Physiological and Hemodynamic Effects

The intra-aortic balloon pump (IABP) was first introduced into clinical practice in 1968. Early experimental and clinical trials suggested that intra-aortic balloon counterpulsation could provide circulatory assistance to a failing left ventricle. Counterpulsation—balloon inflation during diastole and deflation in systole—augments the intrinsic Windkessel effect, whereby potential energy stored in the aortic root during systole is converted to kinetic energy with the elastic recoil of the aortic root. Counterpulsation leads to a decline in afterload, a reduction in cardiac work, and therefore myocardial oxygen requirements of the ventricle. Augmentation of diastolic pressure when the balloon is fully inflated together with reduction in left ventricular (LV) filling pressures contribute to improved coronary perfusion (Figures 1 and 2). This proposed improvement in myocardial energetics has been further supported by a significant reduction in systemic lactate. These physiological enhancements are thought to be of particular benefit after acute myocardial infarction (AMI), supported by animal studies, which have shown a reduction in infarct size when counterpulsation is used.

Intra-aortic balloon counterpulsation was initially used as a means of supporting patients undergoing surgical revascularization. Percutaneous delivery and improving catheter design and operator experience has precluded the need for femoral arteriotomy and greatly reduced the incidence of vascular complications over time. Complication rates, however, are difficult to determine because of varying definitions, indications for and duration of insertion (Tables 1 and 2).

The IABP is mounted to a catheter and delivered via femoral arterial access, advanced to the descending aorta, with the distal tip positioned 2 to 3 cm distal to the left subclavian artery at the level of the carina. Automation of the device makes it straightforward to use. Inflation occurs immediately after aortic valve closure at the onset of diastole, triggered either by the systemic arterial waveform or the ECG. Deflation occurs immediately before aortic valve opening, at the onset of systole; in atrial fibrillation, deflation is triggered by the R wave on the ECG.

These improved technologies and an enhanced understanding of cardiovascular physiology have led to the widespread use of counterpulsation as an adjunct to percutaneous coronary intervention (PCI) in a variety of high-risk clinical scenarios ranging from patients with AMI complicated by cardiogenic shock (CS) to prophylactic use for prevention of adverse catheter laboratory events during elective high-risk PCI, which we will address in turn. However, these circulatory effects shown experimentally have not been translated to improved clinical outcome with studies of IABP use in PCI, yielding conflicting results and randomized trial data showing limited efficacy. The beneficial effects of IABP on afterload reduction and diastolic augmentation may vary with the hemodynamic setting. This may in part explain the variability in clinical outcomes with IABP use during high-risk PCI. Controversy exists with regard to IABP augmentation of coronary blood flow. Early invasive studies demonstrated a marked increase in coronary blood flow when IABP was used in critically ill patients with ischemia. In the presence of a critical stenosis, IABP had only a minimal effect on coronary blood flow, suggesting that patients with ischemia because of severe coronary obstruction obtain greatest benefit from afterload reduction.

In the presence of coronary autoregulation, increases in diastolic aortic pressure would not be expected to augment flow. Thus, IABP may be of most benefit when autoregulation has been disabled and myocardial perfusion is outside the normal physiological range, such as severe CS or those with persistent ischemia or no reflow. Furthermore, in the presence of extensive MI, the IABP may provide insufficient hemodynamic support to be effective.

Clinical Indications and Outcomes

Registry Data

Interestingly, the International Benchmark Registry (250 US and non-US centers) of over 20,000 patients treated with IABP suggested that 1 in 5 cases of IABP implantation were for CS and 1 in 5 as an adjunct to high-risk PCI. In the context of AMI, IABP was used more frequently during CS (30%) or an adjunct to PCI (30%). Analysis of the CathPCI Registry from the National Cardiovascular Data Registry of patients who underwent high-risk PCI (10% in CS and 80% ST-segment elevation myocardial infarction [STEMI]) with and without the use of IABP found IABP use was slightly less—10% of
The presence of CS is a major adverse prognostic factor and the left ventricle. Aortic recoil during diastole further improves efficiency of diastolic blood flow and thus coronary perfusion. In addition, aortic recoil during diastole further improves efficiency of the left ventricle.

high-risk PCI. They showed significant variation in IABP use among centers with no difference in adjusted mortality. This is at odds with the earlier results of National Registry of Myocardial Infarction (NRMI)-2 registry conducted between 1994 and 1998, which showed, in patients with AMI and CS, mortality decreased when hospitals exhibited high IABP placement rate.

Post-MI and Cardiogenic Shock
AMI is complicated by CS in ≈5% to 10% of cases. Although death from AMI has decreased with aggressive primary prevention and after wide-scale institution of early urgent revascularization, the incidence of CS after MI remains unchanged. The presence of CS is a major adverse prognostic factor and still the most common cause of hospital mortality (60%–70%) associated with AMI. In addition to revascularization, optimal drug therapy, vasopressor, and inotropic support, IABP is the most commonly used mechanical support device to maintain hemodynamic stability in an attempt to improve clinical outcome. The evidence for the use of IABP as an adjunct to PCI in post-MI CS is controversial. A recent meta-analysis of registry data showed no benefit from the use of IABP in CS with regard to 30-day mortality independent of reperfusion strategy, which led to the recent downgrading of the American Heart Association guidelines on hemodynamic support in post-MI CS from a Class I recommendation to Class IIB.

Early use of IABP in post-MI CS was based predominantly on small nonrandomized retrospective studies. In the thrombolytic era, concomitant IABP in the presence of recombinant-tissue plasminogen activator was thought to enhance thrombolysis through augmentation of perfusion pressure and was associated with a reduction in in-hospital and 1-year mortality when compared with thrombolysis alone. In the late 1990s, the multicenter randomized Should We Emergently Revascularize Occluded Coronaries for Cardiogenic Shock (SHOCK) trial showed a benefit to short-, medium-, and long-term survival incurred by early revascularization post-MI complicated by CS. The Thrombolysis and Counterpulsation to Improve Survival in Myocardial Infarction Complicated by Hypotension and Suspected Cardiogenic Shock (TACTICS) randomized trial of IABP-assisted thrombolysis in post-MI CS did not reach its primary end point of improved 6-month survival, but there was trend to increased survival with IABP in patients with significant heart failure. One interpretation is that thrombolysis is an inferior reperfusion strategy, and this may explain why no benefit has been definitively shown with IABP after primary PCI. A meta-analysis of IABP use in patients with AMI showed no effect on outcome; however, in the subset of AMI and CS, there was significantly decreased in-hospital mortality with IABP compared with no IABP. The Cochrane analysis conducted in 2010 generated similar results—the efficacy and safety of IABP versus standard therapy or LV assist device in AMI complicated by CS was examined—no evidence for survival benefit was seen with IABP with heterogeneous effects on hemodynamics and device-related complications (Figure 3).

The IABP-SHOCK Trial was a prospective randomized control trial evaluating clinical outcome in 45 patients with post-MI CS treated with primary PCI with or without IABP support. This small single center study demonstrated no significant difference in Apache II Score between IABP use and no IABP use (Table 3). The IABP-SHOCK II trial was the first large-scale multicenter randomized trial of balloon pump–supported early revascularization in AMI complicated by CS. This randomized 600 patients to IABP or no IABP in addition to optimal revascularization and intensive care. No benefit was shown from IABP support on analysis of 30-day mortality, secondary end points, or any of the subgroup analyses (Table 3). In this trial, patients with mechanical complications such as ventricular septal defect and acute mitral regurgitation from chordal rupture were excluded, where anecdotal evidence strongly supports IABP implantation based on hemodynamic benefits.
There is evidence to suggest that in the context of AMI complicated by CS, use of IABP before primary PCI results in reduced cardiovascular mortality and adverse event rate compared with insertion after primary PCI. In IABP-SHOCK II, nearly 80% of patients had the IABP inserted post-PCI. Although comparison to the preprocedural IABP implantation group revealed no significant difference in all-cause mortality at 30 days, the baseline characteristics of these 2 groups are not reported and an imbalance would make it difficult to draw conclusions from these data. Thus, it must be remembered that IABP-SHOCK II is not a trial of IABP-supported PCI in CS, and one cannot conclude that the IABP has no role in this clinical scenario.

It remains unclear under which conditions (timing, clinical scenarios, and reperfusion) IABP exhibits its beneficial effects. Until it can be established when IABP is beneficial, conflicting results may continue to arise from such trials. Despite the randomized controlled trial data (Table 3) suggesting no benefit to IABP-supported revascularization in post-MI CS patients, IABP use does not seem to be losing favor among physicians. IABP insertion should remain at the discretion of the operating physician and tailored to the clinical picture of the patient.

### Table 1. IABP/Device-Related Complications in Recent Large Registry

<table>
<thead>
<tr>
<th>Registry</th>
<th>Years</th>
<th>Number</th>
<th>All</th>
<th>Access Site</th>
<th>Severe Bleeding</th>
<th>Limb Ischemia*</th>
<th>Severe Limb Ischemia†</th>
<th>Infection</th>
<th>IABP Failure‡</th>
<th>Stroke</th>
<th>IABP-Related Death</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ferguson et al Benchmark registry§</td>
<td>1996–2000</td>
<td>16909</td>
<td>7.0</td>
<td>2.4</td>
<td>0.8</td>
<td>2.9</td>
<td>0.9</td>
<td>NR</td>
<td>2.3</td>
<td>NR</td>
<td>0.05</td>
</tr>
<tr>
<td>Stone et al Benchmark registry‖</td>
<td>1996–2001</td>
<td>5495</td>
<td>8.1</td>
<td>4.3</td>
<td>1.4</td>
<td>2.3</td>
<td>0.5</td>
<td>0.1</td>
<td>2.3</td>
<td>0.1</td>
<td>0.05</td>
</tr>
<tr>
<td>Cohen et al Benchmark registry¶</td>
<td>1996–2001</td>
<td>22663</td>
<td>5.4</td>
<td>NR</td>
<td>0.9 (access site)</td>
<td>NR</td>
<td>0.9</td>
<td>NR</td>
<td>3.6</td>
<td>NR</td>
<td>0.05</td>
</tr>
<tr>
<td>Cohen et al Benchmark registry¶</td>
<td>1997–2000</td>
<td>9332</td>
<td>7.1</td>
<td>3.1</td>
<td>0.9</td>
<td>2.6</td>
<td>0.7</td>
<td>NR</td>
<td>NR</td>
<td>2.0</td>
<td>0.1</td>
</tr>
<tr>
<td>Urban et al Benchmark registry¶</td>
<td>1997–2002</td>
<td>23281</td>
<td>7.2</td>
<td>NR</td>
<td>0.9</td>
<td>NR</td>
<td>0.9</td>
<td>NR</td>
<td>1.2</td>
<td>NR</td>
<td>&lt;0.1</td>
</tr>
<tr>
<td>Valente et al FLORENCE registry¶</td>
<td>2004–2009</td>
<td>481</td>
<td>13.1</td>
<td>NR</td>
<td>6.9</td>
<td>3.1</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
</tbody>
</table>

All values expressed as %. IABP indicates intra-aortic balloon pump; and NR, not reported.

*Reduced pulse.
†Amputation or loss of pulse/sensation requiring surgical intervention.
‡Balloon leak, insertion difficulty, poor inflation/augmentation.

### Table 2. IABP/Device-Related Complications in Recent Large Randomized Control Trials

<table>
<thead>
<tr>
<th>Randomized Trials</th>
<th>Years</th>
<th>Number</th>
<th>All</th>
<th>Minor Bleeding</th>
<th>Severe Bleeding</th>
<th>Minor Major</th>
<th>Infection</th>
<th>IABP Failure*</th>
<th>Stroke</th>
<th>IABP-Related Death</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perera et al† BCIS-1§</td>
<td>2005–2009</td>
<td>151 IABP</td>
<td>25.2</td>
<td>15.9</td>
<td>3.3</td>
<td>NR</td>
<td>3.3</td>
<td>NR</td>
<td>1.3</td>
<td>NR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>150 Control</td>
<td>22.0</td>
<td>7.3; P=0.02</td>
<td>4.0 ns</td>
<td>NR</td>
<td>0; P=0.06</td>
<td>NR</td>
<td>0</td>
<td>NR</td>
</tr>
<tr>
<td>Patel et al‡ CRISP AMI§</td>
<td>2009–2011</td>
<td>161 IABP</td>
<td>9.3</td>
<td>NR</td>
<td>3.1</td>
<td>3.1</td>
<td>1.2</td>
<td>NR</td>
<td>1.9</td>
<td>NR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>176 Control</td>
<td>3.4</td>
<td>NR</td>
<td>1.7</td>
<td>1.1</td>
<td>0</td>
<td>NR</td>
<td>0.6 ns</td>
<td>NR</td>
</tr>
<tr>
<td>Thiele et al§ IABP-SHOCK II¶</td>
<td>2009–2012</td>
<td>300 IABP</td>
<td>41.3</td>
<td>17.3</td>
<td>3.3</td>
<td>NR</td>
<td>4.3</td>
<td>15.7 (sepsis)</td>
<td>0.7</td>
<td>NR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>298 Control</td>
<td>46.3</td>
<td>16.4 ns</td>
<td>4.4 ns</td>
<td>NR</td>
<td>3.4 ns</td>
<td>20.5 (sepsis)</td>
<td>NR</td>
<td>1.7 ns</td>
</tr>
<tr>
<td>O’Neill et al PROTECT II</td>
<td></td>
<td>2007–2010</td>
<td>222 IABP</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>1.4</td>
<td>NR</td>
<td>1.8</td>
<td>NR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>225 Impella 2.5</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>0.9 ns</td>
<td>NR</td>
<td>NR</td>
<td>0; P=0.04</td>
<td>NR</td>
</tr>
</tbody>
</table>

All values expressed as %. BCIS-1, Balloon Pump-Assisted Coronary Intervention Study; CRISP AMI, Counterpulsation to Reduce Infarct Size Pre-PCI Acute Myocardial Infarction; IABP, intra-aortic balloon pump; IABP-SHOCK II, Intra-Aortic Balloon Pump in Cardiogenic Shock II trial; NR, not reported; ns, not significant; and PROTECT II, Prospective Randomized Clinical Trial of Hemodynamic Support With Impella 2.5 Versus Intra-Aortic Balloon Pump in Patients Undergoing High-Risk Percutaneous Coronary Intervention trial.

*Balloon leak, insertion difficulty, poor inflation/augmentation.
†Bleeding criteria: Minor bleed, 2–4 g/dL/dl; major bleed, >4 g/dL/dl. Complications defined: Access-site hematoma or leg ischemia requiring surgical or percutaneous intervention, pseudoaneurysm, femoral artery occlusion.
‡Bleeding criteria: In accordance with Global Use of Strategies to Open Occluded Coronary Arteries (GUSTO) criteria. Minor complications: pseudoaneurysm, hematoma >5 cm. Major complications: major dissection.
§Bleeding criteria: In accordance with GUSTO, moderate vs life-threatening/severe. Major complications: peripheral ischemia requiring intervention.
¶Major complications: Cardiac operation or abdominal vascular operation or vascular surgery for limb ischemia.
Intra-Aortic Balloon Pump for High-Risk PCI

reperfusion (suboptimal PCI result, poor ST-segment resolution on the ECG, failed thrombolysis) or patients with severe LV impairment or have a large area of subtended myocardium at risk. In spite of the variety of definitions, IABP insertion in such high-risk patients in the absence of CS has repeatedly shown to be of no benefit. In the pre-PCI era, a study by Ohman et al compared the use of balloon pump compared with standard therapy and found a lower rate of reocclusion and adverse clinical event rate in the balloon pump group. The Primary Angioplasty in Myocardial Infarction-II trial demonstrated no benefit of balloon pump use over standard treatment on the clinical end points of all-cause mortality or adverse cardiovascular events, including stroke, reinfarction, and Killip class) in 437 patients who underwent primary PCI in the prestenting era. The Counterpulsation to Reduce Infarct Size Pre-PCI Acute Myocardial Infarction (CRISP AMI) trial studied 337 patients with anterior STEMI not complicated by CS treated by primary PCI, with a success rate of 96.9%. Patients were randomized to IABP or no IABP before reperfusion; they demonstrated no reduction in myocardial infarct size as assessed by MRI in the IABP group and similar 6-month mortality in both groups. Although not powered to assess clinical outcome, the incidence of new heart failure and shock occurred less frequently in the IABP group.

Figure 3. Cochrane systematic review: comparison of intra-aortic balloon pump (IABP) with control, effect on 30-day mortality rates (A) and hemodynamics postintervention (B). CI indicates confidence interval; IABP, intra-aortic balloon pump; and LVAD, left ventricular assist device. Reprinted from Unverzagt et al with permission of the publisher. Copyright © 2011 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.
Although CRISP-AMI was unable to demonstrate a benefit from routine IABP insertion in acute anterior MI in absence of CS, patients had an average blood pressure of 130/80 mm Hg and a mean heart rate of 80, suggesting a surprisingly stable patient cohort given the context of anterior MI. Crossover rate because of hypotension was also high in this study (9.3%)—it is likely that these sicker patients reaped the greatest benefit from IABP use. All patients in CRISP-AMI received revascularization within 6 hours, suggesting considerable myocardial salvage; this and the short time from IABP to Thrombolysis in Myocardial Infarction grade flow potentially creates a scenario in which little added benefit is gained from balloon pump use; early revascularization and restoration of flow is likely to diminish the observed benefit we may have otherwise seen from IABP use.\textsuperscript{42} These limitations are not unique to CRISP-AMI, but in fact represent the inherent difficulty in recruiting a cohort of critically ill patients into hemodynamic support trials. There will be an intrinsic degree of bias when randomizing patients, particularly those who are too sick to consent or in centers where not inserting a hemodynamic support device would be considered unethical.

A meta-analysis of IABP use in AMI in the absence of CS showed no reduction in mortality but an increase in complication rates, including major bleeding and stroke in the IABP group (Figure 4).\textsuperscript{27,34} In summary, these data do not support routine use of IABP in AMI outside the setting of CS. However, it may be of benefit if there is evidence of impending hemodynamic instability.

\textbf{Elective High-Risk PCI}

Improved catheter design and advancing technologies mean that complex PCIs are increasingly considered a viable alternative to high-risk coronary artery bypass surgery. Such patients tend to carry a significant risk of procedure-related morbidity and mortality and often have severe LV impairment, multi-vessel coronary disease, a last remaining conduit, or pharmacologically uncontrolled chest pain.\textsuperscript{43} Complex coronary interventions, such as rotational atherectomy, can cause prolonged ischemia, and any decision to intervene in a cohort of patients in whom even transient ischemia from balloon pump use may have disastrous effects must be made cautiously.\textsuperscript{44} Early studies suggested that \textit{elective} or prophylactic IABP use can provide circulatory support for patients undergoing high-risk PCI.\textsuperscript{19} It is thought that prior hemodynamic stabilization can be protective by maintaining perfusion pressure throughout the procedure, thus reducing intraprocedural risk.\textsuperscript{45}

The first reported use of elective IABP support in patients undergoing high-risk PCI in 1990 was in 28 patients with severe LV dysfunction and either multivessel coronary disease or left main coronary artery disease. IABP-support was found to be safe and feasible, with no observed intraprocedural complications of hypotension, death, or MI within 72 hours.\textsuperscript{46} Briguori et al reported a retrospective study of 133 high-risk

| Table 3. Randomized Control Trials of IABP in Post-MI Cardiogenic Shock |
|-----------------------------|-----------------------------|-----------------------------|-----------------------------|
| Trial                       | Reperfusion Strategy        | Patient Numbers | Timing of IABP Insertion | Primary Outcome |
| TACTICS\textsuperscript{33} | Thrombolysis                | 57             | Within 3 h               | 6 mo all-cause mortality; No difference |
| IABP SHOCK\textsuperscript{26} | PPCI                        | 45             | Immediately after        | APACHE II score*; No difference |
| IABP SHOCK II\textsuperscript{17} | PPCI                        | 600            | Before (13%) or immediately after (87%) | 30 day all-cause mortality; No difference |

*Difference over 4 days.

**APACHE II indicates Acute Physiology and Chronic Health Evaluation II Score; IABP, intra-aortic balloon pump; IABP SHOCK, Intra-Aortic Balloon Pump in Cardiogenic Shock; MI, myocardial infarction; PPCI, primary percutaneous coronary intervention; and TACTICS, Thrombolysis and Counterpulsation to Improve Survival in Myocardial Infarction Complicated by Hypotension and Suspected Cardiogenic Shock.**

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{figure4.png}
\caption{Meta-analysis of randomized control trials of intra-aortic balloon pump (IABP) use, by reperfusion strategy, in acute myocardial infarction, demonstrating the differences in risk in 30-day mortality (A) and bleeding rate (B). PAMI-II indicates Primary Angioplasty in Myocardial Infarction II trial; PCI, percutaneous coronary intervention; and TACTICS, Thrombolysis and Counterpulsation to Improve Survival in Myocardial Infarction Complicated by Hypotension and Suspected Cardiogenic Shock. Reprinted from Sjauw et al\textsuperscript{27} with permission of the publisher. Copyright © 2009, The Authors.}
\end{figure}
patients who underwent PCI with elective IABP (61 patients) or no IABP (72 patients) support. The area of myocardium at risk (and extent of multivessel disease) was determined by applying the jeopardy score—the myocardium is divided into 6 segments of equal perfusion, a score of 2 is applied to each significant lesion and a further 2 points for each vessel distal to that lesion, such that a maximum score of 12 can be achieved. In this study, jeopardy score was higher (8.0±2.8 versus 6.7±2.4; *P*=0.008) in the elective balloon pump group. Despite this, they found the use of elective IABP was associated with reduced inprocedural event rate, but demonstrated no significant difference in major adverse cardiovascular or cerebrovascular events (5% versus 10%; *P*=0.29).

A summary of cohort and registry data of IABP use in elective or urgent PCI is provided in Table 4.

### Table 4. Cohort Studies and Registry Data of Patients Receiving IABP Who Underwent Elective or Urgent PCI

<table>
<thead>
<tr>
<th>Study</th>
<th>Number of Patients</th>
<th>Clinical Indication for IABP</th>
<th>Clinical Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMC CS 44</td>
<td>292</td>
<td>PPCI in AMI+CS</td>
<td>Mortality: IABP, 46.7%; no IABP, 28%</td>
</tr>
<tr>
<td>NRMI-2 21</td>
<td>8671</td>
<td>PPCI with CS</td>
<td>Mortality: IABP, 55%; no IABP, 53%</td>
</tr>
<tr>
<td>Cath-PCI registry 22</td>
<td>18990</td>
<td>High-risk PCI (10.5% of total)</td>
<td>In-hospital mortality: 4.9%</td>
</tr>
<tr>
<td>Benchmark registry 20</td>
<td>2282</td>
<td>High-risk PCI (22.7% of total)</td>
<td>Mortality: IABP in AMI, 20%; IABP in AMI+CS, 30.7%</td>
</tr>
<tr>
<td>Brodie et al 19</td>
<td>213</td>
<td>PPCI (Insertion pre vs post PCI)</td>
<td>30-Day mortality: pre, 37%; post, 32.4% ((P&lt;0.0001))</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cath-laboratory events:</td>
<td>CS, 14.5% vs 35.1% ((P=0.009)); high-risk, 11.5% vs 21.9% ((P=0.05))</td>
</tr>
<tr>
<td></td>
<td></td>
<td>In-hospital MACCE:</td>
<td>r-IABP, 5%; p-IABP, 10% ((P=0.29))</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cath-laboratory events:</td>
<td>0% vs 15% ((P&lt;0.001))</td>
</tr>
<tr>
<td></td>
<td></td>
<td>r-IABP, 32%; p-IABP, 4% ((P=0.01))</td>
<td></td>
</tr>
<tr>
<td>Mishra et al 21</td>
<td>115</td>
<td>Elective routine (r) vs prophylactic (p)</td>
<td>30-Day mortality: r-IABP, 27%; p-IABP, 4% ((P=0.01))</td>
</tr>
<tr>
<td></td>
<td></td>
<td>30-Day MACCE rate:</td>
<td>r-IABP, 32%; p-IABP, 4% ((P=0.01))</td>
</tr>
</tbody>
</table>

AMC indicates Amsterdam Medical Center; AMI, acute myocardial infarction; CS, cardiogenic shock; IABP, intra-aortic balloon pump; MACCE, major adverse cardiovascular or cerebrovascular events; NRMI-2, National Registry of Myocardial Infarction-2; PCI, percutaneous coronary intervention; and PPCI, primary percutaneous coronary intervention.

The first randomized control trial to examine the use of elective IABP in high-risk PCI was the Balloon pump–assisted Coronary Intervention Study (BCIS-1). This study used the BCIS-1 jeopardy score, a modification on the Duke’s jeopardy score, which also takes into account left main coronary artery disease and previous coronary artery bypass grafting. Three hundred and one patients with severe LV impairment (ejection fraction <30%) and severe coronary disease (BCIS-1 jeopardy score ≥8) were randomized to PCI with (151 patients) or without (150 patients) IABP. Baseline characteristics were similar in both groups. There was no significant difference in the in-hospital major adverse cardiovascular or cerebrovascular event rates (primary outcome) of patients in the elective IABP (15.2%) compared with no-IABP groups (16%; odds ratio, 0.94; 95% confidence interval, 0.51–1.76; *P*=0.85). Interestingly, long-term all-cause mortality at a median follow-up of 51 months was significantly less in the elective IABP (42 patients) group compared with no IABP (58 patients; hazard ratio, 0.66; 95% confidence interval, 0.44–0.98; \(P=0.039\)); a 34% relative reduction in long-term all-cause mortality compared with unsupported PCI (Figure 5).

The evidence would suggest that routine IABP use does not provide clinical benefit in patients undergoing high-risk procedures or those with AMI in the absence of CS. The current American Heart Association guidance considers it reasonable to consider elective IABP in high-risk PCI in a carefully selected subgroup (Class IIB) but not in patients with AMI in the absence of CS. BCIS-1 did not support routine IABP use in patients with poor LV function and extensive territory of ischemia undergoing PCI; however, there are some limitations to the findings of this study. The BCIS-1 jeopardy score assessed only the amount of myocardium at risk, but not the complexity of disease (the trial was designed pre-SYNTAX). A 12% crossover occurred from the no planned IABP group to IABP, largely because of procedural hypotension. These patients had a higher jeopardy score, suggesting that they may have been at higher risk than the whole study population. Thus, there may be a role for elective IABP in the higher risk spectrum of these patients.

### Alternative Percutaneous Hemodynamic Support Systems

Impella (Abiomed, Aachen, Germany, MA) is a percutaneous hemodynamic support system with a pigtail-mounted microaxial flow pump that is inserted into the ventricle across the aortic valve. Blood is delivered from the left ventricle into...
the aorta, thus mechanically unloading the left ventricle with a reduction in end-diastolic pressure and thus myocardial oxygen demand. The increase in mean arterial pressure and decreased EDP is thought to increase coronary flow.\textsuperscript{55}

PROTECT I (Prospective Feasibility Trial Investigating the Use of the Impella 2.5 System in Patients Undergoing High-Risk PCI) and The Europella Registry, both observational studies, demonstrated the safety and feasibility of Impella 2.5 (flow-rate 2.5 L/min) during high-risk PCI.\textsuperscript{33,54} On comparison of Impella 2.5 with IABP in ISAR-SHOCK (Impella 2.5 Versus IABP in Cardiogenic SHOCK) during high-risk PCI, the Impella (cardiac index, 0.49±0.46 L/min/m\textsuperscript{2}; P=0.02). However, there was no difference in 30-day mortality (46%) between the 2 groups, although this study was not powered to demonstrate clinical outcomes.\textsuperscript{55}

The PROTECT II Study is the only randomized control trial of patients undergoing elective high-risk PCI comparing Impella 2.5 with IABP. This trial was designed to demonstrate superiority of Impella over IABP in terms of the primary outcome of 30-day major adverse events (in-hospital death, stroke, MI), but was halted early because of futility. Of the 452 patients, no difference in 30-day event rate was demonstrated between Impella (35.1%) and IABP (40.1%; P=0.277). A trend toward lower adverse event rate was noted in the Impella arm (n=219; 40.6%) at 90-day follow up compared with the IABP arm (n=224, 49.3%; P=0.066) in the intent-to-treat population; however, this was driven by only 5 further events in the IABP group.\textsuperscript{18} A meta-analysis of percutaneous left ventricular assist device versus IABP in patients with CS demonstrated no early survival benefit from left ventricular assist device use with greater bleeding risk, despite superior hemodynamic support, suggesting percutaneous left ventricular assist device should not be the first choice of mechanical hemodynamic support.\textsuperscript{56}

Conclusions

IABP implantation can provide additional hemodynamic support in the setting of elective high-risk PCI and in post-MI CS. IABP use can reduce procedural event rate and potentially reduce long-term mortality in appropriately selected patients who are at high risk of adverse events. The use of IABP should be at the discretion of the operating physician, but guideline recommendations still support its use in post-MI CS. Other percutaneous support devices may provide superior hemodynamic support to IABP, but there are as yet no randomized data to suggest an improvement in clinical outcomes over IABP. In the context of CS, fluids and inotropic support, followed by IABP, use should still be the mainstay of treatment. Thus, although these trials seem to convey a negative message, there is certainly still a role for IABP in carefully selected subgroup of patients. The IABP is inexpensive, safe, easy to use, and readily available in catheterization laboratories. We support the use of IABP as a first-line mechanical support device in hemodynamic shock, as an adjunct to high-risk PCI where there is a risk of intra-procedural events and select patient groups presenting with AMI.

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