Methods Papers

Translational Research Investigating Underlying Disparities in Acute Myocardial Infarction Patients’ Health Status (TRIUMPH)

Design and Rationale of a Prospective Multicenter Registry

Suzanne V. Arnold, MD, MHA; Paul S. Chan, MD, MSc; Philip G. Jones, MD; Carole Decker, RN, PhD; Donna M. Buchanan, PhD; Harlan M. Krumholz, MD, MS; P. Michael Ho, MD, PhD; John A. Spertus, MD, MPH; for the Cardiovascular Outcomes Research Consortium

Background—Black patients with myocardial infarction (MI) have worse outcomes than white patients, including higher mortality rates, more angina, and worse quality of life. The Translational Research Investigating Underlying Disparities in Acute Myocardial Infarction Patients’ Health Status (TRIUMPH) study was designed to examine whether racial differences in socioeconomic, clinical, genetic, metabolic, biomarker, or treatment characteristics mediate observed disparities in outcomes.

Methods and Results—Between April 11, 2005, and December 31, 2008, 31,567 patients with MI were prospectively screened; 6152 had an eligible MI, and 4340 (71%) were enrolled from 24 US centers. Consenting patients had detailed chart abstractions of their medical history and processes of inpatient care, supplemented with a detailed baseline interview. Detailed genetic and metabolic data were obtained at hospital discharge in 2979 (69%) and 3013 patients (69%), respectively. In a subset of patients, blood and urine samples were obtained at 1 month (obtained in 27% of survivors) and blood samples at 6 months (obtained in 19% of survivors). Centralized follow-up interviews sought to quantify patients’ postdischarge care and outcomes, with a focus on their health status (symptoms, function, and quality of life). At 1, 6, and 12 months, 23%, 27%, and 24%, respectively, were lost to follow-up. Vital status was available for 99% of patients at 12 months.

Conclusions—TRIUMPH is a novel MI registry with detailed information on patients’ sociodemographic, clinical, treatment, health status, metabolic, and genetic characteristics. The wealth of patient data collected in TRIUMPH will provide unique opportunities to examine factors that may mediate racial differences in mortality and health status after MI and the complex interactions between genetic and environmental determinants of post-MI outcomes. (Circ Cardiovasc Qual Outcomes. 2011;4:467-476.)

Key Words: myocardial infarction ▫ angina ▫ outcomes research ▫ health status ▫ registries

Although minority patients bear a disproportionate share of death and disability from cardiovascular disease,1–4 understanding the racial differences in outcomes is complex.5,6 Recognizing and rectifying such racial disparities is a national priority7 and a primary goal of the Department of Health and Human Services’ Healthy People 2010 agenda.8 However, achieving racial equity in outcomes (both mortality and health status: patient symptoms, function, and quality of life) requires research to illuminate the root causes of observed disparities. This is particularly challenging when investigating race, because black and white patients differ substantially in economic, social, clinical, and treatment characteristics. In a previous analysis of the Prospective Registry Evaluating Myocardial Infarction: Event and Recovery (PREMIER) registry that identified significant racial differences in a broad spectrum of outcomes 1 year after a myocardial infarction (MI), these differences did not persist after adjustment for patient factors that also differed by race and site of care.6

Further underscoring the need to define mediators of racial disparities in post-MI outcomes, the evolving epidemic of obesity, metabolic syndrome, and diabetes disproportionately

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From Saint Luke’s Mid America Heart Institute, Kansas City, MO (S.V.A., P.S.C., P.G.J., C.D., D.M.B., I.A.S.); Yale University School of Medicine, New Haven, CT (H.M.K.); and the University of Colorado Health Sciences Center, Denver, CO (P.M.H.).
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Correspondence to John Spertus, MD, MPH, Saint Luke’s Mid America Heart Institute, 4401 Wornall Rd, Kansas City, MO 64111. E-mail spertus@umkc.edu
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affects minorities, and these metabolic disturbances increase the incidence of MI and the adverse outcomes after an MI. Data from the 2003 Behavioral Risk Factor Surveillance System survey of >250,000 adults revealed that 49% of blacks had ≥2 major risk factors for cardiovascular disease, as compared with 36% of whites. Given these trends for worsening metabolic risk factors and the disproportionate burden of these factors in blacks, further insights into the association between diabetes and glucose metabolism with adverse outcomes are needed to better understand and, eventually, minimize racial disparities in post-MI outcomes.

In addition to clinical, socioeconomic, and metabolic factors, racial differences have been reported for both acute and postdischarge treatment. However, studies that examined the outcomes associated with different treatment patterns found no effect of these variations in care on mortality after adjustment for patient factors. Finally, there are racial differences in genetics, but the extent to which these explain differences in clinical presentation and response to medical therapy is poorly understood. Because race is a complex social construct, more detailed information is needed on socioeconomic, treatment, metabolic, and genetic characteristics to better clarify the contribution of each to racial differences in MI outcomes so that a rational strategy to eliminate racial disparities can be designed and implemented.

To address these existing gaps in knowledge, a collaboration of outcome-oriented researchers from the Cardiovascular Outcomes Research Consortium partnered with genetic researchers to conduct the Translational Research Investigating Underlying disparities in acute Myocardial infarction Patients’ Health status (TRIUMPH) study. This National Institute of Health-funded observational study was designed to quantify differences in health status outcomes between black and white patients 1 year after MI and to identify potential determinants of these outcomes. In addition, by collecting detailed social, economic, clinical, laboratory, genetic, and health status information, TRIUMPH has the broader goal of identifying novel genetic and metabolic mediators of mortality and health status after MI for all patients, regardless of race. The purpose of this article is to describe the design of TRIUMPH and how it differs from other registries, to summarize the clinical characteristics of the study sample, and to describe how this data will be used to illuminate new opportunities to improve the quality of care and outcomes of patients with MI.

Background

Over the past 30 years, a number of prospective MI registries have been conducted. Many of them, including the NRMI and CRUSADE registries, have focused on the presentation and acute treatment of MI patients, along with their in-hospital outcomes. The GRACE registry, launched in 1999, was one of the first to gather 6-month clinical outcomes data (mortality, hospitalization, cardiac procedures, and use of certain medications). Although these studies have provided important insights into the in-hospital treatment of MI patients, their outcome assessments were generally limited to short-term mortality, and none of them provided insights into patient-centered outcomes, including symptoms, function, and/or quality of life. They also did not include baseline assessments of patients’ psychosocial or health status, which are known to be prognostically important.

The PREMIER study, which enrolled ~2500 patients from 19 US hospitals in 2003 to 2004, addressed this gap in knowledge by collecting information on patients’ health status (their symptoms, function, and quality of life) at baseline and 1 year after MI. The TRIUMPH study, designed to build on the infrastructure of PREMIER, collected not only extensive information on patients’ socioeconomic factors, clinical factors, and health status but also detailed laboratory and genetic data not available in PREMIER. In addition, TRIUMPH sought to adjudicate all hospitalizations after the index MI to provide much more detailed information on resource utilization. Similarly, although prior studies have examined the association between various biomarkers or genetic variants with mortality, TRIUMPH sought to expand the existing knowledge base by evaluating possible genetic and metabolic determinants of both short- and long-term mortality and patient-centered outcomes, such as angina and quality of life. Thus, the purpose of TRIUMPH is to further illuminate the markers and mediators of racial disparities across a broad spectrum of 1-year outcomes after MI. This report seeks to explain the rationale, methods, and selection biases of TRIUMPH and serve as a resource for better understanding subsequent studies from this unique registry.

Methods

The first step in designing TRIUMPH was to consider the broad range of potential mediators of patient-centered outcomes, so that all relevant determinants could be prospectively captured. Given the focus on racial disparities, it was important to recognize that race is a complex social construct (not limited to skin color) and thus economic, social, genetic, and metabolic characteristics are needed to identify which patient characteristics are most associated with outcomes. Once the desired domains were identified, it was necessary to ensure the generalizability of the study results by developing a representative approach to patient enrollment and to include a broad spectrum of institutions across the United States. Finally, methods for tracking detailed, patient-centered outcomes and for analyzing these data were designed.

Conceptualizing the Determinants of Patient-Centered Outcomes

Although all MI patients are at risk for health status deficits after discharge, a broad range of factors, involving several phases of MI care, may influence patients’ subsequent outcomes. The fundamental goal of TRIUMPH was to independently quantify as many of these potential determinants of outcome as possible, so that those factors most associated with racial disparities in outcomes could be identified. Conceptually, we first defined the processes of MI care and then considered what data elements were needed to best quantify patients’ status at each phase of care. Figure 1 provides a conceptual model for the phases of care that can influence 1-year outcomes.

Phases of MI Care and Relevant Patient Characteristics at Each Phase

MI care consists of an initial presentation, an acute treatment phase, additional care throughout hospitalization, discharge treatment and planning, and follow-up care. Through this process, patients have different rates of postdischarge outcomes, including mortality, readmission, health status, psychological status, and costs. Because the focus of TRIUMPH was on the entire range of these postdischarge outcomes, patients were recruited during the final phase of their care.
hospitalization to identify a cohort that was likely to survive hospitalization and have postdischarge outcomes. Thus, many of the analyses emanating from TRIUMPH are relevant to the care and risk stratification of MI patients preparing for discharge. The most important characteristics for modeling the impact of each phase of MI care differ, and TRIUMPH intentionally sought to quantify factors throughout multiple phases of the treatment process. A more detailed description of TRIUMPH data collection is shown in Figure 2.

### Selecting Measures to Collect in the TRIUMPH Study

Whenever possible, American College of Cardiology/American Heart Association Clinical Data Standards for Acute Coronary Syndromes was used to define clinical characteristics of patients’ comorbidities, presentation, complications, and disposition.26 For categorization of race, patients were first asked to self-report their ethnicity and race, with an explicit opportunity to select multiple racial groups. A 2-generation pedigree was also collected to better evaluate patients’ race, ethnicity, and recent ancestral country of origin, all critical components in genetic epidemiology.27 Procedural characteristics were captured using definitions from the American College of Cardiology’s National Cardiovascular Database Registry28 and the Society of Thoracic Surgeons database.29 These clinical characteristics were captured using definitions from the American College of Cardiology/AHA/National Heart Lung and Blood Institute (AHA/ NHLBI) guidelines.30,31 In addition to disease-specific health status, generic health status was assessed with the Short Form-12,32 which quantifies patients’ overall physical and mental health, and the EQ-5D,33 which can also provide societal-based utilities and patient-reported assessments of overall health. All patient-centered data were collected through a detailed interview conducted by trained data collectors during patients’ presenting hospitalization and at each follow-up assessment. Copies of the surveys are available from the corresponding author.

### Selecting Patients for Enrollment

The goal of TRIUMPH was to recruit a consecutive cohort of MI patients from each enrolling center. Because an important component of the study was to perform a detailed patient interview, patients needed to be prospectively identified as early as possible during their hospitalization. All patients with a positive troponin result, as from the existing literature so that valid, reproducible, and sensitive quantification of each concept could be acquired. Table 1 lists the instruments used to assess these psychosocial and health status factors.

A broad range of outcomes were measured in TRIUMPH, each requiring its own method of collection. The primary health status outcome of the TRIUMPH study was patients’ disease-specific symptoms, function, and quality of life, as measured by the Seattle Angina Questionnaire. The Seattle Angina Questionnaire is a valid, reliable, responsive, and prognostic measure of patients’ perspectives of how their coronary disease affects their symptoms, function, satisfaction with treatment, and quality of life.30,31 In addition to disease-specific health status, generic health status was assessed with the Short Form-12,32 which quantifies patients’ overall physical and mental health, and the EQ-5D,33 which can also provide societal-based utilities and patient-reported assessments of overall health.

### Patient Factors

**Pre-AMI Factors**
- Patient Characteristics
  - (e.g. genetics, metabolic, socio-economic, comorbidity)
- Acute AMI Care
  - (e.g. early aspirin, reperfusion, beta-blockers)
- Risk Stratification and Treatment to Optimize Long-term Outcomes
  - (e.g. revascularization, stress testing, initiation of secondary prevention)
- Transition to Outpatient Care
  - (e.g. education, follow-up plan)
- Outpatient Care
  - (e.g. secondary prevention, angina assessment/treatment, compliance)
- 1-year Survival and Health Status Outcomes

**Inpatient AMI Care**
- MI Patients
- Meds
- PCI
- CABG
- Newly-Discovered Genetic and Metabolic Risk Factors
- Discharge Plans and Treatment
- 1-month Outcomes
- Health Status (SAQ, SF-12)
- Work Status
- Rehabilitation
- Procedures/Treatments
- PT Knowledge
- Labs

**Outpatient AMI Care**
- 6-month Outcomes
- Health Status (SAQ, SF-12)
- Work Status
- Rehabilitation
- Procedures/Treatments
- PT Knowledge
- Labs
- Costs

**12-month Outcomes**
- Health Status (SAQ, SF-12)
- Work Status
- PT Knowledge
- Adjudicated hospitalizations
- Survival
- Resource utilization
- Costs

**1-year Survival and Health Status Outcomes**

**Socio-Demographic Characteristics**
- Race, gender, age
- Social Support
- Employment status
- Economic status
- Living situation
- Education

**Clinical Characteristics**
- Comorbidities
  - (e.g. genetics, metabolic, socio-economic, comorbidity)
- Clinical Syndrome
  - (ST or NSTEMI)
- Disease Severity
  - (e.g. severity, EF, depression, PHQ)
- Medications & compliance

**Patient Characteristics**
- Functional Status/QOL
  - (e.g. SF-12, EQ-5D)
- Desire for shared MDM
- Difficulty obtaining care
- Optimism
- Alcohol and tobacco use
- Self-efficacy/locus of control

**Process of Medical Care**

**Figure 2.** Detailed overview of potential mediators of post-MI outcomes. NSTEMI indicates non–ST-elevation–MI; EF, ejection fraction; QOL, quality of life; SAQ, Seattle Angina Questionnaire; PCI, percutaneous coronary intervention; MDM, medical decision making; and CABG, coronary artery bypass graft.
established by the norms of the recruiting center, were screened for possible inclusion. For sites with large volumes of MI patients, a systematic sampling strategy (eg, screening every second or every third MI case based on the time of the first positive cardiac enzyme level at each site) was performed. Because the timing of consecutive positive laboratory tests is not influenced by patient characteristics or disease severity, no selection biases should have been introduced.

Once a patient was identified, a brief screening form was completed to establish eligibility. Only patients with a type 1 acute MI (ie, spontaneous MI related to ischemia caused by a primary coronary event) were eligible for enrollment. Patients had to fulfill the following criteria for eligibility: (1) age ≥18 years, (2) elevated troponin level (cardiac enzyme elevation as a complication of elective coronary revascularization did not qualify), (3) clinical features of ischemia (eg, prolonged ischemic signs/symptoms, ECG ST changes in ≥2 consecutive leads), and (4) initial presentation to the enrolling institution or transfer within the first 24 hours of original presentation. This latter criterion ensured that the primary clinical decision-making was conducted at the enrolling site. Incarcerated patients were not eligible, and all patients gave written informed consent that was approved by each institution.

Baseline Data Collection

Four discrete sources of data contributed to patients’ baseline data collection. First, a chart abstraction of patients’ presentation, clinical comorbidities, admission medications, presenting ECG, and treatments during the first 24 hours was done. Second, a detailed baseline interview of up to 250 questions was administered, taking from 30 to 50 minutes to complete. Third, all patients were asked to donate blood specimens at the time of enrollment in TRIUMPH for detailed metabolic and genetic analyses. They were also asked to sign a medical records release form so that the records from subsequent hospitalizations could be obtained and adjudicated. Finally, at the time of discharge, patients’ diagnostic data (including angiography and ECG), in-hospital treatment, in-hospital complications, discharge recommendations, discharge medications, follow-up, and final diagnoses (including ICD-9 codes) were collected. ECGs and angiographic reports were abstracted by the principal investigator or their designee at each site. Approximately 800 baseline variables were collected for each patient. All data were entered into a Web-based data collection program that allowed front-end range and logic checks to ensure the accuracy of collected data (Velos, Fremont, CA). In addition, a broad range of additional logic checks were performed by the data-coordinating center on an ongoing basis. Data queries were routinely sent and resolved by the study sites.

Blood Specimen Procurement and Processing

Because TRIUMPH was designed to investigate 1-year (as opposed to in-hospital) outcomes, fasting blood specimens were acquired as close to discharge as possible for laboratory and genetic analyses. This minimized artificial alterations in patients’ lipoprotein profiles caused by transiently heightened adrenergic states at the time of their MI and was thought to be most reflective of patients’ chronic metabolic state. However, given both the dynamic adrenergic state and use acute lipid-lowering therapy, patients’ lipid status before admission may have been underestimated using these measurements. For technical reasons (eg, discharge before labs could be drawn, insufficient sample, etc), some patients who agreed to collection of genetic material did not have blood drawn before hospital discharge. To maximize the number of genetic samples available for analyses, these patients were mailed a saliva-based genetics kit. There were 124 patients (4% of genetic samples) whose genetic data were obtained through this method and an additional 89 patients (3% of genetic samples) whose saliva supplemented genetic data obtained through primary blood collection.

Although genotyping is expected to vary by the type and purpose of subsequent genetic analyses, it is hoped that the analysis of TRIUMPH genetic samples will permit a careful evaluation of the magnitude of outcome differences attributable to genetic factors, as opposed to other patient and health care characteristics. Congruent with the intent of the National Institutes of Health to support data sharing, future collaborators can apply to use these genetic samples by conducting the corresponding author.

Follow-Up Interviews and Laboratories

Follow-up was attempted on all survivors at 1, 6, and 12 months. For patients who did not agree to blood collection and for all patients’ 12-month follow-ups, the interviews were performed by telephone from a single specialized center. For patients who agreed to additional blood collection, an in-home visit was performed by trained medical personnel at 1 and 6 months. Patients were assessed for weight, waist circumference, blood pressure, and pulse. Elderly patients (age ≥65 years) were also assessed for relevant domains for that population, including mobility, strength, balance, cognition, nutrition, endurance, and physical activity, including 15-foot walk speed, chair stands, and hand grip strength. Table 2 details the laboratory tests that were obtained at baseline and follow-up (see online-only Data Supplement Appendix 1 for more detail on the processing of the baseline and follow-up laboratory samples, including the processing of genetic samples).
Follow-up interviews included assessment of the primary health status outcomes of this study in addition to current medications, lifestyle, and secondary risk factor management practices, use of cardiac rehabilitation, and many of the patient-centered domains assessed at baseline. Elderly patients were also assessed with the modified Telephone Interview for Cognitive Status35 and asked to self-report memory difficulties, unintentional weight loss, and exhaustion. All patients were asked to report interval events (eg, procedures, diagnostic tests, hospitalizations, and outpatient visits) since their last study contact. If a patient reported being hospitalized since the previous interview, records of that hospitalization were requested to adjudicate cardiovascular events, including MI, heart failure, or revascularization procedures. Chart abstractions were sent to 2 cardiologists who independently classified the reason for hospitalization. If there was disagreement between the 2 cardiologists, the record was adjudicated by a third senior cardiologist, and if disagreement persisted, up to 5 cardiologists independently reviewed the charts until consensus was obtained.

Selecting Sites for TRIUMPH

The goal of site selection was to capture a broad spectrum of hospitals while also ensuring that compliance with the complex data collection procedures would be maintained. Figure 3 shows the final 24 sites for TRIUMPH enrollment, which include several academic centers (Tufts-New England Medical Center, Yale–New Haven Medical Center, Duke University, Washington University in St Louis, Virginia Commonwealth University, and the Universities of Iowa, Michigan, Wisconsin, and Colorado), inner city hospitals (Truman Medical Center, Cook County, Montefiore Medical Center, Parkland Hospital, Grady Memorial, Henry Ford, and Denver Health Hospitals), single-payer systems (Veterans Affairs Iowa City), and nuniversity hospitals (Chabert Medical Center, Presbyterian Health System, Christiana Care, Bridgeport Hospital, Sentara Leigh Hospital, MeritCare, and Saint Luke’s Mid America Heart Institute) (online-only Data Supplement Appendix 1). Three centers initially participated in the TRIUMPH study but were excluded from analyses because of the small numbers of patients enrolled at these sites. Rural institutions and hospitals providing less specialty care were underrepresented.

Among the 24 centers, 21 were not-for-profit institutions, 1 was for-profit, and 2 were governmental. Ten centers were university-owned, 10 were university-affiliated, and 4 were self-classified as nonacademic. Sixteen centers were in urban areas, and 7 primarily cared for indigent patients. The size of the institutions ranges from 66 to 1000 beds, with a mean of 598 beds. All centers had onsite angiography, 21 performed percutaneous coronary intervention, and 17 performed coronary artery bypass grafting.

Results

The TRIUMPH study began on April 11, 2005, and ended on December 31, 2008. Enrolling patients into TRIUMPH required approximately 5 hours of data collection for each patient (≈15 minutes for screening, ≈2 hours of chart abstraction, ≈45 minutes for interviews, ≈1 hour of data entry, ≈1 hour for blood procurement and site processing, and ≈15 minutes of a cardiologist’s time to interpret electrocardiograms and angiograms). Over the course of the study, 31 567 patients with elevated troponin levels were screened, 6152 were determined to be eligible, and 4563 (74%) were enrolled, of which 223 either did not meet inclusion criteria (204 patients) or were from the 3 excluded sites with low enrollment (19 patients). Thus, the final number of patients eligible for analysis is 4340.

Although detailed information was not collected about patients who were eligible but not enrolled in TRIUMPH, Table 3 compares a few demographic and clinical characteristics between these 2 groups among the 10 top-enrolling centers (where this information was reliably collected and representing 81% of the final cohort). Eligible patients not enrolled were more likely to be older and white than those who agreed to participate. Table 4 describes in more detail the sociodemographic and clinical data for selected patient characteristics of enrolled patients, along with a comparison between
white and nonwhite participants. It is important to note that TRIUMPH was designed to investigate long-term outcomes after an MI, and patients were required to be alive 24 to 48 hours after admission to participate in the enrollment interview. Thus, the low in-hospital mortality rate of 0.6% (24 patients) is not unexpected, and those who died will be excluded for many of the planned analyses of post-MI outcomes.

Adherence to process measures of quality care was generally high among the population, with the majority of patients being prescribed aspirin (95%) and β-blockers (93%) at discharge, concordant with national averages.13 Among patients with left ventricular systolic dysfunction, 85% were prescribed angiotensin-converting enzyme inhibitors. Eighty-three percent of ST-elevation-MI patients received an attempt at primary reperfusion, with 52% of eligible patients receiving thrombolytics within 30 minutes or primary percutaneous coronary intervention within 90 minutes on hospital arrival. White patients were more likely than nonwhite patients to undergo invasive management of their MI and were more likely to receive processes of care considered quality metrics.

As of January 2010, all enrolled patients reached their 1-year follow-up time point. Figure 4 shows the summary of follow-up on the patients enrolled in TRIUMPH. Detailed genetic and metabolic data were obtained during baseline hospitalization in 69% of patients. Vital status was available for 99% of patients at 12 months, at which time 6.5% of patients had died. At the 1-, 6-, and 12-month follow-up time points, 23%, 27%, and 24% of patients, respectively, were lost to follow-up. The demographic and clinical characteristics of those who participated and those who did not participate in follow-up are shown in Table 3. Patients who were younger and nonwhite were less likely to follow up. Patients who were sicker were also less likely to follow up, with heart failure, diabetes, depressed ejection fraction, and longer hospital stay being associated with a lower likelihood of follow-up.

### Table 3. Baseline Characteristics of Patients Eligible for and Enrolled in TRIUMPH

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Enrolled (n=3537)*</th>
<th>Not Enrolled (n=1466)</th>
<th>P Value</th>
<th>Follow-Up (n=3632)†</th>
<th>No Follow-Up (n=631)†</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>58.6±12.4</td>
<td>62.2±14.5</td>
<td>&lt;0.001</td>
<td>59.3±12.0</td>
<td>57.1±13.7</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Male</td>
<td>66.9%</td>
<td>65.7%</td>
<td>0.40</td>
<td>66.9%</td>
<td>65.6%</td>
<td>0.54</td>
</tr>
<tr>
<td>White</td>
<td>64.4%</td>
<td>77.1%</td>
<td>&lt;0.001</td>
<td>72.5%</td>
<td>55.7%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>No insurance</td>
<td>23.4%</td>
<td>24.5%</td>
<td>0.42</td>
<td>21.4%</td>
<td>28.9%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>31.7%</td>
<td>31.0%</td>
<td>0.63</td>
<td>29.7%</td>
<td>35.0%</td>
<td>0.007</td>
</tr>
<tr>
<td>Hypertension</td>
<td>65.9%</td>
<td>69.3%</td>
<td>0.104</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prior myocardial infarction</td>
<td></td>
<td></td>
<td></td>
<td>20.2%</td>
<td>24.6%</td>
<td>0.012</td>
</tr>
<tr>
<td>Prior heart failure</td>
<td></td>
<td></td>
<td></td>
<td>7.4%</td>
<td>14.3%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>ST-elevation on admission</td>
<td>45.5%</td>
<td>40.3%</td>
<td>0.019</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peak troponin, ng/mL</td>
<td>29.3±75.2</td>
<td>23.7±55.3</td>
<td>0.075</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ejection fraction, %</td>
<td>49.0±12.9</td>
<td>47.2±13.8</td>
<td>0.004</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coronary angiography</td>
<td>93.5%</td>
<td>86.2%</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GRACE score, 6-mo mortality</td>
<td>100.1±29.2</td>
<td>100.8±34.3</td>
<td>0.554</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Length of stay, d</td>
<td>5.5±6.5</td>
<td>6.5±8.5</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*From the top 10 enrolling hospitals; represents 81% of the total study population.
†Includes only patients who survived to 1 month (ie, had the opportunity to participate in follow-up).

Discussion

Although improving the quality of American health care is a national priority,36 significant barriers remain. Among these is the need to better understand where the greatest opportunities lie in optimizing patient outcomes and how to ensure that all components of our society are able to receive the best treatment. Although one of the Institute of Medicine’s 6 aims for improving the health care of the American population includes making it more evidence-based, in many instances, certain patient characteristics will probably alter the “average” benefit observed in clinical trials. Therefore, to achieve another of the Institute of Medicine’s goals—patient-centeredness—a better understanding of the association of patient characteristics with treatment and outcomes is needed. Furthermore, achieving the Institute of Medicine’s goal of equity in health care requires illuminating patient characteristics and treatments that vary by race so that proactive steps can be developed to minimize differences in care and eliminate disparities in outcomes.

Against this backdrop, TRIUMPH offers a unique opportunity to evaluate racial disparities in outcomes among patients with MI. By prospectively enrolling a multicenter cohort of MI patients, a broad spectrum of patients can be studied with the goal of illuminating novel mediators and moderators of outcomes. Unfortunately, as a result of conscious efforts to enroll a representative MI patient population with regard to race and socioeconomic status independent of likelihood to participate in follow-up (as is often done in clinical trials), nonparticipation in follow-up interviews was slightly greater than the anticipated 20% rate, with lower participation in nonwhite patients. Analyses using follow-up data will need to address this selection bias with advanced statistical techniques, such as assigning an inversely weighted propensity score to each patient to emphasize the scores for those most likely to miss data.24,37,38 Toward that end, the collection of detailed socioeconomic, clinical, treatment,
Table 4. Baseline Characteristics of TRIUMPH Patients

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>All (n=4340)</th>
<th>White (n=3022)</th>
<th>Nonwhite (n=1305)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sociodemographics</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age, y</td>
<td>59.1±12.3</td>
<td>59.9±12.3</td>
<td>57.1±12.2</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Male</td>
<td>67%</td>
<td>71%</td>
<td>58%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>White</td>
<td>70%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>51%</td>
<td>59%</td>
<td>33%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>No insurance</td>
<td>21%</td>
<td>18%</td>
<td>34%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>High school education</td>
<td>79%</td>
<td>85%</td>
<td>67%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td><strong>Clinical factors</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ST-elevation on admission</td>
<td>43%</td>
<td>48%</td>
<td>32%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Hypertension</td>
<td>67%</td>
<td>62%</td>
<td>78%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Prior MI</td>
<td>21%</td>
<td>20%</td>
<td>24%</td>
<td>0.005</td>
</tr>
<tr>
<td>Prior PCI</td>
<td>20%</td>
<td>20%</td>
<td>18%</td>
<td>0.062</td>
</tr>
<tr>
<td>Prior heart failure</td>
<td>9%</td>
<td>6%</td>
<td>15%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Diabetes</td>
<td>31%</td>
<td>27%</td>
<td>40%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Family history of heart disease</td>
<td>74%</td>
<td>79%</td>
<td>63%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>49%</td>
<td>51%</td>
<td>44%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Chronic kidney disease</td>
<td>7%</td>
<td>5%</td>
<td>13%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Chronic lung disease</td>
<td>7%</td>
<td>7%</td>
<td>8%</td>
<td>0.73</td>
</tr>
<tr>
<td>History of smoking</td>
<td>59%</td>
<td>59%</td>
<td>60%</td>
<td>0.93</td>
</tr>
<tr>
<td>Body mass index, kg/m²</td>
<td>29.5±6.5</td>
<td>29.4±6.1</td>
<td>29.8±7.3</td>
<td>0.12</td>
</tr>
<tr>
<td><strong>Disease severity</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic blood pressure, mm Hg</td>
<td>143±30</td>
<td>141±30</td>
<td>148±31</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Diastolic blood pressure, mm Hg</td>
<td>83±19</td>
<td>82±19</td>
<td>86±19</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Heart rate on admission, bpm</td>
<td>83±22</td>
<td>82±23</td>
<td>85±21</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Ejection fraction, %</td>
<td>49±13</td>
<td>49±12</td>
<td>48±15</td>
<td>0.018</td>
</tr>
<tr>
<td>Peak troponin level, ng/mL</td>
<td>29±73</td>
<td>33±73</td>
<td>19±65</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Initial creatinine level, mg/dL</td>
<td>1.2±1.1</td>
<td>1.2±0.8</td>
<td>1.5±1.6</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Initial hemoglobin level, g/dL</td>
<td>14.0±2.1</td>
<td>14.3±2</td>
<td>13.3±2.3</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>hs-CRP level, mg/L</td>
<td>3.7±5.0</td>
<td>3.7±4.9</td>
<td>3.6±5.3</td>
<td>0.51</td>
</tr>
<tr>
<td>LDL level, mg/dL</td>
<td>95±32</td>
<td>95±31</td>
<td>96±35</td>
<td>0.51</td>
</tr>
<tr>
<td>GRACE score for 6-mo mortality*</td>
<td>101±30</td>
<td>101±30</td>
<td>100±30</td>
<td>0.39</td>
</tr>
<tr>
<td><strong>Hospital procedures</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coronary angiography</td>
<td>92%</td>
<td>95%</td>
<td>85%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Primary PCI</td>
<td>34%</td>
<td>38%</td>
<td>26%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Nonprimary PCI</td>
<td>29%</td>
<td>32%</td>
<td>24%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Coronary bypass surgery</td>
<td>9%</td>
<td>10%</td>
<td>8%</td>
<td>0.007</td>
</tr>
<tr>
<td><strong>Quality performance measures</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aspirin within 24 h</td>
<td>97%</td>
<td>98%</td>
<td>97%</td>
<td>0.47</td>
</tr>
<tr>
<td>Aspirin at discharge</td>
<td>95%</td>
<td>96%</td>
<td>94%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>ACE-I/ARB for left ventricular</td>
<td>85%</td>
<td>87%</td>
<td>83%</td>
<td>0.17</td>
</tr>
<tr>
<td>systolic dysfunction</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smoking cessation counseling</td>
<td>75%</td>
<td>95%</td>
<td>90%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>β-blocker at discharge</td>
<td>93%</td>
<td>80%</td>
<td>66%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Fibrinolytics by 30 min or primary PCI</td>
<td>52%</td>
<td>58%</td>
<td>40%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>PCI by 90 min</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>In-hospital outcomes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>0.6%</td>
<td>0.5%</td>
<td>0.7%</td>
<td>0.43</td>
</tr>
<tr>
<td>Length of stay, d</td>
<td>5.7±7.0</td>
<td>5.5±7.2</td>
<td>6.1±6.3</td>
<td>0.007</td>
</tr>
</tbody>
</table>

PCI indicates percutaneous coronary intervention; hs-CRP, high-sensitivity C-reactive protein; LDL, low-density lipoprotein; ACE-I, angiotensin-converting enzyme inhibitor; and ARB, angiotensin receptor blocker.

*For those eligible.
with genetic and metabolic information, TRIUMPH will allow for even greater insights into the mediators of outcomes after MI and potentially discern some of the complex interactions between genetic and clinical (including treatment) factors. In addition, given the similar structure of the data collection in PREMIER and TRIUMPH (identical inclusion and exclusion criteria, time points of assessment, psychosocial, socioeconomic, health status, and quality-of-life assessments), the data from the 2 registries will be able to be combined for additional unique analyses, such as time trend analyses, model creation and validation, and analyses of rarer events that require increased power.

In summary, TRIUMPH is a prospective study of the outcomes of patients recovering from MI with detailed information about patients’ sociodemographic, clinical, treatment, health status, metabolic, and genetic characteristics. It has been designed to explicitly describe patient-centered health status outcomes 1 year after discharge and to document the determinants and trajectory of that recovery. TRIUMPH should provide unique insights into factors that mediate racial differences in mortality and health status outcomes after MI and, ultimately, these insights will allow for the creation of rational strategies to reduce racial disparities in outcomes.

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Disclosures
Dr Spertus owns the copyright to the Seattle Angina Questionnaire.

References


Translational Research Investigating Underlying Disparities in Acute Myocardial Infarction Patients' Health Status (TRIUMPH): Design and Rationale of a Prospective Multicenter Registry

Suzanne V. Arnold, Paul S. Chan, Philip G. Jones, Carole Decker, Donna M. Buchanan, Harlan M. Krumholz, P. Michael Ho, John A. Spertus and for the Cardiovascular Outcomes Research Consortium

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/content/4/5/e3.full.pdf

Data Supplement (unedited) at:
http://circoutcomes.ahajournals.org/content/suppl/2011/07/20/4.4.467.DC1

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In the article by Arnold et al, which appeared in the July 2011 issue of the journal (Circulation: Cardiovascular Quality and Outcomes, 2011;4:467–476), there was an error with a table.

In Table 4, the numbers for 2 rows were reversed.

For the columns “All,” “White,” and “Nonwhite,” the corresponding values should read as follows for each characteristic:
Smoking cessation counseling: 75%; 80%; 66%
β-blocker at discharge: 93%; 95%; 90%

This correction has been made to the current online version of the article, which is available at: http://circoutcomes.ahajournals.org/content/4/4/467.full.pdf+html.

The authors regret the error.

DOI: 10.1161/HCQ.0b013e318232ea61
Baseline Laboratory Samples

Approximately 20mL of fasting blood was drawn from each subject in 3 tubes for laboratory and genetic analyses. The tubes were processed, refrigerated and sent overnight mail, with freezer packs, to the core laboratory (Clinical Reference Laboratory, Lenexa, KS) on a daily basis. Blood was analyzed for the following: hemoglobinA1c, glucose and insulin levels, high sensitivity C-reactive protein, ApoA1, 25(OH) Vitamin D, intact parathyroid hormone, phosphate, calcium, troponin-T, and pro-brain natriuetic peptide (pro-BNP). Patients’ lipid phenotypes were determined by characterizing multiple lipidomic variables using the Atherotech VAP test (Atlanta, GA) to assess lipids (cholesterol, triglycerides and FFA), multiple lipoproteins (multiple HDL, LDL, IDL, VLDL, and Lp(a) species), and fatty acyl species in the triglyceride fraction (palmitate, palmitoleic, stearate, oleate, linoleate, linolenate, arachidonate, eicosapentaenoate, and docosahexaenoate). A 1ml sample of whole blood was frozen at -80°C for future analyses.

For genetic analyses, genomic DNA was isolated and purified from whole blood using Qiagen QIAamp DNA Blood Midi Kit (if volume <2 mL) or Maxi Kit (if volume >2 mL) (Quiagen, Germantown, MD, USA). DNA samples were divided equally into 2 fractions: one aliquot was transported monthly to the Applied Genomics Core Laboratory at Washington University in St. Louis; the second aliquot was held at Saint Luke’s Mid America Heart Institute for long-term storage at -80°C. For the 7% of patients who provided saliva samples for genetic
analyses, genomic DNA was purified using the Oragene®•DNA sample collection kit (DNA Genotek Inc., Ottawa, Ontario, Canada)\(^2\) at the Applied Genomics Core Laboratory.

After genomic DNA was purified from all available samples (blood and saliva), whole genome amplification was performed on 20 nanograms of DNA from each sample at one time (to optimize uniformity of amplification) using illustra GenomiPhi V2 DNA Amplification Kit (GE Healthcare, Piscataway, NJ, USA). Genomic and whole genome amplified DNA were plated separately (i.e. genomic DNA onto one set of plates and whole genome amplified DNA onto other sets of plates) onto duplicate sets of 96-well plates for future genotyping.

**Follow-up Laboratory Samples**

For patients who agreed to an in-home visit by trained medical personnel at 1- and 6-months, a urine sample and ~18mL of blood divided into 3 tubes were obtained for longitudinal laboratory analyses. These tubes were then sent to the core laboratory for processing. In patients who agreed to blood collection but for which an in-home visit was not possible for technical reasons, kits were mailed to the patients who were asked to take these kits to their physician. The treating physician was asked to complete the clinical measurements of weight, waist circumference, blood pressure, and pulse, and then mail the labs for processing.
References:

1. Qiagen. Sample & assay technologies: Qiaamp system.

2. Genotek D. DNA testing - DNA from saliva - oragene-DNA.