through the Effective Health Care Website. This information was used to inform the Evidence-based Practice Center (EPC) Program decisions about whether to produce an evidence report on the topic, and if so, what type of evidence report would be most suitable.

Issue: Interventional cardiologists have been employing the use of mechanical circulatory support devices (MSCDs) which encompass intra-aortic balloon pumps or intravascular microaxial left ventricular assist devices (i.e. Impella) to provide hemodynamic support in patients undergoing high-risk percutaneous coronary intervention (PCI). It is unclear whether using these devices leads to better clinical outcomes or whether they are unnecessary. A systematic review on effectiveness and harms of use of MSCDs would help interventional cardiologists determine appropriateness of use and health plan administrators make better decisions regarding coverage of these devices.

Findings: A new systematic review (SR) would potentially be duplicative. We found two existing and one in-process review that addresses the topic. For these reasons the EPC Program will not consider this nomination further.

Background

Percutaneous coronary intervention (PCI), also known as coronary angioplasty, is a nonsurgical procedure that improves blood flow to the heart. Doctors perform PCI to open coronary arteries that are narrowed or blocked by the buildup of atherosclerotic plaque in patients with unstable angina, acute myocardial infarction, and multi-vessel coronary artery disease.[1] According to the National In-patient Sample, approximately 550,000 such procedures are performed annually in the United States.[2] To protect the myocardium from ischemia and support cardiac function during PCI, interventional cardiologists have been using mechanical circulatory support devices (MCSDs), which include ventricular assist devices (VADs; aka intravascular microaxial ventricular assist devices) and intra-aortic balloon pumps. VADs are mechanical pumps used to support heart function by facilitating blood flow usually from the left ventricle to the aorta and coronary vessels leading to increased end organ perfusion.[1] Early versions of VADs were bulky and cumbersome but improvements in miniaturization technology have led to development of small percutaneously inserted versions such as Impella VADs (Abiomed, Danvers, MA).[3] The other percutaneous VADs that may be used is TandemHeart Percutaneous Ventricular Assist Device (pVAD)™ system (CardiacAssist, Pittsburgh, PA) or HeartMate Left Ventricular Assist System (Abbott, Chicago, IL).

PCI (also termed high-risk PCI) with mechanical circulatory support can be performed on either an emergent or elective basis.[4-7] In the emergent setting, the patient is usually decompensated and in cardiogenic shock.[4, 7] In contrast, high-risk PCI with MCSDs can also be performed in an elective setting on stable patients with reduced ejection fraction but are *not* in shock to relieve symptoms such as chest pain. [5, 6] Use of MCSDs especially VADs during high-risk PCI can be costly but is covered by Medicare and insurance carriers when the patient is in established cardiogenic shock. Whether MCSDs are necessary or improve clinical outcomes and quality of life among patients undergoing high-risk PCI who are *not* in cardiogenic shock is unclear. Existing guidelines published in 2021 by the American College of Cardiology Foundation, American Heart Association, and the Society for Cardiovascular Angiography and Interventions[8, 9] recommend that in selected high-risk patients, elective insertion of an appropriate hemodynamic support device, such as intra-aortic balloon pump and Impella percutaneous left ventricular assist device, as an adjunct to PCI may be reasonable to prevent hemodynamic compromise during PCI. They note that extracorporeal membrane oxygenation and the TandemHeart (CardiacAssist, Inc, Pittsburgh, PA) devices are rarely used to support complex PCI. The routine use of hemodynamic support devices for complex PCI has not been shown to reduce cardiovascular events.

A recent analysis found increasing use of percutaneous VAD over intra-aortic balloon pump during PCI, with variation in use which was unchanged after adjusting for patient characteristics. They noted that greater use of percutaneous VAD was not associated with lower risk of mortality but was associated with greater cost[10].

Nomination Summary

This topic was nominated by an individual who did not wish to be contacted for follow-up. We did not have the opportunity to clarify further the nomination.

Scope

1. What is the effectiveness and comparative effectiveness of mechanical circulatory support devices in providing hemodynamic support in patients undergoing percutaneous coronary intervention (PCI)?

2. What are the harms and comparative harms of mechanical circulatory support devices in providing hemodynamic support in patients undergoing PCI?

Table 1. Questions and PICOTS (population, intervention, comparator, outcome, timing and setting)

Questions	1. Effectiveness	2. Harms
Population	Adults aged ≥18 years undergoing PCI	
Interventions	Mechanical circulatory support devices (intra-aortic balloon pump or intravascular microaxial left ventricular assist device)	
Comparators	Other mechanical circulatory support device No mechanical circulatory support device	

Outcomes	Primary outcomes
	• Mortality
	  ○ All-cause
	  ○ Cardiovascular mortality
	• Quality of life
	Secondary outcomes
	• Non-fatal myocardial infarction
		Primary outcomes
		• Serious adverse events
		  ○ Vascular injury
		  ○ Infection
		  ○ Major bleeding
		• Other complications associated with use of device

	• Non-fatal stroke • Length of hospital stay	
Timing	All	
Setting	All elective/non-emergent hospital settings	

Abbreviations: PCI=percutaneous coronary intervention

Assessment Methods

See Appendix A.

Summary of Literature Findings and Selection Criteria Assessment

We found two existing systematic reviews and one in-progress systematic review addressing the nomination. All three assessed the comparison of VAD vs. intra-aortic balloon pump; and two addressed mechanical circulatory support compared to no mechanical circulatory support. One focused on high risk PCI[11], one focused on high risk PCI with stent placement[12], and the third focused on PCI specifically in patients with cardiogenic shock[13].

Given these three systematic reviews and limited nomination details no further assessment is required. Please see Appendix B for detailed assessments of individual EPC Program selection criteria.

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Appendix A: Methods

We assessed nomination for priority for a systematic review or other AHRQ Effective Health Care report with a hierarchical process using established selection criteria. Assessment of each criteria determined the need to evaluate the next one. See Appendix B for detailed description of the criteria.

Appropriateness and Importance

We assessed the nomination for appropriateness and importance.

Desirability of New Review/Absence of Duplication

We searched for high-quality, completed or in-process evidence reviews published in the last three years up to August 23, 2022 on the questions of the nomination from these sources:

- AHRQ: Evidence reports and technology assessments
    - AHRQ Evidence Reports https://www.ahrq.gov/research/findings/evidence-based-reports/index.html
    - EHC Program https://effectivehealthcare.ahrq.gov/
    - US Preventive Services Task Force https://www.uspreventiveservicestaskforce.org/
    - AHRQ Technology Assessment Program https://www.ahrq.gov/research/findings/ta/index.html
- US Department of Veterans Affairs Products publications
    - Evidence Synthesis Program https://www.hsrd.research.va.gov/publications/esp/
    - VA/Department of Defense Evidence-Based Clinical Practice Guideline Program https://www.healthquality.va.gov/
- Cochrane Systematic Reviews https://www.cochranelibrary.com/
- PROSPERO Database (international prospective register of systematic reviews and protocols) http://www.crd.york.ac.uk/prospero/
- PubMed https://www.ncbi.nlm.nih.gov/pubmed/

Appendix B. Selection Criteria Assessment

Selection Criteria	Assessment
1. Appropriateness	
1a. Does the nomination represent a health care drug, intervention, device, technology, or health care system/setting available (or soon to be available) in the U.S.?	Yes, this topic represents interventions available in the United States.
1b. Is the nomination a request for an evidence report?	Yes, this topic is a request for a systematic review.
1c. Is the focus on effectiveness or comparative effectiveness?	The focus of this review is on effectiveness and comparative effectiveness.
1d. Is the nomination focus supported by a logic model or biologic plausibility? Is it consistent or coherent with what is known about the topic?	Yes, it is biologically plausible and is consistent with what is known about the topic.
2. Importance	
2a. Represents a significant disease burden; large proportion of the population	Approximately 550,000 PCI procedures are performed each year in the United States.
2b. Is of high public interest; affects health care decision making, outcomes, or costs for a large proportion of the US population or for a vulnerable population	Yes, evidence concerning effectiveness and safety of PCI will influence care decisions
2c. Incorporates issues around both clinical benefits and potential clinical harms	Yes, this nomination addresses both benefits and potential harms of MCSDs for protected high-risk PCI.
2d. Represents high costs due to common use, high unit costs, or high associated costs to consumers, to patients, to health care systems, or to payers	Yes
3. Desirability of a New Evidence Review/Absence of Duplication	
3. A recent high-quality systematic review or other evidence review is not available on this topic	We found two existing systematic reviews and one in-progress systematic review addressing the nomination. All three assessed the comparison of VAD vs. intra-aortic balloon pump; and two addressed mechanical circulatory support compared to no mechanical circulatory support. One focused on high risk PCI[11], one focused on high risk PCI with stent placement[12], and the third focused on PCI specifically in patients with cardiogenic shock[13].

Abbreviations: ACCF= American College of Cardiology Foundation; AE=adverse event; AHA=American Heart Association; AHRQ=Agency for Healthcare Research and Quality; IABP=intra-aortic balloon pump; MACE=major adverse cardiovascular events; MCSDs=mechanical circulatory support devices; PCI=percutaneous coronary intervention; SCAI=Society for Cardiovascular Angiography and Interventions; VAD=ventricular assist device;