

## Acute Myocardial Ischemia/Infarction

## Contemporary Utilization and Outcomes of Intra-Aortic Balloon Counterpulsation in Acute Myocardial Infarction

## The Benchmark Registry

Gregg W. Stone, MD, FACC,\* E. Magnus Ohman, MD, FACC,† Michael F. Miller, PhD,‡ Debra L. Joseph, BSN,§ Jan T. Christenson, MD, FECTS,|| Marc Cohen, MD, FACC,¶ Philip M. Urban, MD, FACC,# Ramachandra C. Reddy, MD, FACC,\*\* Robert J. Freedman, MD, FACC,†† Karen L. Staman, MS,‡‡ James J. Ferguson III, MD, FACC§§

*New York and Brooklyn, New York; Chapel Hill and Durham, North Carolina; Langhorne and Philadelphia, Pennsylvania; Fairfield, New Jersey; Geneva, Switzerland; Alexandria, Louisiana; and Houston, Texas*

- OBJECTIVES** We sought to examine contemporary utilization patterns and clinical outcomes in patients with acute myocardial infarction (AMI) requiring intra-aortic balloon pump (IABP) counterpulsation.
- BACKGROUND** Despite increasing experience with and broadened indications for intra-aortic counterpulsation, the current indications, associated complications, and clinical outcomes of IABP use in AMI are unknown.
- METHODS** Between June 1996 and August 2001, data were prospectively collected from 22,663 consecutive patients treated with aortic counterpulsation at 250 medical centers worldwide; 5,495 of these patients had AMI.
- RESULTS** Placement of an IABP in AMI patients was most frequently indicated for cardiogenic shock (27.3%), hemodynamic support during catheterization and/or angioplasty (27.2%) or prior to high-risk surgery (11.2%), mechanical complications of AMI (11.7%), and refractory post-myocardial infarction unstable angina (10.0%). Balloon insertions were successful in 97.7% of patients. Diagnostic catheterization was performed in 96% of patients, and 83% underwent coronary revascularization before hospital discharge. The in-hospital mortality rate was 20.0% (38.7% in patients with shock) and varied markedly by indication and use of revascularization procedures. Major IABP complications occurred in only 2.7% of patients, despite median use for three days, and early IABP discontinuation was required in only 2.1% of patients.
- CONCLUSIONS** With contemporary advances in device technology, insertion technique, and operator experience, IABP counterpulsation may be successfully employed for a wide variety of conditions in the AMI setting, providing significant hemodynamic support with rare major complications in a high-risk patient population. (J Am Coll Cardiol 2003;41:1940-5)  
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Following its introduction, intra-aortic balloon pump (IABP) counterpulsation was principally applied to stabilize medical and surgical patients with hemodynamic collapse and to increase myocardial oxygen supply as a last resort in

patients with incipient cardiac arrest (1,2). Although the IABP is still widely used in patients with cardiogenic shock, accumulating clinical experience and trial data have resulted in significant expansion of the indications for aortic counterpulsation in patients with acute myocardial infarction (AMI) (3). Evidence may be cited supporting the use of the IABP in AMI patients with ventricular septal rupture and acute mitral insufficiency (4,5), post-infarct angina (6), recalcitrant ventricular arrhythmias (7), and progressive

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heart failure despite medical therapy (8). In patients with AMI, the IABP may improve cardiac performance and hemodynamic measures while the ischemic myocardium recovers (9), decrease the incidence of recurrent ischemia (10,11) and infarct-related artery reocclusion after reperfu-

From the \*Cardiovascular Research Foundation and Lenox Hill Hospital, New York, New York; †University of North Carolina, Chapel Hill, North Carolina; ‡M. F. Miller Statistical Services, Langhorne, Pennsylvania; §Datascope Corp., Fairfield, New Jersey; ||University of Geneva Hospital, Geneva, Switzerland; ¶Hahnemann University Hospital, Philadelphia, Pennsylvania; #Hôpital de la Tour, Geneva, Switzerland; \*\*State University of New York Health Science Center, Brooklyn, New York; ††St. Francis Cabrini Medical Center, Alexandria, Louisiana; ‡‡Duke Clinical Research Institute, Durham, North Carolina; and §§Texas Heart Institute, Houston, Texas. The Benchmark Counterpulsation Outcomes Registry was partly supported by Datascope Corp. Ms. Joseph is an employee of Datascope, a manufacturer of intra-aortic balloon pumps and the sponsor of the Benchmark Registry. Dr. Miller is a statistical consultant to Datascope. Several authors (Drs. Stone, Ohman, Christenson, Cohen, Urban, Reddy, Freedman, and Ferguson) have received small consultation fees in relation to the registry.

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#### Abbreviations and Acronyms

AMI	= acute myocardial infarction
CABG	= coronary artery bypass grafting
IABP	= intra-aortic balloon pump
LMCA	= left main coronary artery
SHOCK	= SHould we emergently revascularize Occluded Coronaries for cardiogenic shock?

sion therapy (12,13), improve survival when used in conjunction with thrombolytic therapy compared with thrombolytic therapy alone (14,15), and enhance rescue angioplasty for failed thrombolysis (16).

Despite the increasing experience with and broadened indications for aortic counterpulsation, the current utilization patterns, associated complications, and clinical outcomes of patients with AMI in whom an IABP is required are unknown. As previously reported, the Benchmark Counterpulsation Outcomes Registry was developed to examine the patient profiles, device indications, hemodynamic measures, clinical outcomes, and complications associated with IABP in a broad cross section of patients (17). The present report summarizes contemporary usage patterns and outcomes in patients with AMI requiring IABP counterpulsation from this large global registry.

## METHODS

The details of the ongoing Benchmark Counterpulsation Outcomes Registry, the participating sites, study organization, and methodology for data collection and analysis have previously been described (17). In brief, the Benchmark Registry collects detailed clinical and device level data in consecutive patients receiving an IABP on an institutional level and affords individual hospitals the ability to compare and contrast outcomes and usage patterns to the database as a whole. The current analysis includes all consecutive patients with AMI in participating institutions in whom an IABP was placed between June 1996 (or the time of institution initiation into the registry) and August 2001. Concomitant medications and adjunctive procedures were left to the discretion of the treating physician.

**End points, definitions, and statistical methods.** The four principal clinical end points were ischemia, bleeding, IABP failure, and in-hospital mortality. Major limb ischemia was defined as a loss of pulse or sensation, or abnormal limb temperature or pallor requiring surgical intervention. Minor ischemia involved decreased arterial flow, as manifested by a diminished pulse that resolved with balloon removal, not otherwise resulting in impairment of organ function. Severe bleeding was defined as requirement of blood transfusion or surgical intervention, or association with hemodynamic compromise. Minor hematoma and oozing from a puncture site not requiring blood transfusion or surgical intervention was defined as nonsevere bleeding. Failure of the IABP was defined as poor augmentation,

inability to deploy, or any IABP leak suggested by blood inside the catheter tubing, gas loss, or catheter alarm. All-cause hospital mortality was recorded as mortality occurring from any cause during IABP use or after IABP removal. Mortality directly related to IABP was also tabulated. A major IABP-related complication was defined as major limb ischemia, severe bleeding, IABP leak, or mortality directly attributed to IABP. Components of the clinical diagnosis of AMI, as well as infarct location, were not prespecified but defined on-site using standard, local definitions. Cardiogenic shock, however, was prospectively defined as systolic blood pressure  $\leq 90$  mm Hg for  $\geq 1$  h (or necessitating intravenous pressors of IABP for support), associated with signs of systemic hypoperfusion (cool, clammy skin, urine output  $< 30$  ml/h, or decreased level of consciousness) or a cardiac index  $< 2.0$  l/min/m<sup>2</sup>, secondary to cardiac dysfunction and not responsive to volume replacement alone.

Descriptive summaries included frequency and percent distributions for the categorical variables, and the sample mean value  $\pm$  SD for continuous variables. The paired *t* test was used to compare the effect of IABP placement on hemodynamic measures. Stepwise logistic regression was performed to determine the independent correlates of in-hospital mortality, considering age, gender, diabetes mellitus, previous MI, previous coronary artery bypass graft surgery (CABG), peripheral vascular disease, left main coronary artery (LMCA) involvement, cardiogenic shock, and performance of percutaneous or surgical revascularization in the model. All variables that were significant by univariate analysis (likelihood ratio chi-square test), with a *p* value  $< 0.10$ , were included in the multivariate model. All analyses were performed using SAS statistical software, version 8 (SAS Institute, Cary, North Carolina). The registry was validated by three audits (two independent and one internal), which demonstrated a high degree of accuracy ( $> 95\%$  accuracy for check-box items and  $> 90\%$  accuracy for dates). The largest external audit was performed by StatTrade Inc. (Morrisville, Pennsylvania), and involved 485 records (20.7%) entered in 1999.

## RESULTS

**Clinical features and indications.** Between June 1996 and August 2001, 22,663 patients received an IABP at 250 centers (185 U.S. centers and 65 centers outside the U.S.); AMI was the principal diagnosis in 5,495 (24%). The mean age of the AMI population was  $65.0 \pm 12.3$  years (range 20 to 100 years); 34% were women. Twenty-six percent of patients had diabetes mellitus, 25% had previous MI, 8% had previous CABG, and 9% had peripheral vascular disease. Of patients undergoing cardiac catheterization, 59% had triple-vessel disease and 16% had LMCA involvement. The mean ejection fraction was  $36.5 \pm 14.3\%$ . As seen in Table 1, approximately one-half of the patients with AMI required an IABP for cardiogenic shock or hemodynamic

**Table 1.** Principal Indications for Intra-Aortic Balloon Pump Use in 5,495 Patients With AMI

Cardiogenic shock	27.3%
Support for high-risk catheterization and angioplasty	27.2%
Mechanical complications of AMI (VSD and PMR)	11.7%
Pre-operative support for high-risk cardiac surgery	11.2%
Refractory post-MI unstable angina	10.0%
Weaning from cardiopulmonary bypass	4.8%
Refractory left ventricular failure	4.5%
Refractory ventricular arrhythmias	1.3%
Intra-operative support during surgery	0.5%
Other or indication not recorded	1.5%

AMI = acute myocardial infarction; MI = myocardial infarction; PMR = papillary muscle rupture; VSD = ventricular septal defect.

support during or after cardiac catheterization or percutaneous intervention, whereas a variety of alternative reasons were present in the other half of patients.

**Performance and complications of IABP.** The IABP was inserted percutaneously in 98% of patients and by femoral artery cutdown in 2%. A 9.5F system was utilized in 65% of patients and an 8F system in 35%. A sheath was employed in 80% of patients, whereas in 20%, insertion was sheathless. Of the balloon insertions, 2.3% were unsuccessful due to a balloon leak, poor balloon inflation, poor augmentation or difficulties associated with balloon insertion. As shown in Table 2, IABP placement resulted in significant reductions in systolic and diastolic arterial pressures, with no impact on heart rate. The mean duration of IABP in the overall registry cohort was  $3.2 \pm 2.2$  days (median 3 days, range 1 to 42 days).

One or more complications of IABP therapy occurred in 8.1% of patients (Table 3), although major complications (severe limb ischemia, severe bleeding, balloon leak, or death directly due to IABP insertion or failure) occurred in only 2.7% of cases. Considering the five most common indications for aortic counterpulsation, the occurrence of major IABP-related complications did not significantly vary (cardiogenic shock in 2.9%, support for high-risk catheterization and angioplasty in 2.7%, surgery in 2.6%, mechanical complications of AMI in 2.2%, and refractory unstable angina in 3.1%;  $p = 0.57$ ). Death was directly attributed to the IABP in only three patients (0.05%).

**Angiography and revascularization procedures.** Angiography was performed in 5,348 patients (97.3%) during the index hospitalization, and 4,476 patients (81.5%) underwent coronary revascularization procedures, split approxi-

**Table 2.** Effect of IABP Placement on Hemodynamic Measures

	Pre-IABP	Post-IABP	p Value
Systolic blood pressure (mm Hg)	109 ± 28	108 ± 25	<0.001
Diastolic blood pressure (mm Hg)	65 ± 17	62 ± 17	<0.001
Augmented diastolic blood pressure (mm Hg)	—	122 ± 29	—
Mean arterial pressure (mm Hg)	82 ± 21	87 ± 21	<0.001
Heart rate (beats/min)	89 ± 24	90 ± 23	0.59

Data are presented as the mean value ± SD.  
IABP = intra-aortic balloon pump.

**Table 3.** Failure and Complications of the IABP (n = 5,495)

Complications	
Any access-site bleeding	4.3%
Severe access-site bleeding	1.4%
Any limb ischemia	2.3%
Major limb ischemia	0.5%
Amputation	0.1%
Transfusion	1.4%
Vascular surgery	0.7%
Infection	0.1%
Deep venous thrombosis	0.1%
Superficial vein thrombosis	0.1%
Stroke	0.1%
Bowel, renal, or spinal cord infarction	0.1%
IABP-related mortality	0.05%
IABP failure	
Any	2.3%
IABP leak	0.8%
Poor inflation	0.6%
Difficult insertion	0.1%
Poor augmentation	1.1%
Premature IABP removal	2.1%
IABP replaced	0.5%

IABP = intra-aortic balloon pump.

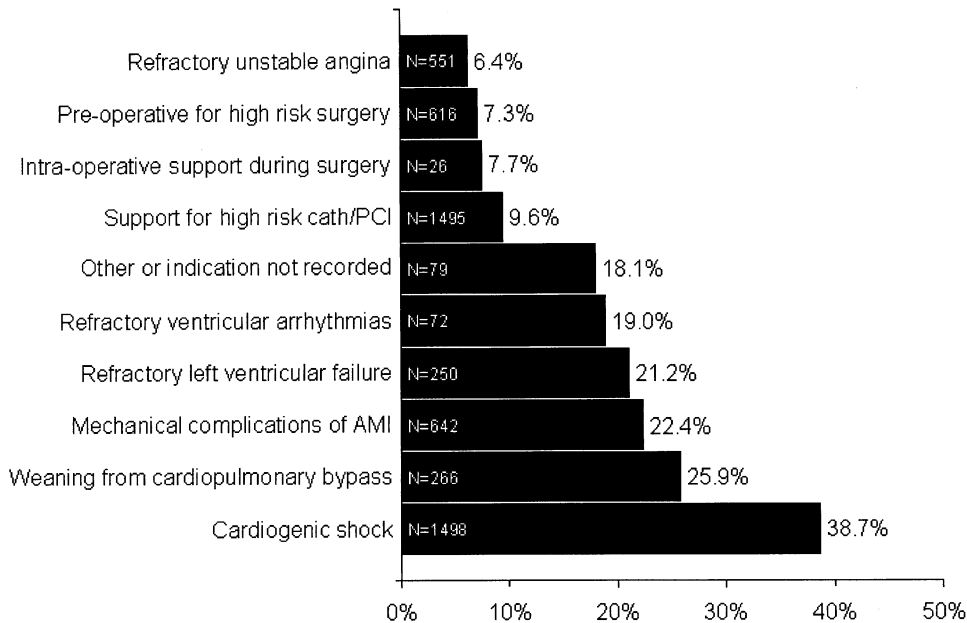
mately equally between percutaneous intervention (41.5%) and CABG (40.0%). An additional 192 patients (3.5%) underwent additional surgical procedures without revascularization. A detailed list of the percutaneous and surgical procedures performed in patients with AMI receiving an IABP appears in Table 4. The rates of major IABP-related complications were similar among patients undergoing angioplasty (2.8%), surgery (2.6%), or conservative management with or without angiography (2.7%).

**In-hospital mortality.** The mean duration of hospitalization was  $11.5 \pm 9.9$  days (range 1 to 96 days). In-hospital death occurred in 1,098 (20%) of 5,495 patients with AMI in whom an IABP was placed; 581 (53%) of the 1,098 deaths occurred with the IABP in situ, whereas the remainder occurred after the device had been removed. As seen in Figure 1, in-hospital mortality ranged from 6.4% in patients

**Table 4.** Percutaneous and Surgical Procedures in Patients With Acute Myocardial Infarction Receiving an Intra-Aortic Balloon Pump\*

Percutaneous (n = 2,282)	
Balloon angioplasty	100%
Stent	79.5%
Atherectomy	2.3%
Laser	0.1%
Other	3.3%
Surgical (n = 2,388)	
Bypass graft surgery	92.0%
Minimally invasive bypass grafting	0.9%
Mitral valve repair or replacement	9.1%
Aortic valve replacement	2.0%
Ventricular assist device	1.5%
Ventricular septal defect repair	0.5%
Orthotopic cardiac transplantation	0.4%
Transmyocardial revascularization	0.3%
Other	3.1%

\*More than one procedure per patient may have been performed.



**Figure 1.** In-hospital mortality of 5,495 patients with acute myocardial infarction (AMI) requiring intra-aortic balloon pump counterpulsation, stratified by principal usage indication. PCI = percutaneous coronary intervention.

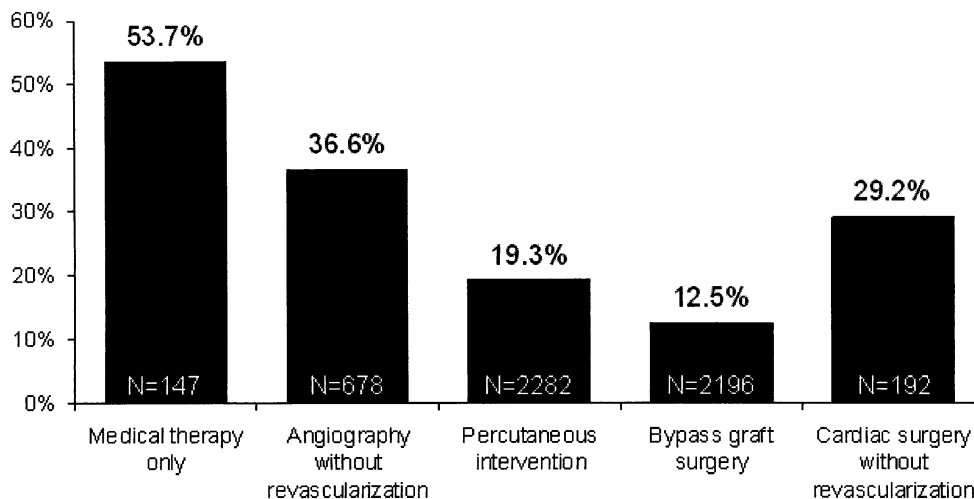
in whom the IABP was placed for refractory unstable angina to 38.7% in patients requiring aortic counterpulsation for cardiogenic shock. In-hospital mortality in patients with an IABP also varied considerably, based on the use of revascularization procedures, ranging from 12.5% in patients undergoing CABG to 53.7% in those managed conservatively (Fig. 2). Independent predictors of mortality in patients with AMI requiring IABP placement are shown in Table 5.

**DISCUSSION**

The principal findings of this study are: 1) IABP counterpulsation is used in patients with AMI for a variety of purposes that extend beyond traditional indications; 2)

severe IABP-related complications are infrequent in patients with AMI, even in those in cardiogenic shock; and 3) in-hospital mortality rates in this high-risk population vary considerably, based on IABP indication and use of revascularization procedures.

**Indications for IABP use in AMI.** According to the 1999 Task Force on Practice Guidelines of the American Heart Association and American College of Cardiology (18), class I indications for IABP use in AMI include: 1) cardiogenic shock as a stabilizing measure for angiography and prompt revascularization; 2) acute mitral regurgitation or ventricular septal defect complicating AMI as stabilizing therapy for angiography and repair/revascularization; 3) recurrent, intractable ventricular arrhythmias with hemodynamic insta-



**Figure 2.** In-hospital mortality stratified by the performance of angiography and percutaneous or surgical coronary revascularization.

**Table 5.** Independent Correlates of In-Hospital Mortality by Logistic Regression Analysis

	Multivariate Odds Ratio (95% CI)	p Value
Cardiogenic shock	3.95 (3.41-4.58)	<0.0001
Age >75 yrs	2.36 (2.02-2.77)	<0.0001
Previous myocardial infarction	1.52 (1.29-1.79)	<0.0001
Female gender	1.47 (1.26-1.71)	<0.0001
Previous bypass surgery	1.42 (1.12-1.81)	0.004
Peripheral vascular disease	1.29 (1.03-1.63)	0.03
Diabetes mellitus	1.18 (1.00-1.39)	0.0497
Performance of percutaneous or surgical revascularization	0.38 (0.33-0.45)	<0.0001

CI = confidence interval.

bility; and 4) refractory post-myocardial infarction angina as a bridge to angiography and revascularization. In the present series, these four categories comprised only ~50% of the indications for IABP use in patients with AMI. Significant numbers of patients also received an IABP prophylactically before angiography, percutaneous intervention, or surgical revascularization, prompted by the frequent presence in this population of prognostically adverse features such as depressed left ventricular function and significant LMCA or triple-vessel disease. Although the utility of IABP counterpulsation has not been established in these settings by randomized clinical trials, the data from this large series provide insight into contemporary usage patterns of IABP counterpulsation and associated outcomes for these clinical situations.

**Performance and complications of IABP counterpulsation.** Placement of an IABP resulted in notable augmentation of diastolic blood pressure and a significant though small reduction in systolic blood pressure, with no change in heart rate. These findings suggest that the major hemodynamic and clinical benefits of IABP counterpulsation will be realized in patients with systemic hypotension, with relatively little reduction in afterload or myocardial oxygen demand. A limitation of this study, however, is that right heart catheterization was not routinely performed before and after IABP insertion (and the data were not recorded), thus potentially masking any possible benefit of preload reduction lowering the pulmonary capillary wedge pressure.

A unique finding of this study is in regard to the analysis of successful IABP placement: in only 2.2% of patients could IABP counterpulsation not be established due to balloon leak, poor inflation, poor augmentation, or insertion difficulty. Moreover, despite earlier reports documenting high rates of adverse events secondary to IABP usage (3,19-21), major IABP-related complications in patients with AMI in this large, contemporary series were relatively infrequent (2.7%). As a result, only 2.1% of patients required premature discontinuation of the device. These findings represent real-world documentation that advances such as percutaneous insertion, smaller catheter diameter, and appropriate use of adjunctive pharmacology have considerably reduced the incidence of serious vascular compli-

cations (19-27). Thus, it is reassuring that the hemodynamic benefits of IABP may be realized in this high-risk patient cohort with relatively low risk.

**Use of revascularization procedures and mortality.** The in-hospital mortality of patients with AMI requiring an IABP varied greatly with the principal usage indication and performance of coronary revascularization. The value of an early revascularization strategy after IABP placement in patients with cardiogenic shock has recently been clearly demonstrated (28,29) and appears to currently be the predominant intent at most centers, as angiography was performed in more than 97% of AMI patients in the Benchmark Registry (with revascularization in nearly 82%). The mortality of patients with AMI requiring IABP support was greatest in those in whom angiography and revascularization were not performed, consistent with previous small, randomized trials that found no survival benefit of IABP counterpulsation in patients with AMI managed conservatively (30,31). Indeed, in the present series, the performance of coronary revascularization was a powerful independent predictor of survival by multivariate analysis. Moreover, the 38.7% rate of in-hospital mortality in the 1,498 patients with cardiogenic shock in the current report is similar to the 46.7% 30-day mortality rate in 152 patients assigned to the invasive arm of the SHould we emergently revascularize Occluded Coronaries for cardiogenic shock? (SHOCK) trial (28). In both studies, >80% of patients were revascularized. Finally, given its size and broad geographic representation, the current registry may be used to "benchmark" in-hospital mortality rates of patients with AMI requiring IABP counterpulsation for conditions other than shock. Indeed, comparative outcomes data are regularly given to the individual sites participating in the Benchmark Registry to facilitate quality-control implementation.

**Study limitations.** The present study is a large-scale, voluntary prospective registry and, as such, has the limitations inherent in all registries, including selection (reporting) bias for patient recruitment and a lack of documentation of all relevant variables related to outcome. Site-to-site variations in personnel and resources allocated to the registry cannot be excluded, nor can regional, local, and individual differences in patients and practice patterns. To the extent possible, some of these concerns may be alleviated by the prospective nature of the registry, the results of the validation audits demonstrating high accuracy and compliance, and the use of multivariate analysis to correct for differences in patient characteristics. The Benchmark Counterpulsation Outcomes Registry, representing the largest contemporary experience with IABP usage, therefore, should be viewed as complementary to well-designed, randomized, controlled clinical trials. However, no adequately powered, controlled trial has ever been performed to demonstrate whether IABP counterpulsation does indeed improve clinical outcomes and/or reduce mortality in patients with AMI and shock undergoing reperfusion therapy

or in a subset of such patients. As the entry criteria for the Benchmark Registry required IABP usage, data from this study cannot be used to support such a conclusion. Frequency and outcomes data are also not available for patients in whom IABP usage might have been beneficial, but in whom placement of the device was contraindicated because of peripheral vascular disease, aortic insufficiency, or other adverse conditions. Finally, as right heart catheterization data were not routinely collected in this study, no statements can be made regarding the efficacy of IABP to reduce preload and afterload in the AMI setting, either in patients with or without cardiogenic shock.

**Reprint requests and correspondence:** Dr. Gregg W. Stone, Cardiovascular Research Foundation, 55 East 59th Street, 6th Floor, New York, New York 10022. E-mail: gstone@crf.org.

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