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Current PCI Landscape and Opportunities for Improvement

An overview of the landscape, contemporary data, quality measures, and technologic trends that will guide complex CAD cases toward complete revascularization.

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Cardiovascular disease is a leading cause of death, claiming more lives each year than cancer and chronic lung disease combined, and accounts for approximately 15% of total United States health care expenditures.[1] Estimated direct costs of cardiovascular disease in the United States has increased from $103.5 billion in 1997 to $213.8 billion in 2015 and are projected to continue to increase between now and the year 2035.[1]

The rate of hospital readmission after percutaneous coronary intervention (PCI) is currently 8% to 17%.[2,3] Conservatively, this means 114,600 patients are readmitted to the hospital within 30 days of their procedure, with 25% of patients readmitted within 6 months after PCI.[2,3] An examination of recent data describing outcomes after PCI demonstrates an opportunity to achieve better quality outcomes and is discussed here.

PATIENTS ARE CURRENTLY UNDERTREATED

Although the National Inpatient Sample reports approximately 955,000 PCI procedures are performed on approximately 700,000 patients in the United States each year,[4] there is a large population of severe, symptomatic coronary artery disease (CAD) patients either not treated or "undertreated" due to increased risk of acute kidney injury (AKI), hemodynamic compromise, or comorbidities that prevent them from receiving treatment. The recently reported ISCHEMIA trial excluded high-risk populations, such as those with left main disease, significantly compromised left ventricular ejection fraction, and severely symptomatic patients. Despite similar survival in the lower-risk patients in this trial, questions remain about the impact of completeness of revascularization and potential late risk of myocardial infarction for medically treated patients.[5] Furthermore, PCI was associated with greater symptomatic benefits, particularly in the most symptomatic patients.[6] Two-thirds of heart failure (HF) patients have significant CAD. Despite this, Doshi et al[7] and O'Connor et al[8] reported that most patients admitted to the hospital for new-onset HF are not receiving testing for ischemic CAD either during their hospitalization or within 90 days before or after. Among 17,185 patients with new-onset HF, only 6,672 (39%) were tested, most with left ventricular ejection fraction ≤ 40%.[7,8] The low frequency of diagnosis leads to undertreatment of CAD patients, with or often without HF, and presents an opportunity to revisit our strategy and protocols for optimized patient care.

THE IMPORTANCE OF COMPLETE REVASCULARIZATION

Given that nearly 25% of all PCI procedures are for left main and multivessel disease, revascularization strategies are an important factor in achieving the best possible clinical outcomes. For many of these complex patients, complete revascularization in a single setting may pose patient safety issues due to renal dysfunction, contrast required, or operator fatigue.

Nearly 7% of all PCI patients have AKI,[9] with high-risk PCI patients being at an even greater risk. AKI is associated with a 10% in-hospital mortality, which increases to 34% when dialysis is required.[9] Due to concerns regarding renal insufficiency, staging has become an accepted approach and occurs in approximately 14% of patients,[10] typically those at high risk or with renal dysfunction.

While staging may limit total contrast administered, complete revascularization in a single setting often leads to a shorter hospital stay and eliminates the inertia to bring patients back for a second procedure, all supporting a more "surgery-like" result. Complete revascularization in a single setting is associated with a 30% to 50% reduction in major adverse cardiac and cerebrovascular events (MACCE) (Figure 1).[11-14] Incomplete revascularization, which occurs in as much as 45% of all high-risk PCI procedures, has been shown to have a detrimental impact on post-PCI survival.[11,12,15,16]

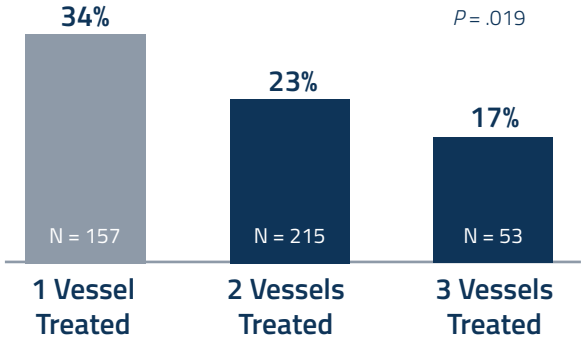

Figure 1. MACCE at 90 days. From PROTECT II clinical study (IABP and Impella arms, all patients).[13]

Improvements in PCI treatment strategies are needed to ensure complete and optimized revascularization with less renal risk. This presents an opportunity to achieve better long-term clinical outcomes with the benefits of a single procedure.

TOOLS TO IMPROVE PCI OUTCOMES

Despite broad availability, advanced techniques designed to improve PCI outcomes remain underutilized (Table 1). Drug-eluting stents have achieved broad adoption and, when combined with ancillary antiplatelet therapy, may provide better outcomes for unprotected left main disease, particularly in high-risk patients.[17] Other technologies, such as intravascular ultrasound (IVUS) and optical coherence tomography (OCT), both designed to provide information about CAD plaque that aids in stent sizing and optimal stent expansion, are only used in approximately 15% of PCI procedures despite proven ancillary benefit.[18,19] Atherectomy is used in approximately 5% of PCI procedures nationwide but is more broadly adopted in high-risk cases (14%-30%)[15,20-22] and, in the PROTECT III study in which atherectomy was used in conjunction with the Impella® heart pump (Abiomed, Inc.), in 43% of the cases.[23] Given the low MACCE of 16.8% in PROTECT III (Figure 2), the clinical benefit of atherectomy plus Impella suggests PCI outcomes could be further optimized with this approach.

ADDRESSING ENHANCED COMPLETE REVASCULARIZATION

The Impella heart pump enhances cardiac flow by providing continuous-flow hemodynamic support to unload the left ventricle. Its mechanism of action may provide renal protection against AKI or drastically reduce the severity of renal injury, enabling complete revascularization in a single setting.

TABLE 1. CURRENT PCI OUTCOMES

Total US PCI Patients Per Year	Outcomes
~101,000	▪ **45% have IR (23.5% of 955,000 PCIs are left main or multivessel)** ▪ 30%–50% reduction in MACCE with complete revascularization vs IR
~133,700	▪ **14% of PCI are patients staged** ▪ Not all staged patients return for the second procedure
~66,850	▪ **7% of PCI patients have AKI** ▪ 50% of high-risk PCI patients are at significant risk of AKI ▪ AKI has a 10% in-hospital mortality rate that increases to 34% if dialysis is required
~114,600	▪ **8%–17% of patients are readmitted within 30 days for cardiovascular issues** ▪ 25% of patients are readmitted within 6 months after PCI
~165,100	▪ **17% AMI cardiogenic shock/other forms of shock** ▪ NCSI best practice protocol survival is 72%, with 98% native heart recovery ▪ INOVA SHOCK health system protocol survival is 77%
~52,400	▪ **5% of PCI procedures include coronary atherectomy** ▪ 14%–30% of all high-risk PCI procedures
~19,100	▪ **2% of all PCI procedures include Impella hemodynamic support** ▪ Impella-protected PCI procedures in 2018 (elective, urgent, emergent)

Abbreviations: AKI, acute kidney injury; AMI, acute myocardial infarction; IR, incomplete revascularization; MACCE, major adverse cardiac and cerebrovascular events; NCSI, National Cardiogenic Shock Initiative; PCI, percutaneous coronary intervention; US, United States.

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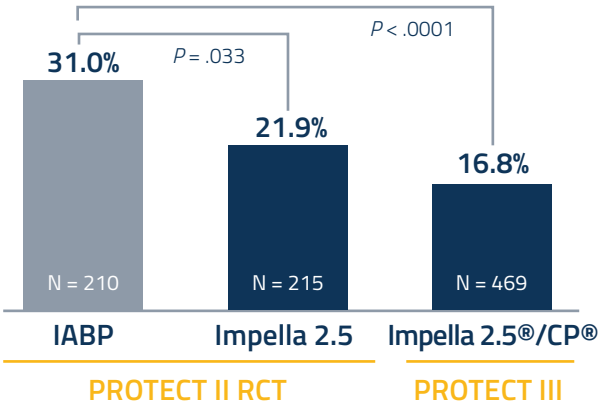

Figure 2. PROTECT III outcomes compared to PROTECT II. Composite MACCE at 90 days. RCT, randomized controlled trial.

The Global cVAD Renal Protection Study, the most comprehensive analysis to date assessing the impact of the Impella heart pump on renal function, reported an AKI incidence rate of 4.9% at 48 hours compared with the predicted AKI rate of 22% (Mehran risk scoring), a 77.6% risk reduction (Figure 3).[24] The renal protection from Impella was most effective in patients with the highest baseline risk score.[24]

Similarly, in a retrospective, single-center study in which 230 patients undergoing high-risk PCI received either Impella support or no hemodynamic support, the incidence of AKI was significantly lower in patients with Impella support (5.2% vs 27.8%; $P < .001$).[25] Furthermore, Impella patients were significantly more complex based on a higher frequency of nonsurgical candidates with a higher incidence of three-vessel disease (47% vs 31%), longer procedure times (148 min vs 121 min), and a higher median volume of contrast.[25]

Although current guidelines recommend AKI prevention protocols and use of the Impella heart pump has shown a sixfold reduction in AKI requiring dialysis in high-risk PCI, it is significantly underutilized, with only a small percentage of PCI patients in the United States receiving Impella support. It is suspected that even high-volume complex PCI hospitals using Impella in 10% to 20% of their high-risk cases may still be underutilizing hemodynamic support.

The use of hemodynamic support during PCI for high-risk patients, such as those with a low ejection fraction, renal insufficiency, and/or complex anatomy, helps maintain hemodynamic stability, which enables a more efficient and complete revascularization.[26]

THE IMPORTANCE OF IMPELLA SUPPORT IN IMPROVING SHOCK OUTCOMES

Over the past decade, advances in PCI and the initiation of treatment protocols have resulted in a dramatic decrease in deaths due to acute myocardial infarction (AMI). However, treatment of AMI complicated by cardiogenic shock has been slow to change and is considered by many to be the "last frontier" for ST-segment elevation myocardial infarction.

Approximately 165,000 patients present with cardiogenic shock each year, often with multivessel disease, and many are not yet treated based on accepted protocols. Of these cardiogenic shock patients, approximately 52,000 are treated with an intra-aortic balloon pump (IABP).[4] The significant use of IABP is surprising given it has a class III recommendation in both Europe and Japan, and its use in many countries is decreasing over recent years. However, use in the United States has remained relatively constant at approximately 52,000, despite a lack of clinical benefit in the IABP-SHOCK II trial.[27] However, the use of Impella for cardiogenic shock, as well as Protected PCI, amounts to only half the IABP cases at 23,500 per year,[28] and despite its proven clinical benefit(s), continues to be significantly underutilized.

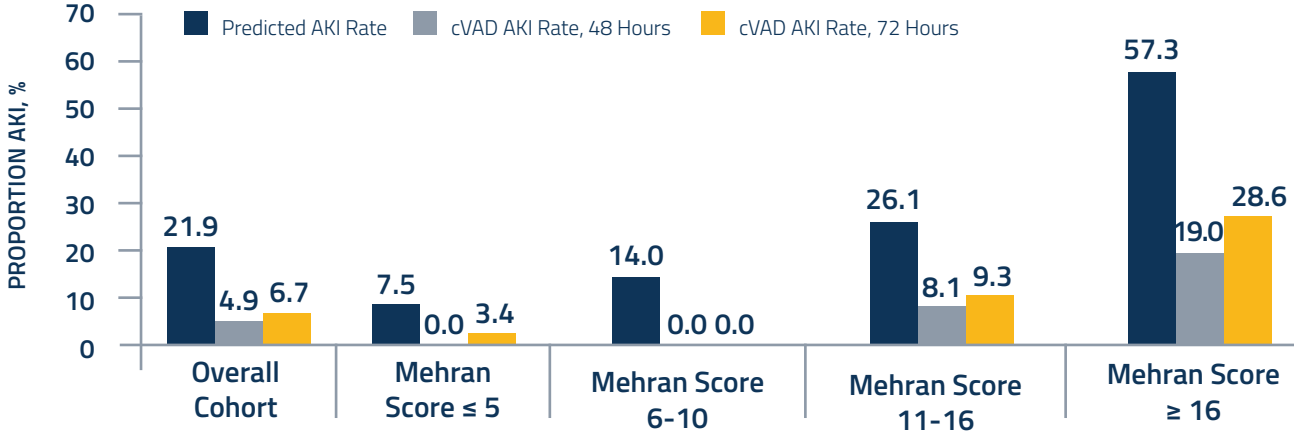

Figure 3. Incidence of AKI based on increasing Mehran risk score severity.

CONCLUSION

The current PCI landscape is often inconsistent with regard to the extent of screening for high-risk CAD, in which case revascularization (particularly complete revascularization) could significantly improve patient symptoms and quality of life, and could potentially increase survival. Technology has increased in terms of stents, coronary imaging, and hemodynamic support to allow safer high-risk PCI. Unfortunately, the application of these technologies is often incomplete, limiting the opportunity to provide high-quality nonsurgical revascularization to patients without other options. This incomplete adoption represents a major challenge to educate and encourage optimal CAD management. ■

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