Safety and Cost-Effectiveness of Early Discharge After Primary Angioplasty in Low Risk Patients With Acute Myocardial Infarction

CINDY L. GRINES, MD, FACC, DOMINIC L. MARSALESE, MD, FACC, BRUCE BRODIE, MD, FACC,*
JOHN GRIFFIN, MD, FACC,† BRYAN DONOHUE, MD, FACC,‡
COSTANTINO R. COSTANTINI, MD, FACC,§ CARLOS BALESTRINI, MD,∥
GREGG STONE, MD, FACC,¶ THOMAS WHARTON, MD, FACC,# PAOLO ESENTE, MD, FACC,**
MICHAEL SPAIN, MD, FACC,†† JEFFREY MOSES, MD, FACC,‡‡
MASAKIYO NOBUYOSHI, MD, FACC,§§ MIKE AYRES, MD,∥∥ DENISE JONES, RN, BSN,
DENISE MASON, RN, BSN, DEBRA SACHS, MS, LORELEI L. GRINES, PhD,
WILLIAM O'NEILL, MD, FACC, FOR THE PAMI-II INVESTIGATORS¶¶

Objectives. The second Primary Angioplasty in Myocardial Infarction (PAMI-II) study evaluated the hypothesis that primary percutaneous transluminal coronary angioplasty (PTCA), with subsequent discharge from the hospital 3 days later, is safe and cost-effective in low risk patients.

Background. In low risk patients with myocardial infarction (MI), few data exist regarding the need for intensive care and noninvasive testing or the appropriate length of hospital stay.

Methods. Patients with acute MI underwent emergency catheterization with primary PTCA when appropriate. Low risk patients (age ≤70 years, left ventricular ejection fraction >45%, one- or two-vessel disease, successful PTCA, no persistent arrhythmias) were randomized to receive accelerated care (admission to a nonintensive care unit and day 3 hospital discharge without noninvasive testing [n = 237] or traditional care [n = 234]).

Results. Patients who received accelerated care had similar in-hospital outcomes but were discharged 3 days earlier (4.2 ± 2.3 vs. 7.1 ± 4.7 days, p = 0.0001) and had lower hospital costs ($9,658 ± 5,287 vs. $11,604 ± 6,125 p = 0.002) than the patients who received traditional care. At 6 months, accelerated and traditional care groups had a similar rate of mortality (0.8% vs. 0.4%, p = 1.00), unstable ischemia (10.1% vs. 12.0%, p = 0.52), reinfarction (0.8% vs. 0.4%, p = 1.00), stroke (0.4% vs. 2.6%, p = 0.07), congestive heart failure (4.6% vs. 4.3%, p = 0.85) or their combined occurrence (15.2% vs. 17.5%, p = 0.49). The study was designed to detect a 10% difference in event rates; at 6 months, only a 2.3% difference was measured between groups, indicating an actual power of 0.19.

Conclusions. Early identification of low risk patients with MI allowed safe omission of the intensive care phase and noninvasive testing, and a day 3 hospital discharge strategy, resulting in substantial cost savings.

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Serious complications, including death, usually occur within 48 h of myocardial infarction (MI) (1–6), well before noninvasive testing is performed. Numerous studies have described methods of determining clinical risk, (1–3,6–11); however, none have prospectively tested this information in the early management of patients with MI. Moreover, national guidelines recommend that patients with MI undergo extensive observation, monitoring and noninvasive testing (12), and 70% receive catheterization (13,14). Although angiographic criteria, including Thrombolysis in Myocardial Infarction (TIMI) flow grades (15), multivessel disease and left ventricular ejection fraction (LVEF), are of prognostic importance (16–22), cath-

Abbreviations and Acronyms

CHF	=	congestive heart failure
CK-MB	=	creatine kinase, MB fraction
ECG	=	electrocardiogram, electrocardiographic
LVEF	=	left ventricular ejection fraction
MI	=	myocardial infarction
PAMI-II	=	second Primary Angioplasty in Myocardial Infarction study
PTCA	=	percutaneous transluminal coronary angioplasty
TIMI	=	Thrombolysis in Myocardial Infarction

eterization is often performed just before hospital discharge. Delayed catheterization data cannot be used to discharge patients early, and the potential benefits are greatly diminished because most deaths will have occurred before hospital discharge (4,23,24).

The purpose of the second Primary Angioplasty in Myocardial Infarction (PAMI-II) study was to determine whether clinical and catheterization data could be used to prospectively identify low risk patients with MI who could safely go without intensive care and noninvasive testing and be discharged from the hospital on day 3.

Methods

Clinical centers. This study was conducted in 34 clinical centers in five countries. The study sites were diverse and included urban and rural settings and teaching and nonteaching hospitals. Two participating centers performed emergency percutaneous transluminal coronary angioplasty (PTCA) procedures but had no elective PTCA or coronary artery bypass graft surgery programs. Physicians and catheterization laboratory staff were available on a 24-h basis.

Study group. Patient selection required symptom onset <12 h in duration and evidence of MI as reflected by electrocardiographic (ECG) ST segment elevation in at least two contiguous leads; the presence of left bundle branch block or a nondiagnostic ECG; or angiographic evidence of MI that was determined by the presence of an occluded vessel and regional ventricular dysfunction. Patients were not enrolled if they had cardiogenic shock or clinical indications for intraaortic balloon pumping in the emergency room; if there was a lack of peripheral vascular access; or if there was a bleeding risk prohibiting the use of aspirin and heparin. The study was approved by each center's institutional review board, and all patients gave written, informed consent.

Catheterization and PTCA procedure. Patients were treated with chewable aspirin (325 mg), a 10,000-U bolus of heparin, intravenous nitroglycerin and, in the absence of contraindications, intravenous beta-adrenergic blocking agents. Emergency catheterization was performed using ionic contrast agents to avoid thrombolytic complications (25). It was suggested that PTCA not be performed if the patient was unlikely to benefit (i.e., infarct-related vessels with ≤70% stenosis or those supplying a very small amount of myocardium); these patients were treated medically. Bypass surgery was recommended for patients with unprotected left main coronary artery stenoses >60% or severe three-vessel disease with spontaneous reperfusion of the infarct-related vessel. PTCA was recommended for all others. Additional heparin was given to achieve an activated clotting time between 350 and 400 s (26,27), which was maintained throughout the procedure. A visual estimation of LVEF by contrast ventriculography was used for acute risk stratification.

Acute risk stratification and randomization. Based on clinical and angiographic features after PTCA, the operator stratified patients into low and high risk groups. Low risk status required that all the following criteria be met: age ≤70 years, no persistent arrhythmias after reperfusion (requiring lidocaine infusion or pacemaker), one- or two-vessel disease (≥70% stenosis), LVEF >45% and successful PTCA of a native coronary artery. Patients identified as low risk were randomized to receive accelerated care versus traditional care. Accelerated care consisted of 1) admission to a nonintensive care unit that was typically used for patients who would have elective PTCA, and 2) full-dose heparin for 48 h, followed by half-dose heparin for an additional 12 h to avoid a rebound hypercoagulable state (27,28). Noninvasive testing was not recommended, and the patients were to be discharged on day 3 in the absence of clinical contraindications, such as arrhythmia, hypotension, chest pain, congestive heart failure (CHF), stroke, renal insufficiency, sepsis or other conditions requiring in-hospital treatment. Traditional care consisted of admission to a coronary care unit, noninvasive testing that was routine for the enrolling institution, intravenous heparin for 72 h and a hospital stay of at least 5 days.

Patients who did not meet low risk criteria were considered high risk and were randomized to receive or not receive prophylactic intraaortic balloon counterpulsation. The results in this group have been previously reported (29).

End points and definitions. The primary end point was the combined occurrence of death, reinfarction, unstable ischemia, stroke or CHF by 6 months. These events were selected because they are thought to be "unsatisfactory outcomes" after reperfusion therapy (30). The null hypothesis of this study was one of no difference between accelerated and traditional care groups regarding the primary end point (expected event rate of 15%). To detect an absolute difference of 10% with an alpha level of 0.05 and a power of 0.8, a minimum of 400 patients were required for a two-tailed test.

Angioplasty success was defined as <50% stenosis and TIMI flow grade 2 or 3; *reocclusion* as a previously patent (TIMI flow grade 2 or 3) infarct-related vessel that demonstrated TIMI flow grade 0 or 1 with ≥90% stenosis; *CHF* as Killip class II to IV (31); *reinfarction* as recurrent clinical symptoms in association with an increase in creatine kinase, MB fraction (CK-MB) above its previous nadir; and *recurrent unstable ischemia* as clinical symptoms associated with ECG changes, hypotension, new murmur, CK-MB elevation or the need for emergency revascularization.

Data collection. Data were collected prospectively by research nurses at each of the 34 clinical centers. Data were audited by an independent study coordinator who traveled to sites to randomly cross reference case report forms and medical records. Angiographic data were reported on the basis of the operator's visual assessment, because this interpretation was used for risk stratification, subsequent randomization and clinical decision making. Data were abstracted from hospital bills obtained from U.S. sites to determine in-patient charges, which were then converted to cost using each hospital's Medicare charge/cost ratio. Follow-up data from hospital, office records and telephone calls were submitted on standardized case report forms 1 and 6 months after enrollment. On-site clinical audits were performed in 49.6% of cases, and the remaining cases were audited by reviewing copies of hospital records. Discrepancies between the site and study auditor were adjudicated by two or three additional medical personnel who had no knowledge of the the randomization scheme.

Statistical analysis. Data were entered into a commercially available data base package (Microsoft Access), and statistical analyses were performed using conventional software (SAS). When comparing treatment groups, the chi-square or two-tailed Fisher exact test was used for categoric variables and the t test for continuous variables (Mann-Whitney U test for continuous variables with nonnormal distribution). Differences in event-free survival were determined using the Kaplan-Meier method.

Results

Overall study group. Between September 1993 and January 1995, 1,100 patients were enrolled and underwent catheterization at 34 clinical centers. Angiographic information was used to decide the appropriate therapy for each patient: Primary PTCA was performed in 982 patients (89%), bypass surgery alone in 53 (5%) and medical therapy alone in 65 (6%). PTCA was successful in 96.1% of attempts and resulted in TIMI flow grade 3 in 92.9% of vessels. Emergency bypass surgery for failed PTCA was required in 0.5% of patients. Overall, in-hospital mortality was 2.9% (2.8% for PTCA, 5.7% for bypass surgery and 1.5% for medical). Stroke was observed in 1.0%, reinfarction in 1.8%, recurrent ischemia in 10.3% and CHF in 8.5% of patients.

Risk stratification and randomization. Of the 1,100 patients recruited, 192 were not randomized (48 of whom were considered low risk but were treated medically) and 437 were randomized in the high risk strata (29). Four hundred seventy-one patients were stratified as low risk and randomized to receive accelerated care (n = 237) or traditional care (n = 234). Baseline clinical and angiographic characteristics were similar between the two groups (Table 1). Patients randomized to receive accelerated care had no increase in the incidence of in-hospital adverse events, death (0.4% vs. 0.4%, p = 1.00), reinfarction (0.4% vs. 0.4%, p = 1.00), unstable ischemia (5.9% vs. 8.1%, p = 0.35), stroke (0% vs. 1.7%, p = 0.06), CHF

Table 1. Clinical and Angiographic Characteristics in Low Risk Group With Myocardial Infarction

	Accelerated Care (n = 237)	Traditional Care (n = 234)	p Value
Age (yr)	55 ± 10	56 ± 10	0.21
Male	77.6%	75.2%	0.54
Previous MI	11.2%	10.4%	0.79
Hypertension	37.7%	37.6%	1.0
Diabetes, insulin-dependent	2.2%	3.9%	0.27
Thrombolytic eligible	75.7%	80.9%	0.18
Diseased vessels			
1	75.6%	74.8%	0.83
2	23.1%	23.1%	
3*	1.3%	2.1%	
Post-PTCA TIMI flow grade			
0–1*	0.4%	0.4%	0.54
2	1.3%	1.7%	
3	98.3%	97.8%	
Post-PTCA % stenosis	20 ± 13	20 ± 12	0.71

*Risk stratification deviations by physician. Data presented are mean value ± SD or percent of patients. MI = myocardial infarction; PTCA = percutaneous transluminal coronary angioplasty; TIMI = Thrombolysis In Myocardial Infarction.

(4.2% vs. 3.9%, p = 0.84) or the combined end point (10.1% vs. 12.8%, p = 0.36).

Of the 237 patients randomized to receive accelerated care, protocol-designated contraindications for early discharge were present in 59 (25%). These included death in 0.4%, transient ischemic attack in 0.4%, chest pain (either ischemic or nonischemic) in 7.7%, CHF in 1.7%, arrhythmia in 8.5%, bleeding in 3.0% and fever in 3.4%. Of the 178 patients eligible for early hospital discharge, 142 (80%) were discharged on day 3. Reluctance to discharge early was observed more frequently in foreign sites; within the United States, 137 (92%) of 149 eligible patients were discharged on day 3. Overall, patients randomized to receive accelerated care had a shorter length of hospital stay (4.2 ± 2.3 vs. 7.1 ± 4.7 days, p < 0.0001) and lower hospital cost ($9,658 ± $5,287 vs. $11,604 ± $6,125, p = 0.002) owing to reduced charges for room and board, pharmacy, laboratory and cardiac testing (Fig. 1).

Follow-up data at 6 months are available in 452 (96.0%) of 471 low risk patients. Readmission for recurrent unstable ischemia or MI occurred in 4.2% and 3.9% (p = 0.84) and target vessel revascularization was performed in 9.8% and 8.6% (p = 0.66) of accelerated and traditional care groups, respectively. By 6 months, the timing and frequency of death (0.8% vs. 0.4%, p = 1.00), reinfarction (0.8% vs. 0.4%, p = 1.00), unstable ischemia (10.1% vs. 12.0%, p = 0.52), stroke (0.4% vs. 2.6%, p = 0.07), CHF (4.6% vs. 4.3%, p = 0.85) or the combined occurrence of any event (15.2% vs. 17.5%, p = 0.49) were similar between accelerated and traditional care groups (Fig. 2).

A priori, sample size was calculated to detect a 10% difference in the primary end point between groups. However, our results indicate a 2.3% to 2.7% difference between accel-
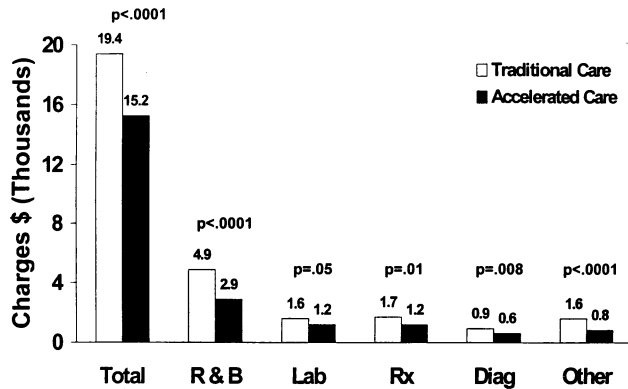
Figure 1. Hospital charges for low risk patients with MI. Low risk patients with MI randomized to receive accelerated care incurred reduced hospital charges for room and board (R & B), pharmacy (Rx), laboratory (Lab) and diagnostic testing (Diag). Estimated total cost (using each hospital's Medicare charge to cost ratio) favored the accelerated group by $1,946 ($9,658 ± $5,287 vs. $11,604 ± $6,125, p = 0.002) over the traditional care group.

Figure 2. Event-free survival for low risk patients with MI randomized to receive accelerated versus traditional care. No significant difference in the timing of events (death, recurrent MI, ischemia, stroke, heart failure) was found between accelerated (mean [±SE] 160.5 ± 3.8) and traditional care groups (mean [±SE] 177.4 ± 4.7) (p = 0.6). When mean event-free survival times for the two groups were compared using the log-rank test or the Wilcoxon test, neither was significant (p = 0.602 and 0.631, respectively). Neither test offers evidence that the two treatments differ with respect to time of event.

erated and traditional care groups. Thus, the actual power of the statistical test was 0.24 for in-hospital and 0.19 at 6 months (alpha 0.05).

Discussion

Primary PTCA has been shown to be a safe and effective method of providing reperfusion therapy for acute MI, and when compared with thrombolysis, it reduces the risk of recurrent ischemia (32–34), reinfarction, death and stroke (35,36). Thus, our focus in the PAMI-II trial was to determine whether acute catheterization data could be used to risk stratify patients after primary PTCA, and whether an accelerated hospital course was safe and cost effective in low risk patients.

Although there is increasing pressure to contain cost and discharge patients as soon as possible after MI, limited data exist regarding the safety of early hospital discharge. In a small, prospective study, 18% of post-thrombolysis patients were candidates for early discharge. These patients had reduced hospital expenses, returned to work earlier and had similar long-term outcomes compared with patients discharged at 7 to 10 days (37). However, this study required that all patients undergo exercise thallium imaging, and the majority also underwent catheterization. Mark et al. (18) retrospectively evaluated thrombolytic-treated patients who survived without early bypass surgery within the first 4 days of MI. In this cohort, LVEF >45% with the absence of multivessel disease, sustained arrhythmias or hypotension was predictive of freedom from late complications. This report first demonstrated the need for catheterization data to identify patients at risk for complications, and furthermore estimated that 30% of thrombolytic-treated patients were suitable for hospital discharge on day 4.

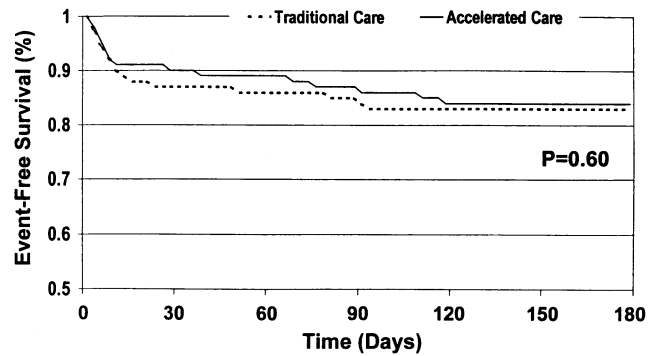A recent retrospective analysis concluded that patients who

have no clinical complications within the first few days after thrombolysis may be safely discharged (38). However, *in-hospital* events occurring after day 3 in those "uncomplicated" patients included death (0.9%), stroke (0.3%), reinfarction (2.4%) and recurrent ischemia (8.9%). Given these data and other reports (39,40) demonstrating that recurrent ischemia after thrombolysis occurs unpredictably, it is not surprising that the investigators opted to keep these uncomplicated patients in the hospital for an average of 9 days.

In contrast, randomized trials of primary PTCA versus thrombolysis have demonstrated that PTCA-treated patients have reduced rates of recurrent ischemia and shorter hospital stays (32–34,41). The ability of primary PTCA to achieve high rates of TIMI flow grade 3 (42), with a minimal residual stenosis (43–46), is likely to be responsible for the low event rates.

Our study confirmed that low risk patients treated with primary PTCA have excellent clinical outcomes. Given the low event rate, it was not surprising that elimination of the intensive care unit and noninvasive testing, with a day 3 hospital discharge strategy, did not adversely affect outcomes. This accelerated approach reduced hospital costs by $2,000. Given the fact that the cost of thrombolytic therapy and primary PTCA (followed by traditional care) is similar (33,47–49; Mark DB, Cost effectiveness of thrombolysis vs. angioplasty: GUSTO-IIB angioplasty substudy [presented at the 45th Annual Scientific Session of the American College of Cardiology, Orlando, Florida, March 1996]), this accelerated care approach may reduce the cost of health care by $293 million annually (assuming that 250,000 patients with MI in the United States are thrombolytic eligible, that an additional 30% of patients in this study were thrombolytic ineligible and that 45% would qualify as low risk). However, these savings may be overestimated, given the recent national trend toward a reduction in length of hospital stay.

Study limitations. One limitation of this study is the lack of power to detect small differences in the primary end point. Only large differences (10%) in event rates could be detected with the number of patients enrolled in each group. However, declining hospital reimbursement has driven earlier discharge of patients with MI, in the absence of much data. This study was conducted with a sample size of 471 patients, which is nearly six times larger than the groups in other published trials (37), thus providing support for the concept of early hospital discharge.

Clinical implications. After primary PTCA, clinical information combined with early catheterization data allows for identification of low risk patients with MI who can safely forego intensive care and noninvasive testing, the majority of whom can be discharged on day 3. Wide application of this management strategy may result in substantial cost savings.

Appendix

The Second Primary Angioplasty in Myocardial Infarction (PAMI-II) Study Group

Clinical centers. *William Beaumont Hospital, Royal Oak, Michigan*: Cindy L. Grines, MD, *Principal Investigator*, William W. O'Neill, MD, Dominic L. Marsalese, MD, Marc Brodsky, MD, H. Friedman, MD, V. Gangadharan, MD, L. Goldman, MD, R. Levin, MD, G. Pavlides, MD, R. Ramos, MD, V. Savas, MD, R. Safian, MD, T. Schreiber, MD, S. Ajluni, MD, S. Almany, MD, J. Boatman, MD, Denise Jones, RN, BSN, Denise Mason, RN, BSN; *Moses H. Cone Hospital, Greensboro, North Carolina*: Bruce R. Brodie, MD, Thomas D. Stuckay, MD, Richard A. Weintraub, MD, Tracie Gregory, RN; *Virginia Beach General Hospital, Virginia Beach, Virginia*: John J. Griffin, MD, Denise R. Bondy, BA, RN; *Allegheny General Hospital, Pittsburgh, Pennsylvania*: Bryan C. Donohue, MD, David M. Lasorda, DO, Richard Begg, MD, Susan Petuolo, RN; *Hospital Santa Case de Misericordia, Curtiba, Brazil*: Costantino Costantini, MD, Eny Goeder, RN; *Instituto Modelo de Cardiologia, Cordoba, Argentina*: Carlos Balestrini, MD, Cesar Serra, MD, Jose Sala, MD; *El Camino Hospital, Mountain View, California*: Gregg Stone, MD; *Stanford University Hospital, Stanford, California*: Stephen Osterlie, MD, Cheryl McWard, RN; *Exeter and Portsmouth Regional Hospitals, Exeter and Portsmouth, New Hampshire*: Thomas P. Wharton, Jr., MD, James M. Schmitz, MD, Frank A. Fedele, MD, Nancy McNamara, RN; *St. Joseph's Hospital and Health Center, Syracuse, New York*: Paolo Esente, MD, Susan Wagner, RN; *St. Francis Hospital, Tulsa, Oklahoma*: Michael G. Spain, MD, Victoria Wagner, RN; *Lenox Hill Hospital, New York, New York*: Jeffrey Moses, MD, Nancy Cohen, RN; *Kokura Memorial Hospital, Kitakyushu, Japan*: Masakiyo Nobuyoshi, MD, Yoshihisa Nakagawa, MD; *Fort Sanders Regional Medical Center, Knoxville, Tennessee*: Mike Ayers, MD, Dan Slutzker, MD, Jane Souther, MD, Vicky Rhule, RN; *Mid-America Heart Institute, Kansas City, Missouri*: Thomas Shimshak, MD, Geoffry Hartzler, MD, Patty Eikenberry, LPN, Cheryl Dreiling, RN; *St. Vincent Hospital, Indianapolis, Indiana*: Donald Rothbaum, MD, Susan Gowen, RN; *United Hospital/Grand Forks Clinic, Grand Forks, North Dakota*: Noah Chelliah, MD, Carolyn Gray, RN; *Hospital General "Gregorio Maranon," Madrid, Spain*: Juan Luis Delcan, MD, Jore Lopez Sandor, MD, Eulogio Garcia, MD; *Lakeland Regional Medical Center, Lakeland, Florida*; Kevin F. Browne, MD, Ronald Vliestra, MD, Mary Telatnik, RN; *Methodist Hospital, Lubbock, Texas*: Paul Overlie, MD, Karen Davis, RN; *St. Patrick Hospital, Missoula, Montana*: W. Stan Wilson, MD, Katie Mackey, RN; *St. Joseph Medical Center/Elkhart General Hospital, South Bend, Indiana*: Donald Westerhausen, Jr., MD, Dawn Edwards, MS, RN; *Guthrie Healthcare System, Sayre, Pennsylvania*: Marcis T. Sodums, MD, Victoria Schiefen, RN, Kamie Hoey, RN; *Providence Hospital, Portland, Oregon*: Bradley H. Evans, MD, Karen Rydell, RN; *Florida Hospital South, Orlando, Florida*: Russell Ivanhoe, MD, A. Ralph Rodriguez, MD, Mary Reynolds, RN; *The Heart Institute of St. Joseph Hospital, Atlanta, Georgia*: Christopher U. Cates, MD, William Knopf, MD, Jan Shaftel,

RN; *Eastern Carolina University School of Medicine, Greenville, North Carolina*: A. Kahn, MD; *Riverside Hospital, Columbus, Ohio*: Nathan Kander, MD, RN; *North Shore University Hospital, Manhasset, New York*: Stanley Katz, MD, Lisa Chepurko, RN; *Wake Medical Center, Raleigh, North Carolina*: Joel Schneider, MD; *State University of New York at Stony Brook, Stony Brook, New York*: John P. Dervan, MD; *St. John Hospital, Detroit, Michigan*: Theodore Schreiber, MD, Christine Trevino; *Baptist Memorial Hospital, Memphis, Tennessee*: Joseph Samaha, MD, Barbara Hamilton, RN; *The Heart Center of Fort Wayne, Fort Wayne, Indiana*: Brian Lew, MD; *Hinsdale Hospital, Hinsdale, Illinois*: Jerome Hines, MD

Data and safety monitoring. *William Beaumont Hospital, Royal Oak, Michigan*: Gerald Timmis, MD; *University of Michigan Medical Center, Ann Arbor, Michigan*: Bertram Pitt, MD; *Boston University, Boston, Massachusetts*: Thomas J. Ryan, MD

Coordinating center. *William Beaumont Hospital, Royal Oak, Michigan*: Cindy L. Grines, MD, Lorelei L. Grines, PhD, Debra Sachs, MS, Denise Jones, RN, BSN, Mariann Graham, RN, BSN, Phyllis McKinney, Holly Jewett, Antoinette Kreis

Core angiographic laboratory. *William Beaumont Hospital, Royal Oak, Michigan*: Sandeep Khurana, MD, Mariann Graham, RN, BSN, Ludmilla Mitina, Randall McPherson

Economic analysis. *William Beaumont Hospital, Royal Oak, Michigan*: Tom Catlin, BA, Eric Jackson

Electrocardiographic analysis. *William Beaumont Hospital, Royal Oak, Michigan*: Terry Bowers, MD

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