

Percutaneous Coronary Intervention in Cardiogenic Shock

A review of the current and evolving percutaneous interventions.

BY AMAR R. CHADAGA, MD, AND TIMOTHY A. SANBORN, MD

Cardiogenic shock represents the most ominous challenge in acute myocardial infarction (MI), with historic mortality rates ranging from 70% to 90%.¹⁻³ Although the pathophysiology varies, the most common etiology of cardiogenic shock is an acute MI with left ventricular failure leading to refractory hypotension and hypoperfusion.⁴⁻⁶ Historically, this complication occurs in approximately 7% to 8% of acute MIs.^{1,3,7}

However, recent investigations have demonstrated an encouraging trend toward decreased incidence and mortality from cardiogenic shock.⁷⁻¹⁰ Improvements in mortality and incidence are thought to mirror the increased use of intra-aortic balloon pump (IABP) counterpulsation and emergent coronary reperfusion strategies. This is reflected in the fact that the placement of an IABP and primary percutaneous coronary intervention (PCI) in young patients is an American College of Cardiology (ACC)/American Heart Association (AHA) class 1 recommendation.^{11,12} More recently, data from 775 hospitals with revascularization capability extracted from the Second, Third, and Fourth National Registry of Myocardial Infarction (NRMI-2, NRMI-3, NRMI-4) revealed that mortality rates in cardiogenic shock decreased from 60.3% in 1995 to 47.9% in 2004.¹³

Despite encouraging trends in mortality and incidence, cardiogenic shock continues to cause unacceptable mortality rates. More alarmingly, there has been no detectable temporal increase in revascularization rates despite the aforementioned ACC/AHA guidelines.¹³ A

description of the current percutaneous interventional techniques, consensus guidelines, and evolving technologies is presented in this article.

CURRENT INTERVENTIONAL TECHNIQUES FOR CARDIOGENIC SHOCK

IABP Counterpulsation

IABP has been used in the setting of shock for 30 years.¹⁴ In 1994, a study by Prewitt et al involving canines showed that under moderate hypotension, IABP enhances the rate of clot dissolution with thrombolysis, and thus IABP is almost always used in combination with fibrinolytic therapy or PCI or both.^{15,16} The NRMI-2 database demonstrated a significant reduction in mortality with IABP use in combination with fibrinolysis (67% vs 49%) in almost 24,000 patients with cardiogenic shock.¹⁷ This synergistic effect was also noted in the SHOCK trial registry and GUSTO-I trial.^{18,19} After dividing the NRMI-2 hospitals into three tertiles (low-, intermediate-, and high-IABP volume hospitals), Chen et al showed that in acute MI complicated by cardiogenic shock, the crude mortality rate decreased with increasing IABP volume (65.4%, lowest volume tertile; 54.1%, intermediate volume tertile; and 50.6%, highest volume tertile [*P* for trend <.001]).²⁰ There have been no randomized clinical trials investigating the efficacy and safety of combined IABP and fibrinolytic therapy in cardiogenic shock. Placement of an IABP is an ACC/AHA class 1 recommendation (level of evidence: B) in cardiogenic shock refractory to pharmacologic therapy.¹¹

Primary PCI

Despite maximal medical management (fibrinolytic therapy plus IABP), mortality rates in cardiogenic shock continue to hover around 50%,^{18,19} and the focus has turned to early revascularization. After early single-institutional observational series, the GUSTO-I investigators evaluated the outcome of shock in 2,972 patients, some of which underwent percutaneous coronary angioplasty (PTCA).⁴ This trial found that although angioplasty was performed in only 19% of patients with shock, PTCA resulted in a mortality rate of 31% compared with 61% for patients who did not undergo dilation. Selection bias appeared to contribute to these startling results and thus further analysis of the GUSTO-I data was pursued.²¹ In 1997, Berger et al²¹ published an observational study of 2,200 patients in the GUSTO-I trial. After adjusting for differences between the two groups, the 30-day mortality rate was 38% with early angiography, and an aggressive strategy was independently associated with reduced 30-day mortality. An independent survival benefit associated with aggressive revascularization strategies has also been noted in several other studies, including the California State Database,²² NRMI-2,⁹ and GUSTO-III.²³

“Given the improved mortality rates with IABP and primary PCI, it is natural to assume that these treatment modalities have synergistic potential.”

Despite multivariate logistic regression analyses being performed in the aforementioned trials, inherent and undetectable selection bias appeared to be confounding outcomes because patients undergoing an early aggressive strategy were younger and healthier. It is for this reason that the SHOCK trial²⁴ was conducted. The SHOCK study randomly assigned 302 patients with acute ST-segment elevation MI, or new left bundle branch block, complicated by shock to either an early revascularization strategy (angioplasty 55%, bypass surgery 38%) within 6 hours of randomization or initial medical stabilization and delayed revascularization. At 30 days, 53% of the emergency revascularization group survived versus 44% of the initial medical stabilization group. Although the 30-day survival data did not reach statistical significance (95% confidence interval, 0.96, 1.53; $P=.109$) by 6, 12, and 60 months, the survival differences had increased and were statistically significant.^{25,26} In addition, at 1 year, survivors in the emergency revascularization arm had good functional status

and had a lower rate of deterioration than the initial medical stabilization patients.²⁷ However, survival benefit in the SHOCK trial was limited to patients <75 years of age. In part because of this trial, primary PCI is a class 1 recommendation (level of evidence: A) for patients <75 years with cardiogenic shock.¹²

Elderly patients who experience acute MI complicated by cardiogenic shock comprise a high-risk population. In patients aged 75 years or older, the SHOCK trial revealed a mortality rate of 75% in the emergency revascularization arm versus 53% in the initial medication therapy group ($P=.01$).²⁴ This subgroup was composed of 56 patients. Other studies with larger enrollments have disputed these results. Indeed, the SHOCK Registry, which enrolled patients during the same time frame as the SHOCK Randomized Trial, found an in-hospital mortality rate of 48% in 103 elderly patients undergoing early revascularization (vs a mortality rate of 81% for those aged ≥ 75 years undergoing late or no revascularization).²⁸ The Northern New England Cardiovascular Disease Study Group studied a total of 310 patients (74 of which were ≥ 75 years of age) who underwent PCI for cardiogenic shock.²⁹ The mortality rate of the elderly subgroup was 46%, which is significantly less than the 75% mortality rate reported in the SHOCK trial. Finally, Prasad et al investigated a series of 61 consecutive elderly patients with cardiogenic shock undergoing PCI.³⁰ The 30-day mortality rate was found to be 47%, with the estimated survival rate 1 year after discharge at 75%. Inherent in all of the aforementioned studies is selection bias, and numerous considerations (ie, functional status, comorbidities, etc.) should be discussed when selecting the appropriate treatment plan for this high-risk population. Given these considerations, primary PCI is a class IIa recommendation (level of evidence: B) for patients aged 75 years and older with cardiogenic shock.¹²

Primary PCI + IABP

Given the improved mortality rates with IABP and primary PCI, it is natural to assume that these treatment modalities have synergistic potential. Indeed, the SHOCK trial utilized IABP support in both arms of the trial in 86% of the patients and noted statistical improvement in mortality at 6 and 12 months in the primary PCI arm versus the initial medical therapy group.²³ However, NRMI-2 found no reduction in in-hospital mortality associated with the use of IABP in patients undergoing primary PCI for cardiogenic shock (47% mortality with IABP vs 42% mortality without IABP).¹⁷ A canine study concluded that IABP counterpulsation accelerates but does not significantly improve

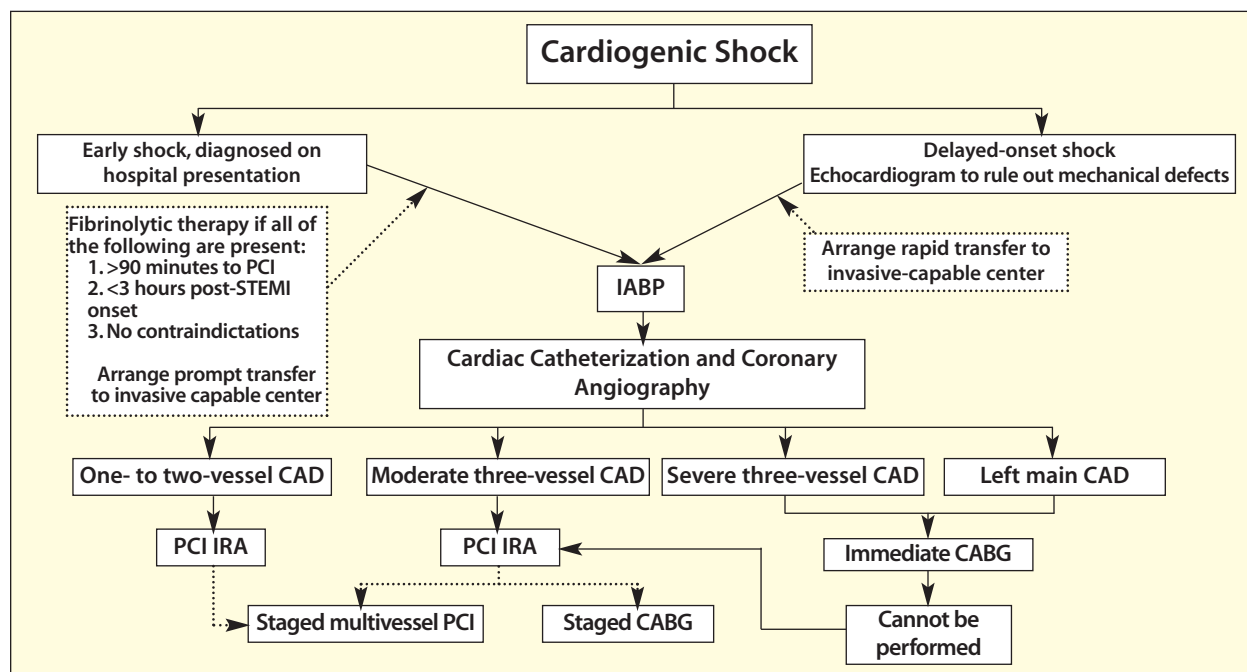


Figure 1. Recommendations for initial reperfusion therapy when cardiogenic shock complicates STEMI. Early mechanical revascularization with PCI/CABG is a class I recommendation for candidates <75 years of age with ST elevation or left bundle branch block who develop shock >36 hours from STEMI, and in whom revascularization can be performed within 18 hours of shock. It is a class IIa recommendation for patients 75 years of age or older with the same criteria. IABP is recommended when shock is not quickly reversed with pharmacological therapy as a stabilizing measure for patients who are candidates for further invasive care. Dotted lines indicate that the procedure should be performed in patients with specific indications only. CABG=coronary artery bypass graft surgery; CAD=coronary artery disease; IABP=intra-aortic balloon pump; IRA=infarct-related artery; STEMI=ST-elevation myocardial infarction. (Reprinted with permission from ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines [ACC/AHA/SCAI Writing Committee to Update the 2001 Guidelines for Percutaneous Coronary Intervention] © 2005 by the American College of Cardiology Foundation and the American Heart Association, Inc.)

the recovery of left ventricle (LV) systolic function after reperfused acute MI.³¹ Furthermore, high-risk patients showed no decrease in infarct size or improvement in clinical outcome when IABP was used after PTCA.^{32,33} Thus, although IABP is recommended in cardiogenic shock, the independent role of IABP when used in combination with PCI is harder to define, especially in high-risk patients.

Advances in PCI

In the years after the SHOCK trial, myriad changes have occurred in the field of interventional cardiology, none more important the increased use of stents (with or without platelet glycoprotein IIb/IIIa inhibitors) rather than conventional PTCA.³³ In general, stents have been found to improve TIMI flow, as well as decrease infarct artery reocclusion, and are now used for the majority of patients undergoing percutaneous coronary revascularization.^{34,35} Regarding cardiogenic shock

patients in particular, stents are associated with a mortality benefit. Chan et al prospectively examined 96 consecutive patients who underwent emergent PCI for cardiogenic shock.³⁶ In stented patients, mortality at 2.5 years was 43% compared with 68% for patients treated with PTCA. However, this study also included two other arms of patients treated with IIb/IIIa inhibitors whose salutary effects on shock were demonstrated in the PURSUIT trial.³⁷

Thus, in the study by Chan et al, patients were classified as receiving stent plus abciximab, stent alone, PTCA plus abciximab, or PTCA alone. During 2.5 years after emergent PCI for cardiogenic shock, the mortality rates for stent plus abciximab, stent only, PTCA plus abciximab, and PTCA alone were 33%, 43%, 61%, and 68%, respectively ($P=.028$). Further studies have demonstrated this synergistic mortality benefit in the use of stenting and platelet glycoprotein IIb/IIIa inhibitors in cardiogenic shock.^{38,39}

CONSENSUS GUIDELINES: PERCUTANEOUS INTERVENTIONS IN CARDIOGENIC SHOCK

Class I

- Primary PCI is recommended for patients younger than 75 years with ST elevation or left bundle branch block who develop shock within 36 hours of MI and are suitable for revascularization that can be performed within 18 hours of shock, unless further support is futile because of the patient's wishes or contraindications/unsuitability for further invasive care (level of evidence: A).¹¹

- IABP is recommended when shock is not quickly reversed with pharmacological therapy as a stabilizing measure for patients who are candidates for further invasive care (level of evidence: B).¹¹

Class IIa

- Primary PCI is reasonable for selected patients aged 75 years or older with ST elevation or left bundle branch block who develop shock within 36 hours of MI and are suitable for revascularization that can be performed within 18 hours of shock. Patients with good previous functional status who are suitable for revascularization and agree to invasive strategy may be selected for such an invasive strategy (level of evidence: B) (Figure 1).¹²

EVOLVING TECHNOLOGY: PERCUTANEOUSLY IMPLANTED DEVICES

To address the unacceptable mortality rates in cardiogenic shock, and given the aforementioned disparity in data concerning whether IABP is the most favorable left ventricular assist device with primary PCI, newer technologies are evolving to optimally treat those patients at highest risk.

Left Atrial-to-Femoral-Arterial Ventricular Assist Device: The Tandem Heart

The TandemHeart PTVA System (CardiacAssist, Inc., Pittsburgh, PA) is a low-speed, centrifugal continuous-flow pump used for stabilization of patients with cardiogenic shock or as a bridge to definite surgical treatment (Figure 2). This system and its percutaneous implantation have been described in detail elsewhere.⁴⁰ Briefly, a

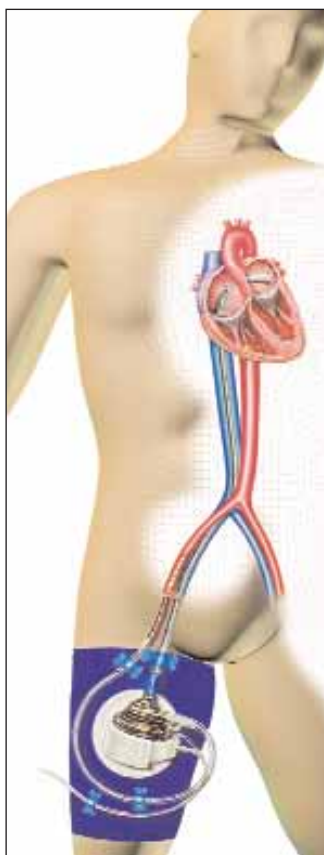


Figure 2. The TandemHeart PTVA System consists of a low-speed centrifugal continuous-flow pump. Once implanted, it delivers flow up to 4 L/min at 7,500 rpm.

venous inflow cannula is inserted into the left atrium after transseptal puncture and dilation to 21 F. From the left atrium, oxygenated blood is removed and returned via a 12-F arterial cannula in the femoral artery to the lower abdominal aorta by way of a centrifugal pump. Two 12-F arterial cannulae in both femoral arteries are recommended in smaller patients to avoid limb ischemia. With bilateral cannulation, the flow is limited to 3 L/min, whereas unilateral cannulation delivers flow up to 4 L/min at 7,500 rpm. Anticoagulation is administered through the device lubrication system with a goal activated clotting time of 180 to 200 seconds.^{41,42}

The initial feasibility trial using this device examined 18 consecutive patients who had cardiogenic shock after MI.³⁹ Sixteen of the 18 patients had adjunctive PTCA and/or stent. The device was placed uneventfully in all patients within 30 minutes, and improvements in all facets of coronary and systemic hemodynamics were noted. Overall 30-day mortality was 44%. Mean blood pressure increased from 63 ± 8 mm Hg to 80 ± 9 mm Hg, while cardiac index improved from 1.7 ± 0.3 L/min per m^2 to 2.4 ± 0.6 L/min per m^2 . Mean duration of cardiac assistance was 4 ± 3 days, whereas mean flow was 3.2 ± 0.6 L/min. The most common complications were groin bleeding and limb ischemia. Similar results were obtained in a later study in which the device was implanted into patients prior to therapeutic intervention.⁴³

Subsequently, a randomized study was designed to assess the hemodynamic effects of IABP in comparison to the TandemHeart ventricular assist device (VAD).⁴¹ Patients in cardiogenic shock, after acute MI, with intended PCI of the infarcted artery, were randomized to either IABP (n=20) or the VAD support (n=21). Thirty-day mortality did not differ significantly (IABP 45% vs VAD 43%), and although the primary outcome of cardiac power index was improved more effectively with the VAD support, there was a significant trend toward more complications, such as severe bleeding and limb ischemia after TandemHeart device support in comparison with IABP support.

The TandemHeart device is FDA approved for extracorporeal support for up to 6 hours for procedures not

(Courtesy of Abiomed, Inc.)

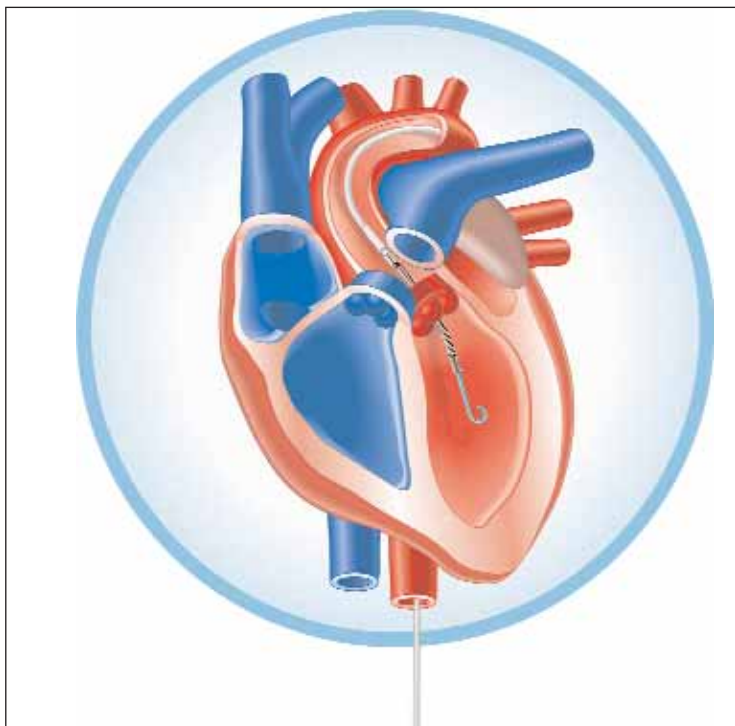


Figure 3. The Impella 2.5 device consists of a miniaturized rotary blood pump that is percutaneously inserted through a 13-F femoral sheath. The device is placed through the aortic valve and provides up to 2.5 L/min at its maximal rotation of 50,000 rpm.

requiring full cardiopulmonary bypass and requires operators to be knowledgeable of transseptal procedure techniques.⁴⁴

Axial Flow Pump: The Impella Recover LP 2.5

Perhaps the most promising percutaneously implanted device on the horizon is the Impella Recover LP 2.5 (Abiomed, Inc., Danvers, MA). The Impella Recover device is a miniaturized rotary blood pump (4 mm, 12 F in outer diameter).⁴⁵ While being mounted on a 9-F pig-tail catheter, it is percutaneously inserted through a 13-F femoral sheath (Figure 3). The device is placed through the aortic valve, aspirates blood from the LV cavity, and expels it in the ascending aorta. The pump provides up to 2.5 L/min at its maximal rotation speed of 50,000 rpm. The device can be left in place up to 5 days and is connected distally to a portable mobile console in which invasive pressures are displayed with the actual rpm of the pump.

In the safety and feasibility study using the Impella Recover LP 2.5 device, 19 consecutive patients with PCI were followed.⁴⁶ The patients constituted a high-risk population: 84% of patients were ≥ 60 years old, 74% had a previous MI, 100% had a LV ejection fraction $\leq 40\%$, and

63% of patients had a LV EF $\leq 25\%$. Successful implantation through the femoral artery and implantation into the LV was achieved in all 19 patients. One patient suffered a large hematoma and required blood transfusion. Two patients in cardiogenic shock had urgent Impella 2.5 LP implantation. One of these patients had the device implanted after not being able to be weaned from bypass following a long and complicated cardiac surgery. The other patient was in cardiogenic shock with imminent multiorgan failure, and a PCI procedure with the Impella 2.5 LP was performed. Both patients died 1 day after implantation, leading the authors to question whether 2.5 L/min is enough for high-risk patients. Although the investigators admitted that the implantation of this device requires more care, time, and effort compared with an IABP catheter implantation, the device appeared safe and feasible in this small high-risk population. In addition, coronary hemodynamics appear to improve via unloading of the LV by the Impella.⁴⁷

Although there have been no trials looking specifically at patients with cardiogenic shock and this device, the FDA has approved a randomized study (The Pivotal Trial for High-Risk PCI) at up to 150 hospitals. The study is currently underway and is recruiting sites and patients; it will compare 327 Impella 2.5 patients to 327 IABP patients. The pivotal study will determine the safety and effectiveness of the Impella 2.5 as compared to optimal medical management with an IABP during high-risk angioplasty procedures.⁴⁸

CONCLUSION

Cardiogenic shock complicating acute MI remains a challenging entity. Questions that persist include safety of primary PCI in the elderly, the efficacy/safety of combination primary PCI and IABP, and if IABP provides the optimal left ventricular support. The SHOCK trial,²³ using a strategy of early revascularization, demonstrated the possibility of improved long-term outcomes, but the mortality in patients with cardiogenic shock remains unacceptably high, and there is evidence suggesting no temporal impact on rates of revascularization despite consensus guidelines.¹³ Stricter adherence to ACC/AHA guidelines and development of devices that improve coronary hemodynamics could provide further improvement in the treatment of patients with acute MI complicated by cardiogenic shock. ■

Amar R. Chadaga, MD, is from the Internal Medicine Division at Evanston Hospital in Evanston, Illinois. He has disclosed that he holds no financial interest in any product or manufacturer mentioned herein. Dr. Chadaga may be reached at (847) 570-2000; achadaga@enh.org

Timothy A. Sanborn, MD, is from the Cardiology Division at Evanston Hospital in Evanston, Illinois. He has disclosed that he holds no financial interest in any product or manufacturer mentioned herein. Dr. Sanborn may be reached at (847) 570-2250; tsanborn@enh.org

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