Editorial

High Risk Percutaneous Coronary Intervention and Intra-Aortic Balloon Pumps
When Is the Safety Net Needed?

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The goal of percutaneous coronary intervention (PCI) is to decrease the coronary obstruction in a durable manner without compromising or damaging the myocardium so that patients may obtain the clinical benefits from the procedure, namely potentially improved survival in the setting of acute myocardial infarction interventions and improvement in health status for elective interventions. Interventional cardiologists make decisions each day aimed at improving the likelihood of both procedural success and resultant patient outcomes. These wide-ranging decisions include procedural planning, adjunctive pharmacotherapy, and device therapy for both coronary devices and possible use of various hemodynamic support devices. It is in this framework that the effectiveness of intra-aortic balloon pump (IABP) counterpulsation devices must be considered because they represent a common tool that interventional cardiologists use for procedure and patient support.

IABP counterpulsation was first reported in 1968 as a cardiac-assist device in a patient with cardiogenic shock, which supported the patient as shock resolved. As an adjunctive hemodynamic support device, the intra-aortic balloon is timed with the cardiac cycle to inflate at the start of diastole, augmenting diastolic pressure, which increases coronary perfusion and oxygen delivery to the myocardium. It is timed to deflate just before the start of systole, thereby reducing afterload. This facilitates ejection of blood from the left ventricle (LV) by decreasing LV work and reducing myocardial oxygen demands, resulting in increased cardiac output. Theoretically, this LV unloading may help at the time of an acute myocardial infarction and prevent infarct expansion and ventricular remodeling.

As with many cardiac devices, key innovations in the development of IABPs have led to decreasing sheath-size requirements and eventually to the ability to place the device percutaneously. These refinements have led to a demonstration of clinical benefit in early studies of patients undergoing PCI for acute myocardial infarction and in patients with cardiogenic shock. However, subsequent studies have not shown a consistent clinical benefit with prophylactic use of IABP counterpulsation in acute myocardial infarction.

In this issue of Circulation: Cardiovascular Quality and Outcomes, Curtis et al* present an analysis of patients in the CathPCI Registry from the National Cardiovascular Data Registry who underwent high-risk PCI with and without the use of IABP counterpulsation. The authors define high-risk PCI as having 1 of the following features: unprotected left main artery as the target vessel, cardiogenic shock, severely depressed LV function, or ST-segment elevation myocardial infarction. The authors identify >180,000 such PCIs between 2005 and 2007, with IABP use in 10.5% of patients. They found significant variation in IABP use across hospitals, with no associated difference in the in-hospital adjusted mortality.

As noted by the Curtis et al, this observational analysis has some limitations, most notably the possibility for unmeasured confounders that may affect the results, such as metrics of clinical severity like heart rate and blood pressure or the clinical specificity around the indications for use. Perhaps the most significant limitation may be the lack of information with regard to the timing of intra-aortic counterpulsation because outcomes from prophylactic use should be considered as significantly different from bailout use. Nevertheless, the findings underscore the variation in use and the current clinical uncertainty with regard to the optimal clinical scenario in which IABP counterpulsation or other ventricular support should be used.

For adjunctive prophylactic support in patients undergoing high-risk PCI, several factors should affect the decision-making. The most current randomized trial in this population (BCIS-1 [Balloon Pump-Assisted Coronary Intervention Study]) found no difference in major adverse cardiovascular events. However, it should be noted that major procedural complications were significantly less with the group randomized to IABP, and 6-month mortality trended lower in the IABP group. Additionally, investigators crossed patients over to IABP support who were doing poorly during the index PCI. Finally, with improved coronary technology and percutaneous techniques, the safety and procedural success has continued to improve. Hence, practicing interventionists currently have mixed data because clinical trial findings do not support prophylactic IABP use with high-risk PCI, with some short- and intermediate-term findings indicating a possible benefit in select patients. These conflicting study results likely lead to the observed practice variation, with each operator attempting to make a determination of the

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procedural risk and benefit of IABP use. When and how much of a safety net is required for a successful procedure?

With regard to the use of IABPs in the setting of acute myocardial infarction without cardiogenic shock, again, the most recent randomized trial data do not support routine prophylactic IABP support in patients. The CRISP AMI (Counterpulsation to Reduce Infarct Size Pre-PCI Acute Myocardial Infarction) trial found no difference with either myocardial infarct size or mortality at 6 months between patients treated with routine intra-aortic counterpulsation before reperfusion versus patients treated with standard-of-care PCI. It should be noted that 15 patients did cross over to IABP use, most often for development of cardiogenic shock during the primary PCI procedure. For patients with cardiogenic shock, a recent meta-analysis questioned the benefit of routine IABP use, finding a benefit from patients treated in the thrombolytic era compared with those treated in the primary PCI era. This analysis may underrepresent an effect because clinical practice recommendations have likely limited trial recruitment. Again, the interventionalist is faced with uncertainty given the clinical trial evidence of no benefit with routine IABP use in patients with acute myocardial infarction without shock contrasted with patients who may rapidly deteriorate into cardiogenic shock where support is currently recommended.

All of these factors must be weighed in the context of individual assessment of skill and ability to perform a successful revascularization. Intra-aortic counterpulsation involves larger arterial access and should not be considered without risk. This calculation becomes even more difficult with newer ventricular support devices because they have the potential for greater hemodynamic support balanced against larger access sizes and higher costs.

So what is needed to help to inform practice? Importantly, the data presented by Curtis et al and the review of the existing data underscore the importance of continued research with regard to cardiac support devices. For IABP counterpulsation, long-term follow-up data are needed from the existing recent randomized trials. Additionally, analyses of patients who crossed over in the randomized trials are needed to understand whether patient characteristics and risks are similar to patients receiving the IABP in the observational studies. These data will help to consolidate existing recommendations. Ongoing trials of IABP in patients with cardiogenic shock adequately powered to evaluate clinical outcomes will also be informative. Careful standardized data collection to determine patient risk, procedural risk, and clinical outcomes is required to allow analysis and generalizability of clinical trial findings with observational registries for cardiac support around PCI. Given the evolving field and the costs to the healthcare system, these data are required for all studies to determine the appropriate use of adjunctive cardiac support devices. Until then, individual coronary operators will continue to determine the risk of each coronary procedure and whether a safety net such as intra-aortic counterpulsation should be used.

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References


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