

BMJ Open The China Patient-Centred Evaluative Assessment of Cardiac Events (China PEACE)-Prospective Study of 3-Vessel Disease: rationale and design

Chenfei Rao,¹ Tasce Bongiovanni,² Xi Li,¹ Huawei Gao,^{1,3} Heng Zhang,^{1,3} Jing Li,¹ Yan Zhao,¹ Xin Yuan,^{1,3} Kun Hua,¹ Shengshou Hu,^{1,3} Harlan M Krumholz,² Lixin Jiang,¹ Zhe Zheng,^{1,3} for the China PEACE Collaborative Group

To cite: Rao C, Bongiovanni T, Li X, *et al*. The China Patient-Centred Evaluative Assessment of Cardiac Events (China PEACE)-Prospective Study of 3-Vessel Disease: rationale and design. *BMJ Open* 2016;**6**:e009743. doi:10.1136/bmjopen-2015-009743

► Prepublication history and additional material is available. To view please visit the journal (<http://dx.doi.org/10.1136/bmjopen-2015-009743>).

Received 19 August 2015
Revised 12 January 2016
Accepted 14 January 2016



CrossMark

For numbered affiliations see end of article.

Correspondence to
Dr Zhe Zheng;
zhengzhe@fuwai.com

ABSTRACT

Introduction: Complex coronary artery disease (left main and three-vessel disease) carries high risks of adverse events and cost burden. However, in China, little is known about which patients are directed toward which treatment strategies and what outcomes are being achieved.

Methods and analysis: Using the China PEACE (Patient-centered Evaluative Assessment of Cardiac Events) research network, this prospective study of three-Vessel Disease, the China PEACE-3VD study, has a plan to consecutively register over 4000 patients with a diagnosis of 3VD and/or left-main disease by elective coronary angiography at 24 large cardiovascular centres in China. We centrally conducted medical record abstraction and SYNTAX Score calculation for all registered patients. The sites invited patients to the prospective cohort, and conducted 1-year follow-up on major events, including cardiac events, symptoms, secondary prevention and quality of life. The estimated entire sample size of eligible patients of 4000 was determined based on both feasibility and consideration of adequate statistical precision for describing the treatment decisions, guidelines adherence and appropriateness of treatment for patients with complex coronary artery diseases. The study is designed to investigate patient, clinician and hospital factors associated with each treatment strategy (percutaneous coronary intervention, coronary artery bypass grafting or medical therapy) as well as appropriateness of treatment choice, current guideline compliance and patient-reported outcomes for patients with complex coronary artery disease in large cardiovascular centres in China, as a foundation for enhanced knowledge in the field and to assist quality improvement initiatives.

Ethics and dissemination: The study protocol was approved by the ethics committee at the China National Center for Cardiovascular Diseases. Findings will be shared with participating hospitals, policymakers and the academic community, to promote quality monitoring, quality improvement and the efficient allocation, and use of coronary revascularisation procedures in China.

Trial registration number: NCT01625312; Pre-results

Strengths and limitations of this study

- The study is the first national, prospective, observational study in China, aiming to describe the use of revascularisation procedures, and the association of treatment and its appropriateness with patients' 1-year outcomes.
- The study seeks to evaluate a broad range of outcomes, including major adverse cardiac and cerebrovascular events at 1 year, and patient-reported outcome measures, assessed with the Chinese-language Seattle Angina Questionnaire (SAQ) and EuroQoL questionnaire (EQ-5D).
- Rigorous data quality auditing methods are used to evaluate the quality of data.
- The participating sites are all large teaching hospitals, which may only represent large cardiac care centres in China and may not be reflective of the care patients receive in smaller or rural hospitals.

INTRODUCTION

With an ageing population and an increasing prevalence of cardiovascular risk factors,^{1 2} China is experiencing a rapid rise in coronary artery disease (CAD).^{1 3-5} Furthermore, the prevalence of the most complex and morbid diseases, three-vessel disease (3VD) and left main (LM) disease, together referred to as 'complex coronary artery disease (CCAD)', is growing concomitantly.⁶⁻⁹ The major treatment strategies for CCAD, coronary revascularisation via coronary artery bypass grafting (CABG) or percutaneous coronary intervention (PCI), has substantially increased in China. In 2013, nearly 30 000 CABG and 390 000 PCI procedures were performed,^{10 11} and the volumes of CABG and PCI continue to increase annually at the rates of about 8% and 15%, respectively.¹⁰⁻¹² Though the introduction of drug-eluting stents has decreased

restenosis rates of PCI,¹³ recent randomised controlled trials have failed to show significant advantages of PCI over CABG for CCAD specifically.^{8 14} Multiple recent guidelines designate CABG in combination with optimal medical therapy (OMT) as the standard of care for CCAD.^{7 15–17}

Studies of real-world practice in Western countries have identified patterns of inappropriate revascularisation use among patients with CCAD, especially use of PCI.^{18–22} In China, the PCI/CABG ratio is 13:1, much higher than the PCI/CABG ratio of 3:1 in many other countries.²³ This high ratio may partly be due to the limited number of cardiac surgery facilities and surgeons, as compared with the number of hospitals and cardiologists with the capability to perform PCI. There are approximately 700 hospitals with the ability to perform cardiac surgery, and over 1000 hospitals with PCI capability in China.^{11 24} Also, patients themselves may be choosing PCI over CABG given the upfront expense necessary in China's healthcare system, which demands as much as \$15 000 prior to CABG, as well as perceptions about the anticipated pain and suffering resulting from an open-heart procedure.²⁵ However, given the inadequate quality measurements and incentives to follow clinical guidelines for procedures in China,²⁶ as well as a disproportionate increase of PCI versus CABG among the majority of regions and hospitals,^{10 27 28} the high ratio of PCI to CABG has raised critical concerns about the selection of the type of revascularisation procedures for CCAD.

The Chinese version of PCI guidelines was published in 2012.²⁹ Foreign guidelines are also widely accepted in China.^{15 16} However, gaps in knowledge remain with regard to adherence of physicians to current guidelines and appropriate use criteria of the chosen treatment. Thoroughly evaluating this information, as well as understanding the variation among regions and hospitals in China, is critical to developing evidence-based and effective quality improvement initiatives for the decision-making process and quality of care for CCAD in Chinese populations.³⁰ Additionally, little is known about variations in treatment decisions, the key predictors of outcomes in order to benchmark levels of achievable outcomes. One study, based on China Cardiovascular Surgery Registry data, identified generally low mortality and complication rates after CABG, but these rates varied substantially by hospital and region.²⁸ Moreover, one single-centre retrospective observational study demonstrated lower rates of adverse events for CABG as compared with PCI using drug-eluting stents for multi-vessel disease.³¹ However, there are no prospective studies evaluating the selection of the type of treatment (CABG, PCI and/or optimal medical therapy) for patients with CCAD in cardiac centres with the capacity to perform both CABG and PCI. We know little about outcomes after these two treatments, including patient-reported outcome measures (PROMs).

To address these gaps, we have leveraged the China Patient-centered Evaluative Assessment of Cardiac Events (China PEACE) research network to perform the China PEACE-Pro prospective Study of 3-Vessel Disease (China PEACE-3VD). As previously described,^{32 33} China PEACE is a collaborative effort among the China National Center for Cardiovascular Diseases (NCCD), the Yale-New Haven Hospital Center for Outcomes Research and Evaluation, the Chinese government and a national network of Chinese hospitals. The goal of this network is to generate new knowledge relevant to practice and policy, and to translate this knowledge into action, to improve care and outcomes for patients with cardiovascular disease.

China PEACE-3VD has a plan to consecutively register over 4000 patients with a diagnosis of 3VD and/or left-main disease by elective coronary angiography at 24 large cardiovascular centres with capability to perform both CABG and PCI in China, to collect data from medical records and SYNTAX Scores, and invite patients to the prospective cohort to conduct 1-year follow-up on major events, including cardiac events and PROMs. China PEACE-3VD is the first national, prospective, observational study of CCAD patients in China, aiming to describe the use of revascularisation procedures, the association of treatment and its appropriateness with patients' 1-year outcomes, and the variation of treatments and outcomes among regions and sites.

There are three major goals of the China PEACE-3VD study. First, we aim to describe the treatment choice for each patient with CCAD in large cardiac care centres in China. Second, we aim to assess the alignment of treatment with the guidelines and appropriate use criteria (see online supplementary materials), and to evaluate the variation of treatment appropriateness among hospitals.^{7 15 17 34–38} Third, we aim to evaluate the relationship between appropriateness of treatment choices and patient outcomes including PROMs over 1 year. Additionally, we want to provide insights into key predictors of treatment strategy choices in-hospital and 1-year outcome for CCAD by evaluating the associations of demographic, clinical risk factors, coronary anatomy complexity (SYNTAX Score),³⁹ and psychosocial and socioeconomic factors, with patient outcomes. Further, we hope that the cohort of China PEACE-3VD can be used to assess the applicability of previously developed risk evaluation models (including the logistic EuroSCORE, SinoSCORE and SYNTAX Scores) for both PCI and CABG in the Chinese population. We will partner with the Chinese government, Chinese Medical Associations and other national and international organisations to disseminate findings from the China PEACE-3VD study to improve the care and outcomes for patients with CCAD.^{39–42} We hope that this study will benchmark levels of achievable outcomes to leverage quality improvement initiatives throughout the country.

METHODS AND ANALYSIS

Design overview

China PEACE-3VD consecutively enrolled patients with the diagnosis of CCAD by elective (scheduled 24 h prior) coronary artery angiography without previous history of CABG or PCI from a broad network of hospitals over a 1-year enrolment period (December 2012 to December 2013) into the prospective cohort. Trained coordinators at each site interviewed patients during their index hospitalisation, as well as at 1-month, 6-month and 12-month intervals following hospital discharge (figure 1). The core lab based at Fuwai Hospital reviewed and calculated all SYNTAX Scores for each patient's index coronary angiography. Medical records were scanned at each participating site and then transferred to the coordinating centre. The 'Real Data Medical Research Inc' group,⁴³ under the supervision of the coordinating centre, is centrally abstracting data from each medical record.

Additionally, patients who were not enrolled in the prospective cohort were added to a registry cohort, with only their medical record data and SYNTAX Scores collected.

Study population and recruitment

From December 2012 to December 2013, the cardiac catheterisation physicians at each local hospital routinely reviewed all elective coronary angiograms (scheduled 24 h before the procedure) within 2 days of the procedure, to identify patients diagnosed with coronary artery disease with significant stenosis ($\geq 50\%$ diameter) in three major coronary arteries or significant stenosis ($\geq 50\%$ diameter) in the left main coronary artery, based on the interventional cardiologist's interpretation. Exclusion criteria were as follows: history of prior revascularisation, an acute myocardial infarction within 24 h prior to the current procedure, or those who had been previously enrolled in the China PEACE-3VD study. Once patients were identified as eligible, we assigned

them a unique study ID. Since an important component of the study was to perform a detailed, in-person, patient interview, patients needed to be prospectively identified as early as possible during their hospitalisation.

We invited all eligible patients to enrol during their hospitalisation. We did not invite patients who were critically ill in the intensive care unit, nor those patients unable to understand the study questions due to cognitive function or language barriers, nor those who had already been discharged. We enrolled consenting patients into the prospective cohort, and then registered all remaining patients into the registry cohort. This registry cohort will be used to assess the representativeness of the study and will also be used to assess the entire range of treatment choices.

Site network

A research network was established in collaboration with 24 tertiary hospitals located in 17 provinces throughout China (figure 2 and online supplementary materials). We selected each hospital based on the following considerations: its capacity for performing both PCI and CABG; its position as a top-3 highest volume hospital for CABG and PCI in the located province or direct-controlled municipality; the study team's prior experience with participating in a clinical study; overall representation of geographic locations across the country; and the feasibility of conducting the study at the given site. All hospitals contacted agreed to participate.

In order to optimise the design, we conducted a pilot study at Fuwai Hospital, one of the leading cardiovascular hospitals in China. From July 2011 to September 2012, we enrolled over 1500 patients in the pilot study.

Data elements

We examined both the English and Chinese language literature for relevant studies to create a candidate list of potential data elements (table 1). Whenever possible,

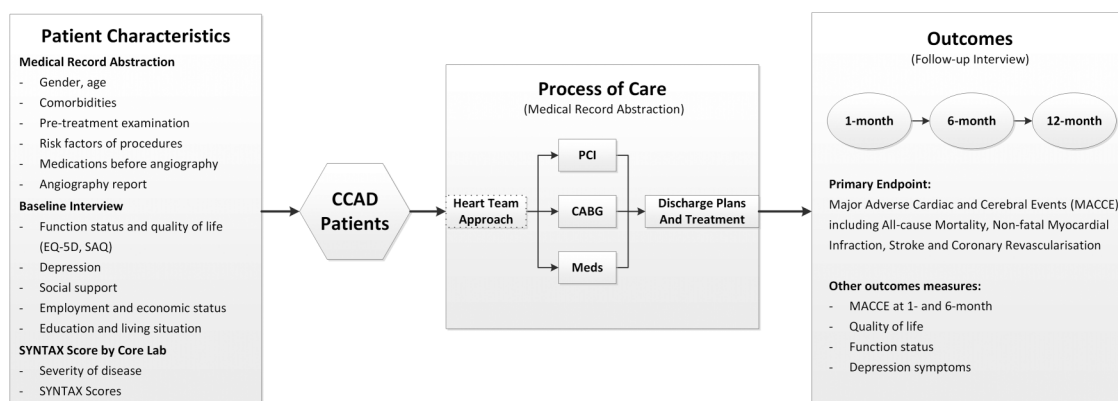


Figure 1 Design and study overview of China PEACE-3VD. CABG, coronary artery bypass grafting; Meds indicates medical therapy; CCAD, complex coronary artery disease; EQ-5D, EuroQol Questionnaire; PCI, percutaneous coronary intervention; PEACE-3VD, Patient-centered Evaluative Assessment of Cardiac Events three-vessel disease study; SAQ, Seattle Angina Questionnaire.



Figure 2 Geographic distribution of China PEACE-3VD participating Centres. PEACE-3VD, Patient-centered Evaluative Assessment of Cardiac Events three-vessel disease study.

the 2013 American College of Cardiology/American Heart Association (ACC/AHA) “Clinical Data Elements and Definitions for Measuring the Clinical Management and Outcomes of Patients With Acute Coronary Syndromes and Coronary Artery Disease” were used to define clinical characteristics of patients’ presentation, comorbidities and clinical risk factors.⁴⁴ Procedural characteristics were obtained using definitions from the AHA/ACCF Clinical Data Elements and Definitions and the Society of Thoracic Surgeons Adult Cardiac Surgery Database.^{44 45} Additionally, we included elements specific to the Chinese context of this study, such as the use of traditional Chinese medicine. As per prior studies, measures were selected from the existing literature whenever possible so that valid and reproducible estimates of each concept could be acquired.^{46 47}

China PEACE-3VD seeks to evaluate a broad range of outcomes. The primary outcome measure is the composite measure of MACCE (major adverse cardiac and cerebrovascular events, the composite end point of all-cause mortality, non-fatal myocardial infarction, stroke and additional coronary revascularisation) at 1 year. The major secondary end points are PROMs at 1 year. The study used the EQ-5D instrument as a measure of generic health-related quality of life,^{48 49} which also enables the estimation of utilities, and the Seattle Angina Questionnaire (SAQ), to assess condition-specific functioning and quality of life.^{50 51} Psychosocial status was assessed for depressive symptoms (8-item Patient Health Questionnaire: PHQ-8).⁵² The detailed questionnaires are available in the online supplementary materials.

Table 1 China PEACE-3VD data elements

Variables	Medical record	SYNTAX Score	Baseline	Follow-up interviews		
				1-month	6-month	12-month
Clinical characteristics						
Medical history	✓					
CAD family history			✓			✓
Lab testing	✓					
Physical testing	✓					
Image examination	✓					
SYNTAX Score		✓				
Treatment						
Progress note	✓					
Drug treatment	✓					
Procedures	✓					
Secondary prevention	✓					
Secondary prevention compliance				✓	✓	✓
Patient characteristics						
Basic information			✓			
Contact			✓	✓	✓	✓
BMI/weight/waistline			✓	✓	✓	✓
Socioeconomic status			✓			✓
Outcomes						
Death				✓	✓	✓
MACCE				✓	✓	✓
Rehospitalisation				✓	✓	✓
Depression			✓	✓	✓	✓
EQ-5D			✓	✓	✓	✓
SAQ			✓	✓	✓	✓
Blood pressure	✓			✓	✓	✓
Blood glucose	✓				✓	✓
Blood lipid	✓				✓	✓
Hepatic function	✓				✓	✓
Renal function	✓				✓	✓

BMI, body mass index; CAD, coronary artery disease; EQ-5D, EuroQol Questionnaire; MACCE, major adverse cardiac and cerebrovascular event; SAQ, Seattle Angina Questionnaire.

Medical record abstraction

Coordinators from each local site scanned all medical charts of patients in either the prospective or registry cohorts, then transmitted the scanned copy to the coordinating centre through the mail on encrypted, password-protected flash drives to the coordinating centre. The medical records were evaluated for completeness and de-identified through covering all personal information in the medical charts. The medical charts included the patients' cardiac and non-cardiac history, non-invasive testing (both, the reports and the recorded ECGs), laboratory results, in-hospital medications and procedures, in-hospital complications, discharge medications and discharge disposition. This information was abstracted by a group of trained abstractors under the supervision of trained quality control personnel, cardiologists and cardiac surgeons. The China PEACE-3VD Study adhered to rigorous standards for medical record transmission and data abstraction, similar to the previously published China PEACE-Retrospective Acute Myocardial Infarction Study and the Percutaneous Coronary Intervention Study.^{32 33}

The case report form and quality control of medical record data abstraction are documented in the online supplementary materials.

SYNTAX Score calculation

The participating hospitals sent all index catheterisation angiography discs of patients in either the prospective cohort or registry cohort to the coordinating centre through a safe transport system. Two specialty-trained cardiologists independently reviewed each angiogram. The Core Lab is calculating SYNTAX Scores. If the difference between the 2 reviewed SYNTAX Scores was larger than 5, a third physician also reviewed the angiogram and resolved disputes. Additionally, the Core Lab is calculating scores on each lesion.

Participant interviews

We interviewed participants in the prospective cohort during their index hospitalisation and at 1-month, 6-month and 12-month intervals. Follow-up interviews were conducted face to face whenever possible.

However, if a patient was unable or unwilling to return to the coordinating hospital, then a telephone interview was acceptable.

Central project managers provided 1-h standardised training to all interviewers, which included training on interview skills, and described the significance of each question during the initial meeting. To ensure coordinators' understanding of inclusion and exclusion criteria and study processes, two project managers conducted on-site monitoring within 2 months of the initial meeting at all sites. The second on-site monitoring visit was conducted 6 months after the initiation of the study, to observe follow-up interviews. All interviews were automatically recorded and transmitted to the coordinating centre. We then randomly selected 10% of these records for review by project managers to ensure adherence to study protocol.

Data management

We treated all data as protected health information and stored it securely in an encrypted and password-protected database at the coordinating centre. We securely stored paper charts in a locked room.

We developed data management procedures using tablet and web-based technology to ensure accurate, efficient and real-time data collection and analysis. The collection, shipping and receipt of data carriers were tracked by the coordinating centre.

Statistical analysis

We will report summary statistics for patient demographic, clinical, psychosocial and behavioural characteristics; use of diagnostic tests; treatments received; and the guideline adherence and appropriateness of in-hospital treatment strategies. We will calculate summary statistics for MACCE, as well as PROMs within 1, 6 and 12 months after enrolment. In order to identify risk factors associated with treatment appropriateness and outcomes, we will use parametric and non-parametric tests for bivariate analyses, such as *t* test, χ^2 test, Fisher's exact test and Wilcoxon rank sum tests. Moreover, multivariable regression analyses, including linear, logistic, Cox proportional hazard and Poisson models, will be used to assess the factors' association with outcomes after adjusting for potential confounders. As patients are clustered within centres and different measurement points of outcomes are clustered within patients, the analyses will account for clustering in the data (eg, generalised estimating equations or random effects models). Some missing data are expected. We will evaluate any potential selection biases introduced by missing data and conduct inverse probability weighting when appropriate, based on a propensity model, for participation in the follow-up assessments, to preferentially weight the data of patients who were most like the patients with missing data regarding outcome measures. In addition, propensity score matching and instrumental

variable methods will be implemented to minimise confounding and selection bias, if necessary.

Sample size calculation

The current study is primarily a descriptive one to generate information on how patients with CCAD are treated and what outcomes they experience. The 1-year enrolment period and estimated entire sample size of eligible patients (both enrolled and not enrolled) of 4000 was determined based on both feasibility and consideration of adequate statistical precision for describing the treatment decisions, guidelines adherence and appropriateness of treatment (see online supplementary materials). We anticipated that the rate of MACCE for the entire cohort was 8% and hypothesised that at least 50% of eligible patients enrolled into the prospective cohort, and the loss-to-follow up rate was less than 10%. The projected sample size was calculated to achieve 84% statistical power at a two-sided 0.05 significance level to detect a primary end point difference of 4%.

We will report on the results of this study by presenting research abstracts at international conferences and by publishing original articles in peer-reviewed journals. Important findings will be shared with participating hospitals and policymakers to promote quality monitoring, quality improvement and the efficient allocation and use of coronary revascularisation procedures in China as well as the rest of the world.

Progress to date

Twenty-four hospitals agreed to participate in the study. All participating sites are tertiary teaching hospitals capable of performing both CABG and PCI. Six sites are located in Northwest China, five in North China, seven in East China and six in South Central China. The distribution of sites by province and region is shown in [figure 2](#).

As of December 2013, we had consecutively enrolled 2339 patients into the prospective cohort, with an additional 2297 patients enrolled into the registry cohort. We began medical record data abstraction and SYNTAX Score calculations in January 2015, and have abstracted 3472 (75.2%) medical records and calculated SYNTAX Scores of 3297 (71.4%) patients. We have also compared demographic and clinical characteristics between the prospective and registry cohorts ([table 2](#)). Patients in the prospective cohort were more likely to be younger and male compared to those in the registry cohort.

The follow-up interviews have been completed. We have interviewed 96% of all enrolled patients at 1 month, 93% at 6 months and 94% at 12 months. We found that the 1-year MACCE and all-cause mortality rates of prospective cohort patients with available outcomes data are 8.3% and 2.9%, respectively ([table 2](#)).

DISCUSSION

The China PEACE initiative provides a platform for translating knowledge into improved care in various

Table 2 Baseline characteristics and cumulative outcomes of patients enrolled and not enrolled in China PEACE-3VD*

Characteristics	Enrolled (n=2089)	Not enrolled (n=1383)	p Value
Age, years	62.4±9.8	63.4±10.3	0.007
Male, %	70.7	67.5	0.051
No insurance, %	25.5	22.7	0.059
Diabetes mellitus, %	27.8	25.7	0.163
Hypertension, %	67.0	65.3	0.306
Prior MI, %	33.5	34.9	0.414
Prior heart failure, %	2.7	3.3	0.370
Prior stroke, %	11.4	12.8	0.228
LVEF <40%, %	5.6	4.6	0.207
SYNTAX Scores	22.0±11.0	22.1±11.3	0.791
One year outcomes, %			
MACCE	8.3		
All-cause death	2.9		
MI	1.4		
Stroke	0.9		
Additional revascularisation	4.3		

*This table included all available data as of July 2015, and the database was not locked.

CABG, coronary artery bypass grafting; LVEF, left ventricular ejection fraction; MACCE, major adverse cardiac and cerebrovascular events; MI, myocardial infarction.

settings of cardiovascular diseases in China. As one of five initial studies from the China PEACE initiative, China PEACE-3VD is a multicentre prospective study designed to develop a repository of data that describes the current presentation, treatment and 1-year outcomes for CCAD in China. This project aims to provide answers to questions about contemporary practice patterns, including variation among institutions and physicians, in procedure use and adjunctive therapy, as well as the appropriateness of treatment and adherence to current guidelines of revascularisation procedures for CCAD. The findings of the China PEACE-3VD Study will be shared with participating sites for further quality improvement initiatives, and with the Chinese government to help inform policy improvement and change.

Inappropriate use of revascularisation procedures is a major problem in developed countries.^{18–22} Chan and colleagues used Appropriate Use Criteria to identify that nearly all acute PCIs in the National Cardiovascular Data Registry CathPCI Registry were appropriate, while PCI treatment during 49.6% of non-acute cardiac catheterisations were classified as inappropriate or uncertain.²⁰ Another study reached similar conclusions using data from the Clinical Outcomes Assessment Programme in Washington State.²¹ With use of New York State's Cardiac Surgery Reporting System and the Percutaneous Coronary Interventions Reporting System, Hannan and colleagues found that 1% of CABG and 14% of PCI were incongruous with current guidelines.¹⁸

The use of CABG as well as of PCI is expanding rapidly in China. The very high ratio of PCI/CABG (13:1) has recently evoked a national debate prompting close examination of the appropriateness of revascularisation. This disproportionate ratio may be somewhat explained by the limited number of cardiac surgeons in China. However, long-term outcomes favour CABG for patients with CCAD, especially those with high SYNTAX Scores.⁸ With inadequate quality measurement and incentives on appropriateness of procedures,²⁶ and a pervasive culture of retribution from family members of patients who die or have adverse events during hospitalisation,^{53 54} clinicians may concentrate on in-hospital and short-term outcomes rather than long-term outcomes and quality of life, leading them to ignore the appropriateness guidelines and offer less-invasive procedures. In the setting of stable CCAD, for which inappropriate procedures have been frequently described in other settings, the chosen treatment may not be suitable for individual patients. Using widely accepted guidelines and Appropriate Use Criteria, the China PEACE-3VD Study will provide a unique opportunity to thoroughly assess the appropriateness and adherence to current guidelines of revascularisation choices, as well as the association of treatment appropriateness with long-term events and PROMs.^{7 15 17 34 37} Further analysis of risk factors for inappropriate revascularisation will provide evidence for the 'inappropriate revascularisation debate' in China, and guide future quality improvement initiatives.

We also expect that the knowledge generated from the China PEACE-3VD Study will be useful internationally. Many developing countries are undergoing a similar epidemiological transition,⁵⁵ with great strides in increasing accessibility of care, but limited monitoring of the appropriateness and quality of care. Through carefully evaluating the appropriateness of treatment, and roles of clinicians and patients in the decision-making process, we may provide valuable evidence for other countries experiencing comparable challenges. Though large trials have illuminated specific outcomes after CABG and PCI, the recovery trajectories of patients who undergo these interventions in real-world practice may be different from those in trial settings. Further analysis of the relationship between revascularisation selection and patients' quality of life and functional status may provide evidence for more wealthy countries to guide cardiac rehabilitation programmes.

The China PEACE-3VD Study is distinctive from many prospective observational studies by its use of data quality control strategies that are commonly adopted by large clinical trials. The study has devoted significant attention to data quality at multiple stages, including coordinators' training and certification, data abstraction and interview monitoring. Our quality control and assurance strategies help ensure the data quality, and promote the translation of knowledge from China PEACE-3VD Study into action.

Our study has several limitations. Only the patients who agreed and signed the informed consent forms were prospectively enrolled and followed. This may have caused selection bias. However, we were able to collect basic information on the index hospitalisation of patients not enrolled, making it possible to assess the influence of enrolment and patients' preference on the representativeness of the study. Additionally, our participating sites are all large teaching hospitals, which may only represent large urban centres in China and may not be reflective of the care patients receive in smaller or rural hospitals. However, our work can still inform quality improvement projects that may reach these smaller hospitals, having the potential to improve care throughout China. For the baseline interview, we only collected data regarding patients' symptoms, treatment and quality of life before hospitalisation. However, interview details may have been influenced for patients undergoing ad hoc PCI that occurred prior to the baseline interview.

As one of five initial studies from the China PEACE initiative, China PEACE-3VD is a multicentre prospective study, seeking to describe the current presentation, treatment and patient outcomes of non-acute CCAD in a multicentre sample of large hospitals in China. This project will provide answers to questions about contemporary practice patterns, including variation among institutions in procedure use and adjunctive therapy, as well as the appropriateness and guideline adherence of revascularisation procedures for CCAD. The findings of the China PEACE-3VD Study will be shared with participating sites, for further quality improvement initiatives, and with the government, to help research findings inform policy.

Author affiliations

¹National Clinical Research Center of Cardiovascular Diseases, State Key Laboratory of Cardiovascular Disease, Fuwai Hospital, National Center for Cardiovascular Diseases, Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing, People's Republic of China

²Yale School of Public Health, Yale University School of Medicine, and Yale-New Haven Hospital, New Haven, Connecticut, USA

³Department of Cardiovascular Surgery, Fuwai Hospital, National Center for Cardiovascular Diseases, Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing, People's Republic of China

Acknowledgements The authors thank Drs Cheng Sun and Dachuan Gu from National Clinical Research Center of Cardiovascular Diseases, State Key Laboratory of Cardiovascular Disease, Fuwai Hospital, National Center for Cardiovascular Diseases, Beijing, China, for their contribution in the collection and translation of study documents.

Contributors CR and TB made substantial contributions to study conception and design, and to the drafting and critical revision of the manuscript for important intellectual content. HG, HZ, JL, YZ, XY, KH, SH and LJ made substantial contributions to the study conception and design, and critical revision of the manuscript for important intellectual content. ZZ and HMK made substantial contributions to study conception and design, drafting and critical revision of the manuscript for important intellectual content, and provided administrative, technical and material support, including study supervision.

Funding This project was supported by the International Science and Technology Cooperation Programme of China (2010DFB33140) and the Key Project in the National Science and Technology Pillar Programme during the 12th 5-year plan period (2011BAI11B02, 2011BAI11B21, 2013BAI09B01).

Competing interests None declared.

Patient consent Obtained.

Ethics approval The Ethics Committee at the China National Center for Cardiovascular Diseases.

Provenance and peer review Not commissioned; externally peer reviewed.

Open Access This is an Open Access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited and the use is non-commercial. See: <http://creativecommons.org/licenses/by-nc/4.0/>

REFERENCES

1. Yang G, Kong L, Zhao W, *et al.* Emergence of chronic non-communicable diseases in China. *Lancet* 2008;372:1697–705.
2. Hu S, Kong L. *Report on Cardiovascular Diseases in China (2011)*. Encyclopedia of China Publishing House, 2012.
3. He J, Gu D, Wu X, *et al.* Major causes of death among men and women in China. *N Engl J Med* 2005;353:1124–34.
4. Moran A, Gu D, Zhao D, *et al.* Future cardiovascular disease in China: Markov model and risk factor scenario projections from the coronary heart disease policy model-China. *Circ Cardiovasc Qual Outcomes* 2010;3:243–52.
5. Li J, Li X, Wang Q, *et al.* ST-segment elevation myocardial infarction in China from 2001 to 2011 (the China PEACE-Retrospective Acute Myocardial Infarction Study): a retrospective analysis of hospital data. *Lancet* 2015;385:441–51.
6. D'Ascenzo F, Presutti DG, Picardi E, *et al.* Prevalence and non-invasive predictors of left main or three-vessel coronary disease: evidence from a collaborative international meta-analysis including 22 740 patients. *Heart* 2012;98:914–19.
7. Patel MR, Dehmer GJ, Hirshfeld JW, *et al.* ACCF/SCAI/STS/AATS/AHA/ASNC/HFSA/SCCT 2012 appropriate use criteria for coronary revascularization focused update: a report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Association for Thoracic Surgery, American Heart Association, American Society of Nuclear Cardiology, and the Society of Cardiovascular Computed Tomography. *J Am Coll Cardiol* 2012;59:857–81.
8. Serruys PW, Morice MC, Kappetein AP, *et al.* Percutaneous coronary intervention versus coronary-artery bypass grafting for severe coronary artery disease. *N Engl J Med* 2009;360:961–72.
9. Hong LF, Li XL, Guo YL, *et al.* Glycosylated hemoglobin A1c as a marker predicting the severity of coronary artery disease and early outcome in patients with stable angina. *Lipids Health Dis* 2014;13:89.
10. Tribune CM. *Report on the latest data of China cardiovascular intervention treatment in 2013*. 2014. <http://www.iijy.com/d-29-198697.html>
11. Deming Zhu CL, Hei F. White Paper On 2013 China cardiac surgery and extracorporeal circulation data. *Chin J Extracorporeal Circ* 2014;2014:129–31.
12. Hu S, Kong L, Gao R, *et al.* *Report On Cardiovascular Diseases In China (2012)*. Encyclopedia of China Publishing House, 2013.
13. Stettler C, Wandel S, Allemann S, *et al.* Outcomes associated with drug-eluting and bare-metal stents: a collaborative network meta-analysis. *Lancet* 2007;370:937–48.
14. Farkouh ME, Domanski M, Sleeper LA, *et al.* Strategies for multivessel revascularization in patients with diabetes. *N Engl J Med* 2012;367:2375–84.
15. Wijns W, Kolh P, Danchin N, *et al.* Guidelines on myocardial revascularization. *Eur Heart J* 2010;31:2501–55.
16. Hillis LD, Smith PK, Anderson JL, *et al.* 2011 ACCF/AHA Guideline for Coronary Artery Bypass Graft Surgery. A report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Developed in collaboration with the American Association for Thoracic Surgery, Society of

- Cardiovascular Anesthesiologists, and Society of Thoracic Surgeons. *J Am Coll Cardiol* 2011;58:e123–210.
17. Levine GN, Bates ER, Blankenship JC, *et al.* 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention: executive summary: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions. *Circulation* 2011;124:2574–609.
 18. Hannan EL, Cozzens K, Samadashvili Z, *et al.* Appropriateness of coronary revascularization for patients without acute coronary syndromes. *J Am Coll Cardiol* 2012;59:1870–6.
 19. Spertus J, Chan P. The need to improve the appropriate use of coronary revascularization: challenges and opportunities. *J Am Coll Cardiol* 2012;59:1877–80.
 20. Seo SM, Choo EH, Koh YS, *et al.* Catholic University of Korea, Percutaneous Coronary Intervention Registry investigators. High-density lipoprotein cholesterol as a predictor of clinical outcomes in patients achieving low-density lipoprotein cholesterol targets with statins after percutaneous coronary intervention. *Heart* 2011;97:1943–50.
 21. Bradley SM, Maynard C, Bryson CL. Appropriateness of percutaneous coronary interventions in Washington State. *Circ Cardiovasc Qual Outcomes* 2012;5:445–53.
 22. Ko DT, Guo H, Wijeyesundera HC, *et al.* Assessing the association of appropriateness of coronary revascularization and clinical outcomes for patients with stable coronary artery disease. *J Am Coll Cardiol* 2012;60:1876–84.
 23. OECD. *Health at a glance 2009*. OECD Publishing, 2009.
 24. Huo Y, Liu Z. Commemorate the 30th anniversary of coronary intervention therapy in China: history and development. *Chin J Cardiol* 2014;10:802–3.
 25. Hu S, Zheng Z, Yuan X, *et al.* Increasing long-term major vascular events and resource consumption in patients receiving off-pump coronary artery bypass: a single-center prospective observational study. *Circulation* 2010;121:1800–8.
 26. Emanuel E, Emanuel L. What is accountability in health care? *Ann Intern Med* 1996;124:229–39.
 27. Zheng Z, Zhang L, Hu S, *et al.* Risk factors and in-hospital mortality in Chinese patients undergoing coronary artery bypass grafting: analysis of a large multi-institutional Chinese database. *J Thorac Cardiovasc Surg* 2012;144:355–9, 59.e1.
 28. Hu S, Zheng Z, Yuan X, *et al.* Coronary artery bypass graft: contemporary heart surgery center performance in China. *Circ Cardiovasc Qual Outcomes* 2012;5:214–21.
 29. Section of Interventional Cardiology, Chinese Society of Cardiology of Chinese Medical Association; Editorial Board of Chinese Journal of Cardiology. [Chinese guideline for percutaneous coronary intervention (pocket guideline)]. *Zhonghua Xin Xue Guan Bing Za Zhi* 2012;40:271–7.
 30. Harris-Hayes M, McDonough CM, Leunig M, *et al.* Clinical outcomes assessment in clinical trials to assess treatment of femoroacetabular impingement: use of patient-reported outcome measures. *J Am Acad Orthop Surg* 2013;21(Suppl 1):S39–46.
 31. Li Y, Zheng Z, Xu B, *et al.* Comparison of drug-eluting stents and coronary artery bypass surgery for the treatment of multivessel coronary disease: three-year follow-up results from a single institution. *Circulation* 2009;119:2040–50.
 32. Dharmarajan K, Li J, Li X, *et al.* The China Patient-Centered Evaluative Assessment of Cardiac Events (China PEACE) retrospective study of acute myocardial infarction: study design. *Circ Cardiovasc Qual Outcomes* 2013;6:732–40.
 33. Li J, Dharmarajan K, Li X, *et al.* Protocol for the China PEACE (Patient-Centered Evaluative Assessment of Cardiac Events) retrospective study of coronary catheterisation and percutaneous coronary intervention. *BMJ Open* 2014;4:e004595.
 34. Hillis LD, Smith PK, Anderson JL, *et al.* 2011 ACCF/AHA Guideline for Coronary Artery Bypass Graft Surgery: executive summary: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Circulation* 2011;124:2610–42.
 35. Fihn SD, Blankenship JC, Alexander KP, *et al.* 2014 ACC/AHA/AATS/PCNA/SCAI/STS focused update of the guideline for the diagnosis and management of patients with stable ischemic heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines, and the American Association for Thoracic Surgery, Preventive Cardiovascular Nurses Association, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. *J Thorac Cardiovasc Surg* 2015;149:e5–23.
 36. Kolh P, Windecker S, Alfonso F, *et al.* 2014 ESC/EACTS Guidelines on myocardial revascularization: the Task Force on Myocardial Revascularization of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS). Developed with the special contribution of the European Association of Percutaneous Cardiovascular Interventions (EAPCI). *Eur J Cardiothorac Surg* 2014;46:517–92.
 37. Patel MR, Dehmer GJ, Hirshfeld JW, *et al.* ACCF/SCAI/STS/AATS/AHA/ASNC 2009 Appropriateness Criteria for Coronary Revascularization: a Report of the American College of Cardiology Foundation Appropriateness Criteria Task Force, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Association for Thoracic Surgery, American Heart Association, and the American Society of Nuclear Cardiology: Endorsed by the American Society of Echocardiography, the Heart Failure Society of America, and the Society of Cardiovascular Computed Tomography. *Circulation* 2009;119:1330–52.
 38. Wolk MJ, Bailey SR, Doherty JU, *et al.* ACCF/AHA/ASE/ASNC/HFSA/HRS/SCAI/SCCT/SCMR/STS 2013 multimodality appropriate use criteria for the detection and risk assessment of stable ischemic heart disease: a report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Heart Failure Society of America, Heart Rhythm Society, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and Society of Thoracic Surgeons. *J Am Coll Cardiol* 2014;63:380–406.
 39. Sianos G, Morel MA, Kappetein AP, *et al.* The SYNTAX Score: an angiographic tool grading the complexity of coronary artery disease. *EuroIntervention* 2005;1:219–27.
 40. Nashef SA, Roques F, Michel P, *et al.* European system for cardiac operative risk evaluation (EuroSCORE). *Eur J Cardiothorac Surg* 1999;16:9–13.
 41. Nashef SA, Roques F, Sharples LD, *et al.* EuroSCORE II. *Eur J Cardiothorac Surg* 2012;41:734–44; discussion 44–5.
 42. Zheng Z, Zhang L, Li X, *et al.* SinoSCORE: a logistically derived additive prediction model for post-coronary artery bypass grafting in-hospital mortality in a Chinese population. *Front Med* 2013;7:477–85.
 43. Inc. RDMR. Home Page of Real Data Medical Research Inc. (<http://www.realdatamed.com/>). Secondary Home Page of Real Data Medical Research Inc. 2013.
 44. Cannon CP, Brindis RG, Chaitman BR, *et al.* 2013 ACCF/AHA key data elements and definitions for measuring the clinical management and outcomes of patients with acute coronary syndromes and coronary artery disease: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Acute Coronary Syndromes and Coronary Artery Disease Clinical Data Standards). *Circulation* 2013;127:1052–89.
 45. Database TSoTSN. The Society of Thoracic Surgeons Adult Cardiac Surgery Database Data Collection Form. 2014. <http://www.sts.org/sts-national-database/>
 46. Arnold SV, Chan PS, Jones PG, *et al.* Translational Research Investigating Underlying Disparities in Acute Myocardial Infarction Patients' Health Status (TRIUMPH): design and rationale of a prospective multicenter registry. *Circ Cardiovasc Qual Outcomes* 2011;4:467–76.
 47. Lichtman JH, Lorenze NP, D'Onofrio G, *et al.* Variation in recovery: role of gender on outcomes of young AMI patients (VIRGO) study design. *Circ Cardiovasc Qual Outcomes* 2010;3:684–93.
 48. EuroQol Group. EuroQol—a new facility for the measurement of health-related quality of life. *Health Policy* 1990;16:199–208.
 49. Li M, Luo N. Application of EQ-5D Chinese version. *Chin J Pharm Econ* 2009;1:49–57.
 50. Spertus JA, Winder JA, Dewhurst TA, *et al.* Development and evaluation of the Seattle Angina Questionnaire: a new functional status measure for coronary artery disease. *J Am Coll Cardiol* 1995;25:333–41.
 51. Li J, Chang G. Assessment of SAQ for measuring quality of life among patients with coronary heart disease. *Chin J Public Health* 2004;20:594.
 52. Kroenke K, Strine TW, Spitzer RL, *et al.* The PHQ-8 as a measure of current depression in the general population. *J Affect Disord* 2009;114:163–73.
 53. [No authors listed]. Ending violence against doctors in China. *Lancet* 2012;379:1764.
 54. [No authors listed]. Chinese doctors are under threat. *Lancet* 2010;376:657.
 55. Nugent R. Chronic diseases in developing countries: health and economic burdens. *Ann N Y Acad Sci* 2008;1136:70–9.

BMJ Open

The China Patient-Centred Evaluative Assessment of Cardiac Events (China PEACE)-Prospective Study of 3-Vessel Disease: rationale and design

Chenfei Rao, Tasce Bongiovanni, Xi Li, Huawei Gao, Heng Zhang, Jing Li, Yan Zhao, Xin Yuan, Kun Hua, Shengshou Hu, Harlan M Krumholz, Lixin Jiang and Zhe Zheng

BMJ Open 2016 6:
doi: 10.1136/bmjopen-2015-009743

Updated information and services can be found at:
<http://bmjopen.bmj.com/content/6/2/e009743>

These include:

- | | |
|-------------------------------|--|
| Supplementary Material | Supplementary material can be found at:
http://bmjopen.bmj.com/content/suppl/2016/02/15/bmjopen-2015-009743.DC1.html |
| References | This article cites 48 articles, 19 of which you can access for free at:
http://bmjopen.bmj.com/content/6/2/e009743#BIBL |
| Open Access | This is an Open Access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited and the use is non-commercial. See: http://creativecommons.org/licenses/by-nc/4.0/ |
| Email alerting service | Receive free email alerts when new articles cite this article. Sign up in the box at the top right corner of the online article. |
-

Topic Collections

Articles on similar topics can be found in the following collections

[Cardiovascular medicine](#) (605)
[Evidence based practice](#) (539)
[Patient-centred medicine](#) (337)
[Research methods](#) (460)

Notes

To request permissions go to:
<http://group.bmj.com/group/rights-licensing/permissions>

To order reprints go to:
<http://journals.bmj.com/cgi/reprintform>

To subscribe to BMJ go to:
<http://group.bmj.com/subscribe/>