Editor’s Perspective

High-Risk Percutaneous Coronary Interventions in Modern Day Clinical Practice

Current Concepts and Challenges

Theodore A. Bass, MD

At its inception, all percutaneous coronary interventions (PCI) were considered high risk. The initial US experience published by the National Heart, Lung, and Blood Institute Registry reported procedural success to be <60% and the need for emergent coronary bypass surgery occurring 6% of the time.1 It was mandatory to have a cardiothoracic surgeon immediately available and an operating room open and ready to go. These outcomes involving a far less complex, lower risk population compared with patients we currently treat would be completely unacceptable today. The evolution of coronary interventions has been remarkable during the past decades attributable to the refinement and development of new device technologies, imaging capabilities, adjunctive pharmacotherapies and the explosive growth in physician and catheterization laboratory team experience. This has resulted in a greatly expanded population who can now be treated by PCI, including sicker patients often with more complex anatomic lesions. Overall reported procedural success rates are now expected to approach 100% and complication rates continue to trend toward or <1%. With this history and in our current environment of expanding databases, public reporting, cost-sensitive resource use, and increased patient expectations, the concept and reality of high-risk PCI continues to evolve.

First and foremost, it is helpful to differentiate complex PCI from high-risk PCI. The interventional cardiovascular community has spent a great deal of effort defining, classifying, and attempting to understand how to best treat patients presenting for complex PCI. The term complex PCI is a descriptor applied to patients presenting with complex, anatomic coronary lesions. These lesions may have a variety of defining characteristics such as severe calcification, extensive thrombotic burden, extreme tortuosity or length, or might be chronically, totally occluded. The lesion location might be located at a coronary bifurcation or in a degenerated saphenous venous bypass graft. Analysis derived from large registries have consistently demonstrated that PCI involving these anatomic/complex lesions results in expected lower procedural success rates with an increased risk of procedural complications when compared with PCI of less anatomically complex coronary lesions.2 We have successfully developed both the technology and interventional techniques to facilitate optimally treating these lesions.

An example of a complex PCI might be a middle-aged male with normal left ventricular (LV) function and increasing angina presenting for PCI with a heavily calcified bifurcation lesion involving the left anterior descending-first diagonal bifurcation. This is indeed different from what should be considered as a high-risk PCI, which might involve the same angiographic lesion, but occurring in an elderly male with a chronically occluded right coronary artery and a severely decreased LV ejection fraction. Therefore, the approach, skill sets, and support systems required to do these interventions with similar anatomic target lesions might be drastically different.

Currently, the definition of high-risk PCI is evolving. There is a growing consensus that this group of patients involves a confluence of characteristics, including complex coronary artery disease (multivessel or left main disease and anatomically complex coronary lesions), hemodynamic compromise (shock or severely depressed LV function), and clinical comorbidities such as advanced age, diabetes mellitus, peripheral vascular disease, heart failure, acute coronary syndromes, or previous cardiac surgery. The Food and Drug Administration (FDA) recently approved the Impella, a temporary percutaneous ventricular assist device to treat patients presenting for high-risk PCI. This recommendation was based on a randomized clinical trial involving symptomatic high-risk patients with 3-vessel disease or unprotected left main coronary disease and severely depressed LV function presenting for nonemergent high-risk PCI. The study found that a strategy using percutaneous ventricular assist device compared with using intra-aortic balloon pump counterpulsation for hemodynamic support when performing PCI in this high-risk population offered clinical benefit.3 This clearly expands the concept of high-risk PCI beyond patients presenting emergently with acute myocardial infarction and cardiogenic shock.

Coronary revascularization appropriateness guidelines similarly acknowledge the broadening concept of high-risk PCI. Many high-risk patients presenting with increasing ischemic symptoms such as angina refractory to medical treatment or heart failure are thought to be appropriate candidates for coronary revascularization.4 Strategies to achieve the most complete revascularization are critically important in this
cohort of patients who often may not be surgical bypass candidates. The concept of attempting more complete revascularization in patients with reduced LV function is not new. A recent quantitative echocardiographic analysis examined the possible benefit of achieving more complete revascularization in high-risk PCI patients presenting with multivessel coronary artery disease and low LV ejection fraction. Patients undergoing more complete revascularization were found to have more reverse LV remodeling, increased LV ejection fraction, and a decrease in end systolic LV volume. Patients with echocardiographic evidence of reverse remodeling were found to have significantly fewer subsequent clinical events, including a decrease in composite myocardial infarction, death, stroke and transient ischemic attack, and less severe heart failure. PCI, especially multivessel PCI in this population frequently requires the use of short-term hemodynamic support to provide the safety backup needed to achieve optimal procedural results. Frequently intra-aortic balloon pump counterpulsation does not provide sufficient hemodynamic support during PCI in these patients and newer more robust ventricular support is required. Currently, 2 FDA approved percutaneous ventricular assist devices, the Impella and the Tandem Heart, are available offering superior hemodynamic support compared with traditional intra-aortic balloon pump counterpulsation. Both these devices present their own benefits and challenges, each requiring expertise in vascular access and deployment. Physician and support team expertise is also required to manage these devices during the PCI and in the postprocedural time period.

Challenges
As new technologies continue to develop allowing us the treat an expanding high-risk population with PCI, the interventional community will be required to address important challenges. It is essential that we more clearly define high-risk PCI. Clinical, anatomic, and cardiovascular functional characteristics all come into play in this heterogeneous population ranging from patients presenting in extremis with acute myocardial infarction and cardiogenic shock to clinically much more stable patients presenting with heart failure or angina with markedly reduced LV function and complex coronary artery disease. Without better formed definitions, it is impossible to develop robust databases needed to track, risk adjust, standardize patient selection protocols and investigate optimal treatment strategies required to move this process forward. We currently attempt to get at this information indirectly such as analyzing the use of short-term mechanical support circulatory devices from national databases such as the National Cardiovascular Data registry Cath PCI Registry or the Nationwide Inpatient Sample, Healthcare Cost and Utilization Project, which however are not designed to provide much guidance about high-risk PCI.

Similar to our experience with percutaneous valve therapies, high-risk PCI involves a multidisciplinary team approach. Many of the patients sent to our practice are turned down for coronary artery bypass grafting or repeat coronary artery bypass grafting by cardiac surgeons. An experienced interventional cardiologist and cardiac surgeon are essential as are catherization laboratory technician and nursing personnel with the knowledge and experience required to handle mechanical circulatory support devices and the skill sets needed to treat often unstable patients. Hospital administration should be part of this team with full transparency about the potential healthcare risks, benefits, and economics involved with developing and maintaining a high-risk PCI program. How to best train physicians and staff to assure competencies when performing these procedures will be a serious question that needs to be addressed.

The economic challenges involved with developing and maintaining a high-risk PCI program are considerable. This not only involves the recruitment and maintenance of a seasoned, competent medical team but also involves the expenses of providing the continuous training, monitoring, and quality assurance required to assure best clinical practice. Many of these high-risk patients are resource depleting from a hospital perspective. The personnel and equipment are costly. Initial cost benefit data support that the realized increased up front expenses are offset by shorter index admission length of stay and lower 90-day episode of care costs compared with intra-aortic balloon pump counterpulsation–treated patients. This is attributed to fewer subsequent readmissions for revascularization procedures and shorter, less expensive readmission length of stay noted in the high-risk PCI population. Importantly, an increase in quality-adjusted life years is noted further supporting clinical benefit in this high-risk PCI population. Regulators and payers will certainly be interested in more data addressing cost benefit issues.

A further challenge relates to the distribution of care for high-risk PCI. Economic models breakdown at safety net hospitals with a significant amount of unfunded or underfunded care. Medical legal concerns when treating this high-risk population might drive practitioners and hospital systems away from participating in a high-risk PCI program. Transparency in public reporting further complicates the issue as we learned from some of the observed unintended consequence of state registry PCI reporting systems. Risk-adjusted mortality would be difficult for this heterogeneous, high-risk population, which includes the clinical spectrum from cardiogenic shock to more elective multivessel, low-LV function PCI.

Often it is the patient with the highest risk for PCI (complex left main disease or cardiogenic shock) who might realize the greatest potential benefit from the procedure. We now have the skill sets and have developed the tools to more safely and effectively treat these patients. The challenge will be how to provide these services in the most effective and efficient ways possible.

Disclosures
None.

References
3 Bass High-Risk PCI in Modern Day Clinical Practice


KEY WORDS: acute coronary syndrome ▪ coronary artery bypass ▪ heart failure ▪ percutaneous coronary intervention ▪ peripheral vascular diseases
High-Risk Percutaneous Coronary Interventions in Modern Day Clinical Practice: Current Concepts and Challenges
Theodore A. Bass

*Circ Cardiovasc Interv*. 2015;8:
doi: 10.1161/CIRCINTERVENTIONS.115.003405
Circulation: Cardiovascular Interventions is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Copyright © 2015 American Heart Association, Inc. All rights reserved.
Print ISSN: 1941-7640. Online ISSN: 1941-7632

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://circinterventions.ahajournals.org/content/8/12/e003405

Permissions: Requests for permissions to reproduce figures, tables, or portions of articles originally published in Circulation: Cardiovascular Interventions can be obtained via RightsLink, a service of the Copyright Clearance Center, not the Editorial Office. Once the online version of the published article for which permission is being requested is located, click Request Permissions in the middle column of the Web page under Services. Further information about this process is available in the Permissions and Rights Question and Answer document.

Reprints: Information about reprints can be found online at:
http://www.lww.com/reprints

Subscriptions: Information about subscribing to Circulation: Cardiovascular Interventions is online at:
http://circinterventions.ahajournals.org//subscriptions/