



## **Percutaneous Coronary Intervention (PCI) without Surgical Back-up Policy Guidance (February 2012)**

### **Background**

Percutaneous coronary intervention (PCI) has been shown to improve quality of life when performed electively in appropriate patients, and it is lifesaving in patients with acute ST-segment elevation myocardial infarction. Initially, PCI was performed at clinical sites with surgical backup as complication rates and rates of urgent surgery were high. Over time as physician experience has increased, techniques have improved, better integration of technology with coronary stents, and antiplatelet and anticoagulation regimens were improved, the need for emergency surgery declined dramatically. Currently, emergency cardiac surgery rates resulting from PCI procedure are at 0.2%.<sup>1</sup> Overall complication rates from PCI are low.<sup>2,3</sup>

Therefore, many clinical care centers are inquiring about performing PCI without surgical backup. Currently, states have varying regulations that allow or prevent the practice.

In general, there are two major reasons for consideration of PCI without surgical back up. The first is to provide access to high-quality timely primary PCI for patients with acute ST-segment elevation myocardial infarction. Several studies show that there is an underutilization of resources in the hub and spoke model of care contributing to an occasional reluctance by physicians to transfer patients to a tertiary care facility, leading to worse patient outcomes and increased morbidity and mortality.<sup>4,5,6</sup> Primary PCI improves patient outcomes and reduces adverse events in patients with ST-segment elevation myocardial infarction (STEMI). Since most patients with STEMI are transported to hospitals without on-site surgical back-up and timely access to primary PCI is important for these situations, it is critical to sustain these programs that are difficult to continue due to financial and human resource issues. Patients with STEMI should theoretically have the opportunity for timely percutaneous revascularization. In such circumstances, each community and each facility in that community should have an agreed-upon plan for how STEMI patients are to be treated that includes which hospitals should receive STEMI patients from emergency medical services units capable of obtaining diagnostic electrocardiograms, management at the initial receiving hospital, and written criteria and agreements for expeditious transfer of patients from non-PCI-capable to PCI-capable facilities.<sup>7</sup>

The second reason for PCI with surgical backup, elective PCI, is to provide local care to accommodate patients and families who do not want to travel significant distances or have certain preferences with their local physicians. This is an important consideration for PCI without surgical backup, but it is important to recognize that the evolving evidence suggests that these centers should have mechanisms in place to ensure high-quality care.

Accordingly, recent guidelines from The American College of Cardiology Foundation (ACCF), American Heart Association (AHA), and Society for Cardiovascular Angiography and Interventions (SCAI)<sup>8</sup> have updated recommendations for PCI without surgical back-up:

- Primary PCI is reasonable in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished.<sup>9,10</sup> Class IIa, Level of Evidence B
- Elective PCI might be considered in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection.<sup>11,12</sup> Class IIb, Level of Evidence B
- Primary or elective PCI should not be performed in hospitals without on-site cardiac surgery capabilities without a proven plan for rapid transport to a cardiac surgery operating room in a nearby hospital or without appropriate hemodynamic support capability for transfer. Class III, Level of Evidence C.

### **Recommended Policy Guidance for States wanting to address the Issue of PCI without Surgical Back-up through Regulation or Legislation.**

If states wish to pursue policy that allows the practice of PCI without surgical backup, the AHA believes that certain criteria should be considered in the development of that policy. Recognize that these criteria are based on prior studies and the Atlantic Cardiovascular Patient Outcomes Research Team (CPORT) trial, which was recently presented as an abstract at the 2011 AHA's Scientific Sessions. However, as studies based on the findings of this trial are published and peer-reviewed, these criteria will likely continue to evolve. This policy guidance applies to hospitals conducting both primary PCI and elective PCI.

- States should require all PCI programs without surgical back-up to participate in programs like the National Cardiovascular Data Registry (NCDR) or the Atlantic Cardiovascular Patient Outcomes Research Team (CPORT) to monitor their quality and outcomes, allowing program leaders to show their commitment to quality by subjecting their program performance to independent peer review.
- The programs should adhere to strict patient-selection criteria(e.g. exclusion of patients with EF < 30%, unprotected Left Main intervention, intervention on last conduit to the heart).
- Have an annual volume of at least 200 to 400 cases.
- Should include only AHA/ACC-qualified operators who meet standards for training and competency.
- Should demonstrate appropriate planning for program development and should complete both a primary PCI development program and an elective PCI development program. Program development to include routine care process and case selection review.
- Agree to develop and maintain a quality and error management program.
- Perform primary PCI 24/7.
- Develop and maintain necessary agreements with a tertiary facility (which must agree to accept emergent and non-emergent transfers for additional medical care, cardiac surgery or intervention).
- Develop and sustain agreements with an ambulance service capable of advanced life support and IABP transfer that guarantees a 30-minute-or-less response time.

References:

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