CORONARY ARTERY DISEASE

Original Studies

The China Patient-centered Evaluative Assessment of Cardiac Events (PEACE) Prospective Study of Percutaneous Coronary Intervention: Study Design

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Background: The number of percutaneous coronary interventions (PCI) in China has increased more than 20-fold over the last decade. Consequently, there is a need for national-level information to characterize PCI indications and long-term patient outcomes, including health status, to understand and improve evolving practice patterns. **Objectives:** This nationwide prospective study of patients receiving PCI is to: (1) measure long-term clinical outcomes (including death, acute myocardial infarction [AMI], and/or revascularization), patient-reported outcomes (PROs), cardiovascular risk factor control and adherence to medications for secondary prevention; (2) determine patient- and hospital-level factors associated with care process and outcomes; and (3) assess the appropriateness of PCI procedures. **Methods:** The China Patient-centered Evaluative Assessment of Cardiac Events (PEACE) Prospective Study of PCI has enrolled 5,000 consecutive patients during 2012–2014 from 34 diverse hospitals across China undergoing PCI for any indication. We abstracted details of patient's medical history, treatments, and in-hospital outcomes from medical charts, and conducted baseline, 1-, 6-, and 12-month interviews to characterize patient demographics, risk factors, clinical presentation, healthcare utilization, and health status using validated PRO measures.

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Additional Supporting Information may be found in the online version of this article.

The primary outcome, a composite measure of death, AMI and/or revascularization, as well as PROs, medication adherence and cardiovascular risk factor control, was assessed throughout the 12-month follow-up. Blood and urine samples were collected at baseline and 12 months and stored for future analyses. To validate reports of coronary anatomy, 2,000 angiograms are randomly selected and read by two independent core laboratories. Hospital characteristics regarding their facilities, processes and organizational characteristics are assessed by site surveys. Conclusion: China PEACE Prospective Study of PCI will be the first study to generate novel, high-quality, comprehensive national data on patients' socio-demographic, clinical, treatment, and metabolic/genetic factors, and importantly, their long-term outcomes following PCI, including health status. This will build the foundation for PCI performance improvement efforts in China.   © 2016 The Authors. Catheterization and Cardiovascular Interventions Published by Wiley Periodicals, Inc.

BACKGROUND

The dramatically rising prevalence of coronary heart disease in China has occurred at the same time as expansions in access to advanced cardiovascular procedures [1–3]. Over the last decade, the volume of percutaneous coronary intervention (PCI) has increased more than 20-fold, with 454,505 procedures reported in 2013 [4]. Despite the magnitude of PCI volume, little information is available regarding the quality of these procedures in China. There is paucity of data on long-term clinical outcomes such as cardiac death and revascularization, as well as patient-reported outcomes (PROs), patients' symptoms, and function and quality of life. In addition, there is a substantial gap in understanding the hospital- and patient-level determinants of patients' health and well-being following PCI. Data on indications for, and appropriateness of, PCI are sparse. Furthermore, there is limited knowledge about how evidence-based therapies are applied in the management of patients after PCI. All of these data are needed to characterize the quality of care provided to patients undergoing PCI and, more importantly, to guide the creation of strategies and tools for quality improvement in China.

Assessments of early and long-term adverse clinical outcomes after PCI are important in understanding the risk-benefit balance of this treatment. In the case of PCI, particularly among patients with stable coronary disease, the procedure is performed with the objective of improving patients' health status [5–7]. In China, few prior studies of PCI included longitudinal data or measured patient care or outcomes, and none focused on health status or other PROs [5–7]. Current evidence regarding long-term adverse cardiac events following PCI in China are largely based on selected patients, such as those enrolled in stent registries [8,9] or in randomized controlled trials [10,11], or those with complex coronary diseases [12–14]. In contrast, numerous studies in western countries have described the efficacy of PCI in reducing the risk of adverse events among patients with acute coronary syndromes [15], as well as improving quality-of-life n both acute and stable settings [16,17]. While these studies have laid a foundation for patient and health service decision-making to improve the quality of PCI, the absence of such data in China limits the opportunity to similarly improve the quality of PCI in China.

To address the substantial gap in understanding the selection, treatment, and outcomes of patients with PCI, we designed and implemented the China Patient-centered Evaluative Assessment of Cardiac Events (PEACE) Prospective Study of PCI. As the first longitudinal study on clinical outcomes and PROs among patients with PCI in China, it aims to: (1) assess indications for and appropriateness of the PCI procedures performed; (2) evaluate the control of risk factors (blood pressure, hemoglobin A1c, blood lipid, obesity, smoking and alcohol consumption) and adherence to medications for secondary prevention in patients hospitalized with PCI; (3) measure long-term clinical outcomes (i.e., death, AMI and/or revascularization) and PROs (i.e., health status, depression, and stress) among patients undergoing PCI in the short (i.e., 1 month) and long term (6 and 12 months); (4) determine patient-level factors associated with these outcomes and generate risk prediction tools using these data; (5) assess hospital level variation in outcomes and the institutional factors associated with this variation.

METHODS

Study Overview

China PEACE is a collaboration between the China National Center for Cardiovascular Disease (NCCD), the Yale-New Haven Hospital Center for Outcomes Research and Evaluation, the Chinese government, and more than 200 Chinese hospitals to improve cardiovascular disease outcomes in China (Fig. 1). The China PEACE Prospective Study of PCI leveraged this research network by recruiting 5,000 consecutive patients undergoing PCI for any indication from 34 tertiary

hospitals located in 20 provinces across China (Fig. 2), and followed them prospectively for 12 months.

The NCCD/Fuwai Hospital ethics committee approved this study and, where required, individual hospitals received approval from their local ethics committee. The Chinese government, which provides financial support for the study, had no role in the design or conduct of the study; in the collection, management, analysis, or interpretation of the data; or in the preparation or approval of the article or any of the articles that will be derived from the study.

Participant

Eligible patients were defined as those admitted to a participating hospital that received PCI for any indication and had at least one coronary stent implanted during the procedure. Only patients who sign informed consent are then enrolled and interviewed at baseline and follow-up. To evaluate potential selection biases, we collected information on patient baseline characteristics, in-hospital care, and in-hospital outcomes for all registered patients through medical chart abstraction (Fig. 4).

Outcomes

The primary outcome is a composite measure of major adverse cardiovascular events, including death, non-fatal AMI and/or revascularization. It is assessed at follow-up interviews conducted at 1, 6, and 12 months in local sites after discharge from initial hospitalization. Secondary endpoints include PROs at 12 month as well as the individual components of major adverse vascular events, re-hospitalization, adherence to medications for secondary prevention (e.g., aspirin, clopidogrel, statin, and beta-blockers), and control of cardiovascular risk factors (e.g., blood pressure, hemoglobin A1c, blood lipid, obesity, smoking, and alcohol consumption) at 12 months.

Data Collection Overview

Data are collected through central medical chart abstraction, interviews by site investigators, physical examinations, and central analysis of blood/urine specimens (Table I, Figure 3). Data elements and variable definitions for this study were modeled after the National Cardiovascular Data Registry Cath PCI registry (NCDR-Cath PCI) [18], the Prospective Registry Evaluating Myocardial Infarction: Events and Recovery Study (PRE-MIER) [19], the (Translational Research Investigating Underlying Disparities in Acute Myocardial Infarction Patients' Health Status study (TRIUMPH) [20] and the Variation in Recovery: Role of Gender on Outcomes Young Acute Myocardial Infarction Patients (VIRGO)

[21]. The adoption of these standardized elements enables direct comparisons with US data. PROs were assessed using instruments previously validated in the Chinese population [19–21], facilitating comparisons of these outcomes as well.

Angiogram Review

We collected all imaging CDs of index PCI procedures ($n = 5,000$). A total of 2,000 angiograms of patients' index PCIs are randomly selected, and reviewed by independent angiographic core labs in China [Core Laboratory in Company of Cardiovascular Research Foundation (Beijing)] and the US (Yale Angiographic Core Laboratory). Staff at these angiographic core labs record angiographic information into predesigned case report forms including the SYNTAX Score [22], vessel morphology, and lesion condition (which is used for assessment of the appropriateness of the index PCI). To assess the consistency of results, 100 angiograms are being reviewed by both core labs. Results of this double-review will be compared, then shared in the two core labs, and ultimately used to guide the rectification of all reviewing results.

Participant Interviews and Laboratories

Participants were interviewed in-person at baseline (i.e., during index hospitalization) by local site coordinators. The baseline questionnaire (Supporting Information 3) used for patient interviews include 130 questions ascertaining detailed information on patient demographics, socio-economic status, risk factors, medical history as well as sleep apnea (Modified Berlin Questionnaire [MBQ]) [23], generic (EQ-5D) [24,25]and disease-specific health status (SAQ) [26,27], depression [28], and stress [29,30]. Site investigators administered the interviews using an electronic data capture program on a tablet computer, in which the real-time logic checks were implemented to ensure the accuracy and completeness of data.

Follow-up interviews were conducted in-person at 1, 6, and 12 months after discharge from the initial hospital stay (Figure 3). Telephone interviews were conducted when in-person interviews were not feasible, such as elderly with mobility. At follow-up interviews, clinical events and PROs were assessed, as well as adherence to medication for secondary prevention and control of risk factors. Blood was obtained at baseline and 12-month follow-up visits (Supporting Information 4: blood and urine collection). A consent form for the long-term storage and future analysis of blood/urine sample was obtained from each enrolled patient. The bio-samples were then transported to NCC and analyzed for lipid profiles and metabolic markers at a
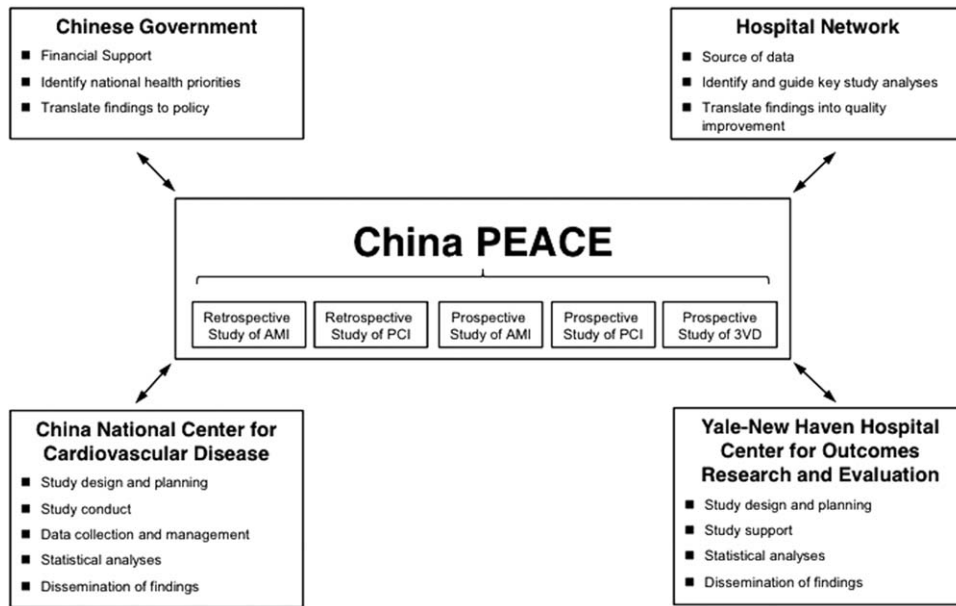
Fig. 1. The China patient-centered evaluative assessment of cardiac events (PEACE) Initiative. Key partners include the Chinese government, collaborating hospitals, the China National Center for Cardiovascular Disease, and the Yale-New Haven Hospital Center for Outcomes Research and Evaluation. The China PEACE Prospective Study of PCI is one of five initial studies from the China PEACE initiative. The topic areas for these five projects concern acute myocardial infarction, coronary catheterization/percutaneous coronary intervention, and multi-vessel coronary artery disease. Future studies will focus on cerebrovascular disease and other cardiovascular conditions. AMI, acute myocardial infarction; PCI, percutaneous coronary intervention. 3VD, Triple-vessel Disease.
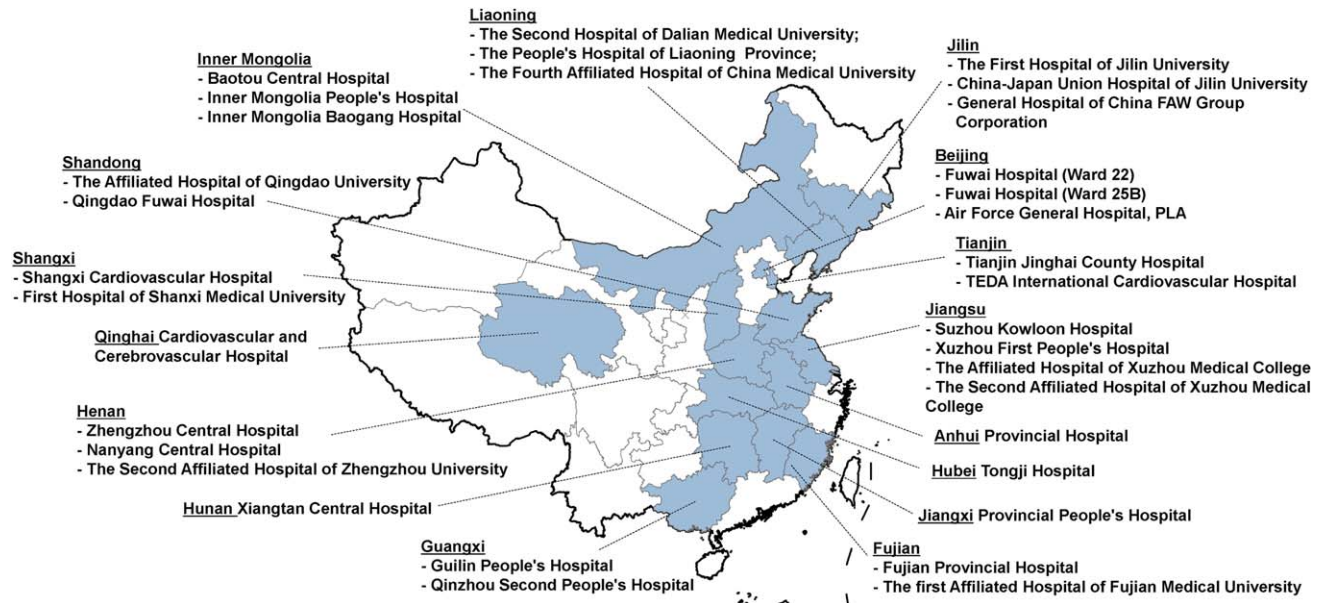

Fig. 2. Geographic distribution of participating hospitals in the China patient-centered evaluative assessment of cardiac events (PEACE), prospective study of percutaneous coronary intervention (PCI). The 34 participating centers are located in 20 of the 31 provinces in China.

central laboratory. All blood/urine samples are stored in the China National Cardiovascular Bio-Bank for future genetic and metabolic analysis.

Statistical Analyses

To address the primary aim of this study, we will calculate summary statistics for major adverse
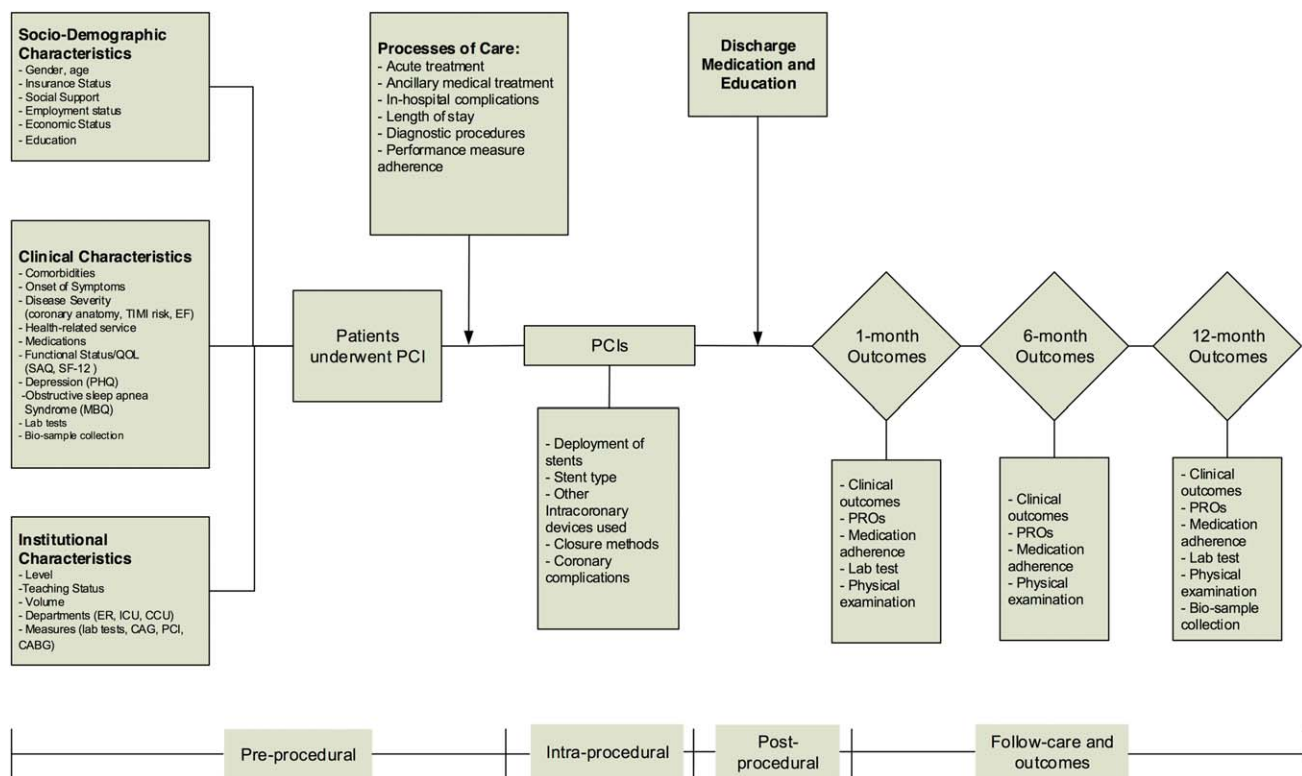
Fig. 3. Detailed overview of potential mediators of post-PCI outcomes, including in-hospital and 12-month outcomes (clinical events, patient-reported outcomes [PROs]) and long-term disease management. EF: ejection fraction; ER, emergency room; ICU, intensive care unit; CCU, cardiac care unit; CAG: coronary angiography; PCI, percutaneous coronary intervention; CABG: coronary artery bypass surgery; SAQ, Seattle Angina Questionnaire; EQ-5D, EuroQol Group 5-Dimension Self-Report Questionnaire; PHQ-8, Patient Health Questionnaire 8-item depression scale.

vascular events, as well as PROMs at 1, 6, and 12 months after PCI (Supporting Information 6: analytic methods and plan). We will report summary statistics for patient demographic, clinical, psychosocial, and behavioral characteristics; use of diagnostic tests; treatments received; and control of cardiovascular risk factors. To help identify factors associated with the primary outcomes, we will use standard parametric and non-parametric tests for bivariate analyses, including t tests, chi-square tests, Fisher's exact test, and Wilcoxon rank sum tests. In addition, appropriate multivariable regression analyses, such as linear, logistic, Cox proportional hazard, and Poisson models, will be conducted to determine independent factors of outcome measures, while adjusting for potential confounders. As patients are clustered within hospitals, the analyses will account for clustering in data when examining alternative treatment strategies (e.g., via generalized estimating equation approaches or random effects models). If longitudinal outcomes are considered, we will further account for the clustering effect within patients at different measurement points. We

will carefully evaluate potential selection biases introduced by missing data and if needed, conduct inverse probability weighting (i.e., preferentially weight the experiences of patients who were most like those who did not participate in follow-up) based upon a propensity model for participation in the follow-up assessments. For observational comparative effectiveness studies, propensity score matching or instrumental variable methods will be used, when necessary, to better account for measured confounders. The creation of risk-standardized adjustment models will serve as a foundation for comparing outcomes among centers for future quality improvement.

DISCUSSION

The China PEACE Prospective Study of PCI is the first longitudinal study in China to capture clinical events and PROs of patients over 12 months following a PCI procedure. This study addresses an important knowledge gap by providing information about long-term outcomes after PCI, including health status

Patient-centered Evaluative Assessment of Cardiac Events
CHINA PEACE
Prospective Treatment Evaluation
Flow Chart of the Patients underwent PCI prior to Discharge
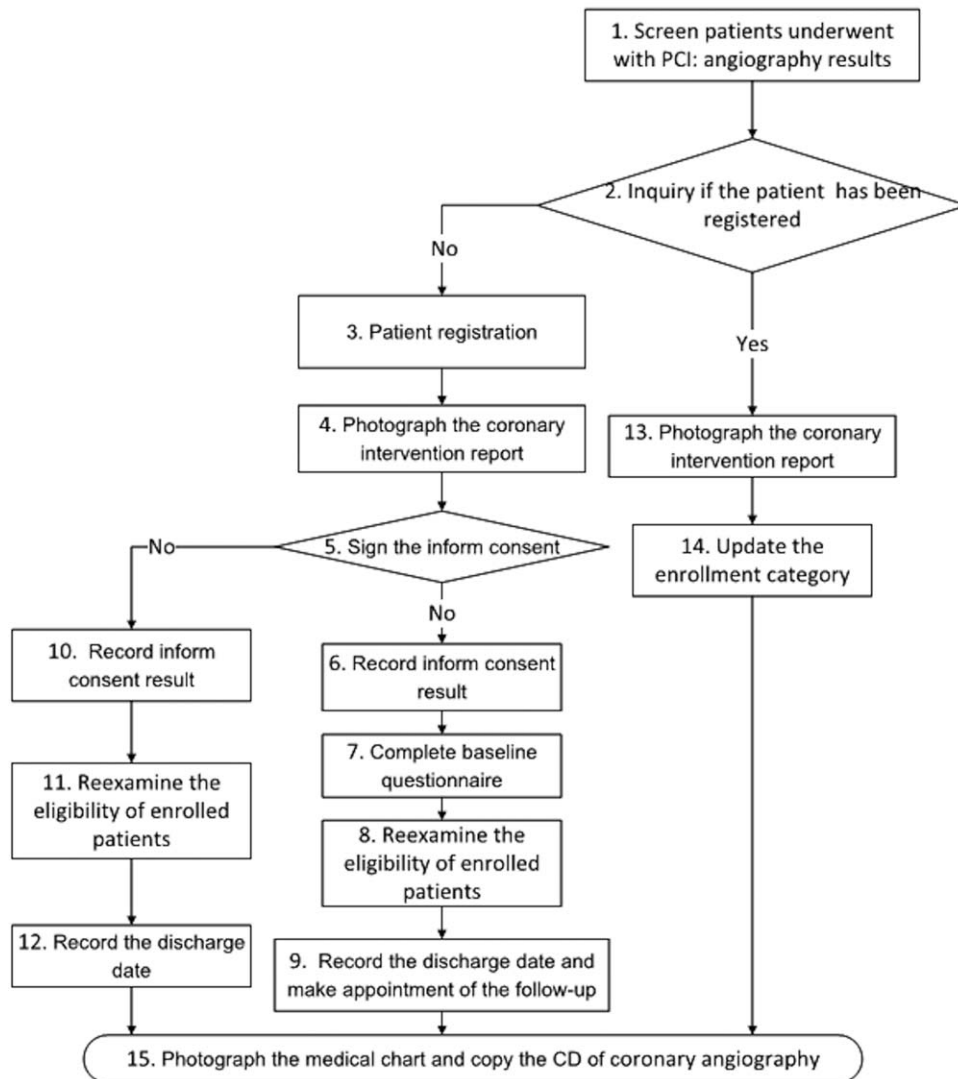
Fig. 4. The study flowchart of China patient-centered evaluative assessment of cardiac events (PEACE), Prospective Study of Percutaneous Coronary Intervention (PCI).

improvement, the principal objective this procedure in stable patients [16]. The collection of detailed demographic, clinical, treatment, and metabolic information will enable a comprehensive understanding of the disease trajectories and patients' experiences, and define the prognostic importance of clinical, biological and institutional factors for a broad range of outcomes. Such information could provide insights into improving the quality and effectiveness of health care among PCI patients in China, as well as those in other low- and middle-income countries.

As PCI, outside of the setting of primary PCI for reperfusion in the setting of an ST-elevation myocardial infarction, is generally undertaken to relieve the signs and symptoms of myocardial ischemia, the effects on symptom relief and quality of life are critically important for patients and health service decision-making [16]. PROs quantify patients' perspectives about the frequency and severity of their symptoms, how their disease impacts functioning, and the degree to which it limits their quality of life [31]. Despite the increasing recognition of the importance of

TABLE I.   Information Collected During the PCI Index Hospitalization and Follow-up

Domain	Scale	Baseline	1 month	6 month	12 month
Medical record review					
Medical history/risk factors		√			
Family history		√			
Clinical characteristics		√			
Diagnostic tests		√			
Treatments/procedures		√			
Discharge medications		√			
In-hospital outcomes		√			
Patient interviews					
Clinical outcomes					
Death			√	√	√
Myocardial infarction			√	√	√
Re-hospitalization			√	√	√
PROs					
CVD functional status	SAQ(21)	√	√	√	√
Health-related quality of life	EQ-5D(19)	√	√	√	√
Depression	PHQ-8(23)	√	√	√	√
Stress	PSS(24)	√	√	√	√
Social support	ESSI(44)	√			√
Obstructive sleep apnea	MBQ(32)	√			
Onset of symptoms					
Seeking care for symptoms		√			
Health care service		√			√
TCM clinic/therapies		√			√
Health care insurance		√			√
Medical expenses		√			√
Socio-economic status		√			√
Education		√			
Work status		√			√
Marital/living status		√			√
Household income		√			√
Health knowledge		√			√
Risk factors					
Lifestyle factors		√			√
Physical activity		√			√
Smoking status		√			√
Alcohol consumption		√			√
Adherence to secondary preventive medications			√	√	√
BMI/weight/hip circumference		√	√	√	√
Local tests					
Blood cell count			√		√
Urine analysis			√		√
Alanine transaminase		√	√		√
Creatinine/BUN		√	√		√
Blood glucose			√		√
Electrocardiogram			√	√	√
Bio-samples for central analysis					
Blood lipid profile		√			√
HbA1c		√			√
Alanine transaminase		√			√
Creatinine/BUN		√			√
Blood glucose		√			√
CK		√			√
Hs-CRP		√			√
Bio-samples for long-term storage					
Plasma/serum		√			√
DNA					√
Urine		√			√
Coronary angiogram				√	

PROs: patient-reported outcomes; CVD= cardiovascular disease; SAQ: Seattle Angina Questionnaire; EQ-5D: EuroQol Group 5-Dimension Self-Report Questionnaire; PHQ-8: Patient Health Questionnaire 8-item depression scale; PSS: Perceived Stress Scale; ESSI: Enhancing Recovery in Coronary Heart Disease (ENRICHD) Social Support Inventory; MBQ: Modified Berlin Questionnaire; BUN: blood urea nitrogen; HbA1c: hemoglobin A1c; HsCRP: high-sensitivity c-reactive Protein; CK: creatine kinase; RNA: riboNucleic acid.

PROs in health care, they have seldom been evaluated in clinical research for PCI in China [32,33]. Moreover, few previous studies have assessed PROs at multiple time points [16], limiting our ability to understand changes in patients' experience over time [34,35]. The China PEACE Prospective Study of PCI will bridge these knowledge gaps, and expand our knowledge on patients' long-term outcomes following PCI.

The data collected in China PEACE Prospective Study of PCI is unprecedented in scope for several reasons. First, we collected detailed data on both patient characteristics (e.g., demographic, clinical, psychosocial, behavioral factors, and hospital care received) and hospital attributes, which is useful in defining the determinants of patients' recovery. Then, the 12-month follow-up period extends traditional assessments of long-term mortality by including PROs, rate of adverse events, adherence to secondary prevention and risk control management. These data can also serve as a foundation for future comparative effectiveness studies of alternative treatment strategies to better understand their association with outcomes in China. In addition, risk-standardized outcomes models can be created to enable inter-institutional comparisons to inform the design of quality improvement strategies. Third, risk models and clinical prediction tools for clinical outcomes and PROs among PCI patients can be developed, which could fill in the gaps that none of existing scores used widely in routine clinical care have included Chinese patients and prediction models of health status outcomes are rare [36]. Moreover, the biosamples collected in this study will satisfy the basic science, translational, or clinical need that advances the care of patient undergoing PCI.

Another unique feature of this study is the imaging and/or angiogram review of index PCI by specialized "core" labs in China and the US. The lack of contemporary information about the quality of clinical interpretations of coronary angiograms may undermine the benefit of PCI, as the presence and severity of coronary stenosis play a key role in the selection of patients [37]. Recent data revealed that physicians tended to assess coronary lesions treated with PCI as more severe than measurements by angiographic core lab [38,39]. Importantly, with the rapid growth of PCI procedures in China, there is rising concern about the selection of patients and the appropriateness of PCI performance [40]. Thus, angiogram review in our study, to a certain degree, might provide valued opportunities to inform clinical interpretation of coronary angiography and, together with the assessment of appropriateness of PCI using Appropriate Use Criteria, will optimize the selection and care of patients undergoing PCI in contemporary practice.

CONCLUSION

The China PEACE Prospective Study of PCI is designed to explicitly examine short- and long-term survival, hospitalization, and PROs up to 12 months after PCI, to characterize trajectories of recovery, and to identify determinants of recovery. This study is uniquely positioned to inform strategies for improving care performance and patients' outcomes by generating novel, high-quality, and comprehensive data on patients' experience following PCI. Findings are intended to improve the efficient and appropriate use of PCI in a manner that optimizes patient outcomes.

ACKNOWLEDGMENTS

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