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Protocol of the China STEMI Care Project: a 10-year project to improve quality of care by building up the regional STEMI care network

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Keywords:	Accreditation, chest pain center, network, reperfusion, ST-elevation myocardial infarction

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This project was initialed in 2011 and will be finished in 2021.

Abstract

Introduction: The China STEMI (ST-elevation myocardial infarction) Care Project (CSCAP) aimed to improve the reperfusion treatment rate and shorten the total duration of myocardial ischemia by establishing a regional STEMI treatment network covering the whole city region, whole city population, and whole disease processes step by step.

Methods and analysis: This is a prospective, multicenter registry involving three stages. And the CSCAP included 18 provinces, 4 municipalities, and 2 autonomous regions in China. Patients with STEMI who met with the third acute myocardial infarction definition of 2012 and the Chinese STEMI diagnosis and treatment guidelines were enrolled. Phase 1 focused on the in-hospital process optimization of primary percutaneous coronary intervention (PPCI) hospitals; phase 2 on the PPCI hospital-based regional STEMI transfer network, including emergency medical services and non-PPCI hospitals; and phase 3 on the whole-city STEMI care network construction by promoting chest pain center accreditation. Systematic data collection, assessment of quality of care, and subsequent improvement were implemented throughout the project to continuously improve the quality of care for patients with STEMI in the project.

Ethics and dissemination: CSCAP, with the establishment of an intrinsic feedback and certification system, will provide a tailored and continuous quality of STEMI care improvement plan based on the conditions of different regions to further integrate the STEMI care network nationwide.

Key words: Accreditation, chest pain center, network, reperfusion, ST-elevation myocardial infarction

Strengths and limitations of this study

CSCAP is the first project that focused on establishing a regional STEMI emergency care network in China, which will help to understand the condition of STEMI care in China extensively. Moreover, quality of STEMI care will be optimized through in-hospital process optimization, PPCI hospital-based regional STEMI transfer network construction, and the whole-city STEMI care network construction step by step. However, hospitals in CSCAP were not randomly selected, which might be because of lack of representatives to some degree. Alternatively, it will provide a tailored quality of care improvement plan based on the conditions of different regions.

Introduction

The disease burden of cardiovascular diseases is increasing, posing a major public health issue in China. China will have another 75 million patients with myocardial infarction in the next 15 years with the increasing risk factors and aging population [1]. The Chinese cardiovascular report in 2016 showed an increase in both the hospitalization ratio and mortality of acute myocardial infarction (AMI) over the years. The mortality of AMI is higher in rural areas than in the city, and the younger population is most vulnerable [2].

Acute ST-elevation myocardial infarction (STEMI), mainly caused by a sudden obstruction of the coronary artery with thrombus, benefits from both increasing reperfusion rate and shortening of the duration from the symptom occurrence to the opening of the target vessel [3 4]. Although implementing evidence-based medicine significantly improves the prognosis of patients with STEMI, the gap of the translational application is still large in real-world settings [5]. A majority of Chinese patients with STEMI miss the optimal treatment timing due to restrictions from both patients and medical services [6]. Additionally, the ratio of significant deficiency in STEMI reperfusion treatment remained at the level of around 55% in the last decade; hence, the in-hospital mortality has not changed significantly yet [7].

The effective treatment of STEMI is a systematic issue, and the solution is neither a novel thrombolytic drug nor an intervention device. It can be brought about by comprehensive factors, including patient health awareness, physician level, physician–patient relationship, medical reimbursement system, prehospital emergency

system, in-hospital treatment, connection mechanism between prehospital and in-hospital care, and posthospital management. Successful experiences from both American Lifeline program and the European Stent – Save a Life can be used for reference. The quality of medical service can be significantly improved when regional STEMI care network is established through close collaboration at different levels of hospitals and the emergency medical system (EMS) [8 9].

China has gradually increased the input of medical insurance in the last few decades. However, how to implement the best treatment for STEMI, keeping in mind the differences in geographical, humanistic, and medical insurance policy coverage, still needs to be discussed. At present, little information exists about whether the foreign STEMI guide is difficult to be widely used in China because of the differences between the East and the West. Therefore, more evidence from China is needed.

Although large-scale studies on AMI or acute coronary syndrome (ACS), such as CPACS, CCC, China-PEACE, and CAMI, have been conducted in China, none focused on establishing a regional STEMI emergency care network [7 10-12]. Serial documents issued by the National Health Commission of China provided favorable government support and further emphasized the importance of the administrative departments of health care at all levels in strengthening the construction of the regional emergency medical treatment system [13-15].

This study aimed to introduce the protocol of a 10-year project named as China STEMI Care Project (CSCAP), including objective, organization, procedures, data collection, assessment and feedback, and updates. The results provided important

evidence for the improvement in STEMI care within the whole region and also useful information when building up STEMI network in other similar regions.

Methods and analysis

Objectives

CSCAP aimed to build up different types of integrated regional STEMI care network covering the whole city region, city population, and disease processes according to different conditions nationwide. It also aimed to improve the awareness of public health and emergency treatment for patients with STEMI, increase the ratio of reperfusion treatment, shorten the overall duration of myocardial ischemia, and implement standard secondary prevention to improve the long-term prognosis through the establishment and optimization of medical care assessment and feedback system with data support.

Study design

CSCAP was a prospective, multicenter registry involving three stages. Phase 1 of CSCAP (CSCAP-1) focused on the in-hospital process optimization of primary percutaneous coronary intervention (PPCI) hospitals. Phase 2 of CSCAP (CSCAP-2) focused on the PPCI hospital-based regional STEMI transfer network construction with their adjacent non-PPCI hospitals and EMS. Phase 3 of CSCAP (CSCAP-3) focused on the whole-city STEMI care network construction by promoting chest pain center (CPC) accreditation (Figure 1). Systematic data collection, assessment of quality of care, and subsequent improvement were implemented throughout this study

to continuously improve the quality of care.

Organizational framework

CSCAP was established by the Chinese Physician Association and supported by the National Health Commission of China in 2011. After collaborating with the European Stent – Save a Life in CSCAP-3, China became its member country in 2017. The project office and steering committee were set up for management and academic support. Data management and statistical analyses were conducted by the School of Public Health of Peking University.

Site selection

CSCAP included 18 provinces (Anhui, Fujian, Gansu, Guangdong, Guangxi, Hainan, Hebei, Heilongjiang, Henan, Hubei, Jiangsu, Liaoning, Shandong, Shanxi, Sichuan, and Zhejiang), 4 municipalities (Beijing, Chongqing, Shanghai, Tianjin, and Yunnan), and 2 autonomous regions (Xinjiang and Inner Mongolia) because of the high incidence of STEMI in North China and economic issues in South China (Figure 2).

A total of 53 tertiary hospitals qualified for PPCI in 14 provinces/municipalities/autonomous regions of China enrolled in CSCAP-1 (Appendix table 1). These hospitals were selected because they were at the top level in their city and potentially a hub for regional network construction in CSCAP-2. A total of 241 PCI hospitals with hundreds of adjunct non-PCI hospitals from 24 provinces/municipalities/autonomous regions were selected to establish the regional STEMI care network in CSCAP-2 (Appendix table 1). A total of seven cities (Harbin,

Hangzhou, Nanning, Qingdao, Shenzhen, Suzhou, and Taiyuan) according to two different EMS types were selected to build up the whole-city STEMI care network in CSCAP-3 (Figure 2).

Patient enrollment and follow-up

Patients with STEMI who met with the third AMI definition in 2012 and the Chinese STEMI diagnosis and treatment guidelines were enrolled [16 17]. All patients received routine clinical assessments and treatments without any experimental intervention. The study was reviewed and approved by the Ethics Board at Peking University First Hospital.

In CSCAP-1, a total of 4191 patients admitted to hospitals, with symptom onset within 12 h regardless of whether receiving reperfusion or symptom onset within 12–24 h needing PPCI, were enrolled consecutively in 2012. In CSCAP-2, a total of 20,810 patients with STEMI occurrence within 30 days regardless of reperfusion were enrolled consecutively from PPCI hospitals three times at 6-month intervals during 2015 to 2017. In CSCAP-3, a total of 30 hospitalized patients with symptom onset within 30 days were enrolled consecutively from each hospital every 3 months. Patients with STEMI were enrolled consecutively from the whole network units, including both PCI and non-PCI hospitals. The patients who survived after hospital discharge were also followed up for 1 year.

Procedures

The treatment flow of the patients with STEMI was based on the STEMI protocol of the Announcement of Improving Medical Emergency Treatment Performance of

Acute Cardiovascular and Cerebrovascular Diseases released by the National Health Commission of China in 2015 [15]. Briefly, this flow chart included 1 center (EMS), 2 types of hospitals (PCI and non-PCI), 3 types of transport methods (EMS to hospital, bypass emergency department (ED), and interhospital), and 11 clinical pathways. Different clinical pathways were selected to execute the optimal emergency treatment based on the visiting time, method, and hospital level (Figure 3). According to typical ischemic symptoms and electrocardiogram (ECG), the procedure was started without results of myocardial biomarkers in case of delay.

Data collection and management

CSCAP collected data of all treatment flow, which were entered into a self-built electronic database together with two existing databases of both CPC accreditation and national PCI registry by trained clinical research coordinators and clinicians in each hospital. Variables included general information of patients, prehospital EMS treatment, in-hospital management, and follow-up management (Table 1). The data quality was monitored, and suspicious contents by review mainly included missing, outlier, and logical error data. When all problems were resolved, the database was locked for statistical analysis.

Key performance index for evaluating the quality of medical care

CSCAP mainly used the describing method to rank data quality and medical quality. Continuous variables were described as mean (standard deviation) or median (interquartile range), while categorical variables were described as percentage. The multivariate regression model was used to evaluate the factors related to the

assessment of medical quality. The Cox model was used to analyze the association between the exposures and medical outcomes. A *P* value <0.05 was defined as a significant difference. All analyses were performed using R (http://www.R-project.org).

A total of 13 primary key performance indexes (KPIs) were selected for medical quality evaluation based on different roles of EMS and hospitals with or without PCI capability in STEMI treatment (Table 2). The circular enrollment–evaluation–improvement method was implemented in both CSCAP-2 and CSCAP-3. Comparison of KPIs with itself and others was conducted for tailed improvements. Quality feedback report contained each KPI of the affiliation and its ranking among all affiliations and all regional affiliations, which was presented as location in quartile interval without ranking results of others.

Ethics and dissemination

CSCAP was the first prospective registry study on the establishment of STEMI regional care network in China step by step, covering the whole city, population, and treatment processes. Some large-scale ACS registry studies have been carried out in China, such as the CCC program focusing on the in-hospital treatment of ACS [11], the CPACS study focusing on the ACS clinical pathway [10], the CAMI study focusing on the hospital treatment of STEMI and non-ST-elevation myocardial infarction (NSTEMI) [12], and the China-PEACE study (retrospective study) [7]. Different from these studies, CSCAP prospectively collected data to analyze the

whole process of STEMI treatment and then provided feedback to units for problem-guided improvement. This study helped understand the condition of STEMI care in China extensively, the gap and differences with other countries, and the issues and solutions, leading to optimized clinical practice and improved medical quality.

An integrated regional network mainly contains PCI hospital, non-PCI hospital, and EMS. The medical system and patient factors together determine the delay in STEMI emergency treatment [18]. Three major types of EMS exist in China: (1) independent-type EMS, which has its own ambulances, (2) command-type EMS, which does not have its own ambulances and uses local hospital ambulances, and (3) affiliate-type EMS, which is based in hospitals and uses its ambulances. On the basis of these comprehensive situations, patients may not be transported to the optimal hospital to receive effective treatment in the shortest period because of incomplete communication [19]. Thus, different types of prehospital information transmission should be considered accordingly for hospital alert and rapid and accurate transport.

Optimizing the in-hospital green channel can significantly shorten the door-to-balloon (D2B) duration, while establishing a CPC was one of the most important methods [20 21]. Integration of multiple resources can help in early diagnosis, risk stratification, and treatment of STEMI and other acute chest pain–related diseases, thus improving efficiency, prognosis, and medical burden. Traditional CPC focuses on the optimization and integration of the in-hospital green channel aimed to shorten D2B time in STEMI care. The concept of a modern CPC in STEMI care expands to establish an effective regional emergency treatment network

aimed to shorten the total ischemia duration, thus maximizing the advantage of reperfusion therapy. Medical system and patient factors together determine the delay of STEMI emergency treatment [18]. Public education for self-awareness improvement, which is one of the elements of the CPC construction, could enable patients to seek medical assistance promptly in case of suspected myocardial infarction, accept timely reperfusion without hesitation, and adhere to primary and secondary prevention. CPC independent accreditation in China was initiated in 2013 with support from the National Health and Family Planning Commission and directed by the Chinese Society of Cardiology and the Chinese Physician Association. Two types of CPC accreditation standards were developed [22 23], which were separately applicable to PCI hospitals and non-PCI hospitals or to relatively small PCI hospitals not able to reach the PCI scale. The first standard focused on the improvement in the emergency PCI capacity and efficiency, while the second one focused on the improvement in thrombolysis and referral capacity to PPCI hospitals. Currently, 460 accredited CPCs and 2721 hospitals were in the waiting list in China by April 2018.

Rapid identification of STEMI and referral to a hospital without PCI certification are also important segments in establishing a regional STEMI emergency treatment system. A large number of patients with coronary heart disease in China are distributed in rural areas, and the mortality of AMI in these regions surpasses the urban areas. Although PPCI is the most effective treatment for STEMI, its implementation is difficult in most of the primary hospitals, which are limited by medical condition, geographic location, and techniques. On the basis of these

conditions of China, early thrombolysis and transfer PCI strategy are the priorities in most of the primary hospitals. Therefore, establishing an effective regional collaboration emergency treatment network to improve the treatment quality of STEMI is extremely important.

The National Cardiovascular Data Registry (NCDR), established since 1997, has become the basis for project implementation and quality evaluation as well as research center medical quality improvement in the United States. It has a positive impact on the clinical practice, medical payment, clinical research, and government decision-making [24 25]. The present study referred to the NCDR model to optimize the STEMI medical quality and established an assessment and feedback system for KPIs, such as efficiency of emergency transport, efficiency of hospital treatment with various levels, and cooperation between network units. For KPI selection, PPCI hospitals focused on the improvement in the emergency PCI capacity and efficiency; non-PPCI hospitals focused on the improvement in rapid diagnosis, thrombolysis, and referral capacity to PPCI hospitals; and EMS focused on the improvement in information transmission to alert hospitals early for rapid and accurate transport.

Since China has a large number of patients, its cardiovascular clinical data resource is the largest in the world. However, Chinese guidelines lack high-quality evidence. Clinical practice has demonstrated that overseas guidelines and evidence may not be applicable to the prevention and treatment of cardiovascular diseases in the Chinese population [26]. CSCAP established a database platform for the STEMI whole-treatment process, including primary prevention, emergency treatment,

in-hospital treatment, and secondary prevention. It was a real-world registry study and provided additional information. For example, this study evaluated the compliance of other related cardiovascular guidelines in real clinical practice, tracked the efficacy and side effects of novel drugs and devices, provided evidence for new guidelines, and compared differences among various hospitals and regions.

However, the present study had some limitations. First, CSCAP was expected to record clinical information of the full-treatment procedure of STEMI, which involved many affiliations and departments. Considering the real situation in ED, many time points of the KPIs could not be recorded manually on time, which might have led to missing and inaccurate data. Mobile device app could record the time variables through a simple click and completed the prehospital ECG transmission. Additionally, the auto capture of data gradually became possible to resolve this issue. All of these were considered in this study. Second, hospitals in CSCAP-1 and CSCAP-2 were not strictly selected according to the radio of PPCI, which might be because of lack of representatives to some degree. The selected hospitals with good conditions were better than the average level in their region. However, the first two phases of CSCAP were not only a description of the current situation of STEMI treatment, but a project to improve the quality of medical care. Therefore, high-level PCI hospitals were suitable to be used as core centers to establish the regional network. These successful experiences might have referral relevance to hospitals in the same region but outside this study, which might be useful for the whole-city network construction in CSCAP-3.

Shortening of the overall ischemia duration and increase in the reperfusion treatment rate are critical issues and challenges in STEMI care. The integration and optimization of a systemic STEMI collaborative network with government support are urgent issues that need to be resolved in China. CSCAP, with the establishment of an intrinsic feedback and certification system, will provide important prospective information for the network construction from PPCI hospital-centered regional network to whole-city covered STEMI transfer network step by step to establish an optimal STEMI care system in China.

Authors' contributions

Yan Zhang coordinated the study, assisted with data collection, performed data analysis, and drafted the manuscript. Bo Yu, Yaling Han, Jianan Wang, Lixia Yang, Zheng Wan, Zheng Zhang, Yuguo Chen, Xianghua Fu, Chuanyu Gao, Bao Li, Jiyan Chen, Ming Wu, Yitong Ma, Xingsheng Zhao, Yundai Chen, Hongbing Yan, Dingcheng Xiang, Weiyi Fang, and Junbo Ge carried out the data collection, and helped to draft the manuscript. Sameer Mehta and Christoph K participated in the design and helped to analyze data and draft the manuscript. Naber, Yong Huo, PI of the project, conceived and designed the project, helped to collect data and draft the manuscript. All authors reviewed the results and approved the final version of the manuscript.

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Conflicts of interest

The authors declare no conflicts of interest.

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Patient consent

Obtained.

Ethics approval

The study was reviewed and approved by the Ethics Board at Peking University First Hospital.

Data sharing statement

No additional data are available.

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Table 1. CSCAP data elements

Category	Example elements
Patient baseline information	Demographics (age, sex, ethnicity, occupation, marriage status, medical insurance, and status)
	Risk factors (smoking status, BMI, hypertension, diabetes, dyslipidemia, peripheral artery disease, prior MI history, prior stroke history, and prior revascularization)
	Clinical presentation (blood pressure, heart rate, and cardiac function classification)
Prehospital information	Patient (symptoms, symptom onset time, first medical contact method/time, and hospital approaching method)
	EMS (response time, transfer process, first ECG time, ECG transmission ratio, and bypass ED)
	Non-PCI hospital (admission time, first ECG time, diagnosis process, reperfusion and other treatment, DI-DO time, and transfer process)
PCI hospital information	Reperfusion (primary PCI, thrombolysis, pharmacoinvasive method and postthrombolysis PCI, indication/contraindication, and nonreperfusion reasons)
	Treatment delay (hospital approaching method, ED/chest pain center, bypass ED, admission time, first ECG time, catheter lab ready time, D2B, D2N, FMC2B, total ischemic time, and

	reasons of delay)
	PCI procedures (operative route, coronary angiography results, aspiration, culprit vessels, aspiration, stent, and elective PCI)
	Thrombolytic procedures (thrombolytic agent, dose, and outcome)
	Medications (loading dose DAPT/statin, antiplatelets, β-blockers, statin, ACEI/ARB, GP IIb/IIIa inhibitor, and anticoagulant with dose and contraindication information)
	Laboratory results (Troponin, CK-MB, creatinine, hemoglobin, HbA1C, glucose, BNP, NT-proBNP, lipids, and UCG)
	Discharge (diagnosis, in-hospital duration, cost, and medications)
	Outcomes (death, non-fatal reinfarction, bleeding, nonfatal stroke, revascularization, and mechanical complication)
Follow-up and management	Presentation status (symptom, cardiac function classification, blood pressure, heart rate, and follow-up on time ratio)
	Laboratory results (lipid profiles, glucose traits, HbA1c, creatinine, hemoglobin, BNP, NT-proBNP, ECG, and UCG)
	Medications (antiplatelets, β-blockers, statin, and ACEI/ARB)
	Risk factor control rate (BP, lipid, glucose, and smoking

	cessation)Outcomes (death, nonfatal reinfarction, stroke, revascularization, rehospitalization due to unstable angina pectoris, heart failure or other cardiovascular reasons, and bleeding)

ACEI, Angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; BMI, body mass index; BNP, brain natriuretic peptide; CK-MB, creatine kinase MB isoenzyme; DAPT, dual antiplatelet therapy; D2B, door to balloon; D2N, door to needle; DI–DO, door in–door out; ECG, electrocardiograph; ED, emergency department; EMS, emergency medical service; FMC2B, first medical contact to balloon; GP IIb/IIIa, glycoprotein IIb/IIIa; HbA1c, glycosylated hemoglobin A1c; MI, myocardial infarction; NT-ProBNP, N-terminal pro–brain natriuretic peptide; PCI, percutaneous coronary intervention; UCG, ultrasound cardiogram.

Table 2. Primary performance measures for medical care quality evaluation

Primary performance measures
Prehospital care
Symptom onset to arrival in hospital (min)
Hospital admission ratio via ambulance (%)
Prehospital ECG transmission ratio (%)
Bypass ED ratio in patients with symptom onset within 12 h (%)
Reperfusion
Overall reperfusion ratio (%)
Thrombolysis ratio in patients with symptom onset within 12 h (%)
Primary PCI ratio in patients with symptom onset within 12 h (%)
D2B in patients with symptom onset within 12 h (min)
D2N in patients with symptom onset within 12 h (min)
Discharge
Usage of both DAPT, statin, β blocker, and ACEI/ARB in patients without contraindication (%)
Outcomes
In-hospital mortality (%)
Follow-up and management
1-Year on-time follow-up ratio (%)
1-Year MACE (%) including mortality, non-fatal myocardial infarction, non-fatal stroke, hospitalization due to heart failure or acute coronary syndrome, etc.

ACEI, Angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker;

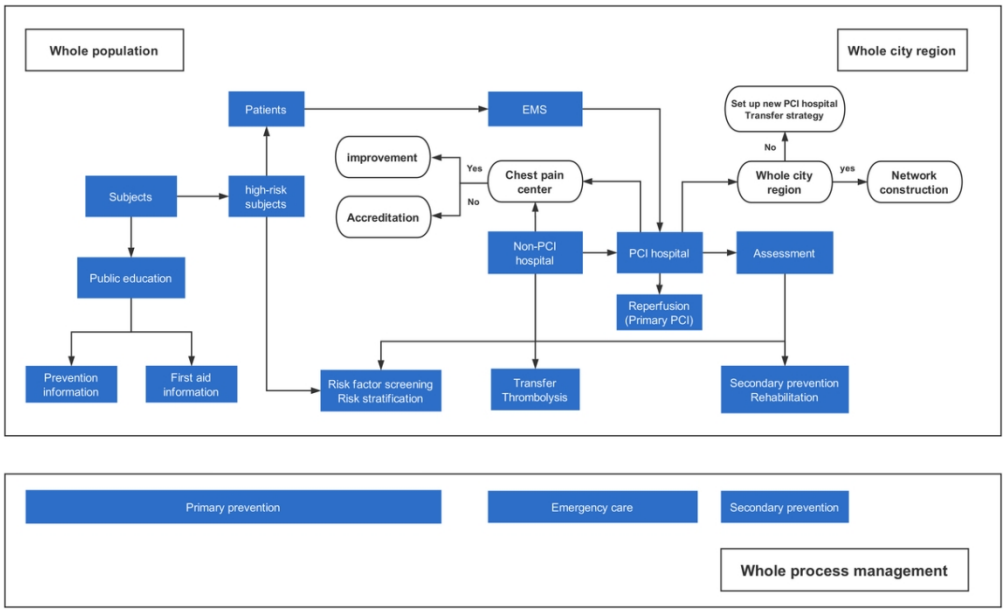
DAPT, dual antiplatelet therapy; D2B, door to balloon; D2N, door to needle; ECG, electrocardiogram; ED, emergency department; PCI, percutaneous coronary intervention; MACE, major adverse cardiovascular event.

Figure legends

Figure 1. CSCAP whole-city STEMI care network construction.

Figure 2. Geographic distribution of CSCAP.

Figure 3. CSCAP STEMI care flow chart.

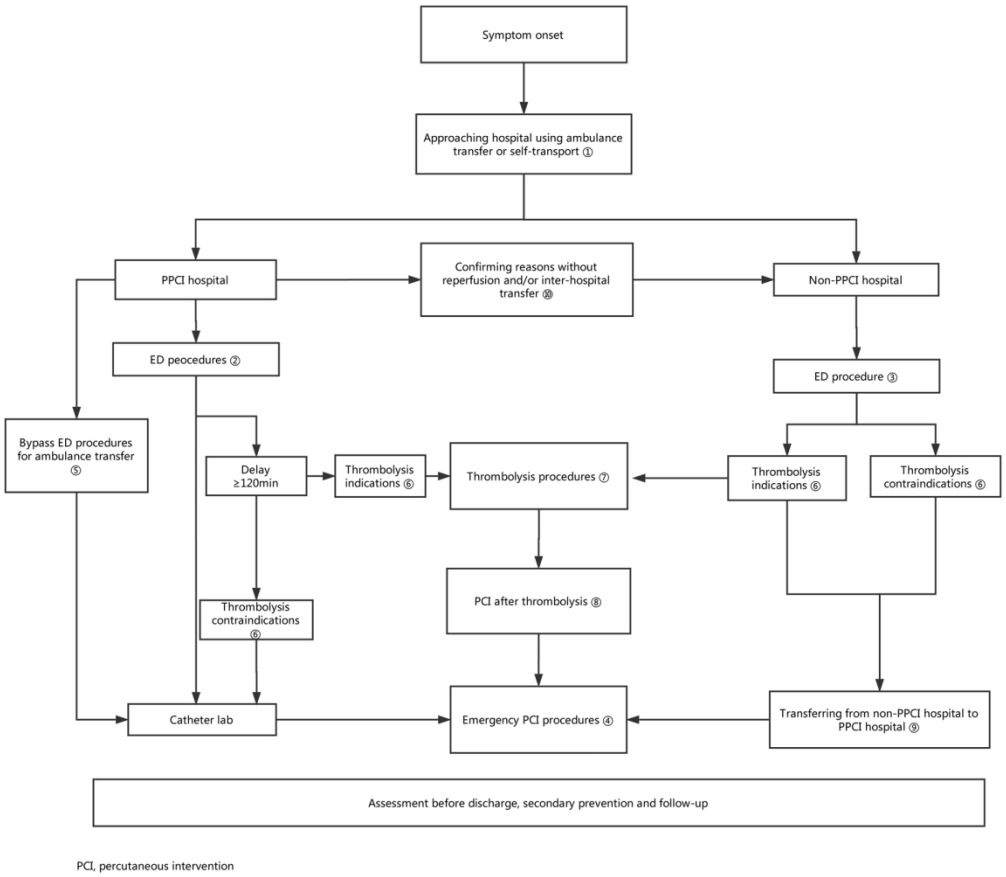


CSCAP whole-city STEMI care network construction.

102x62mm (300 x 300 DPI)

Geographic distribution of CSCAP

170x170mm (300 x 300 DPI)



CSCAP STEMI care flow chart.

148x130mm (300 x 300 DPI)

Appendix table 1 Complete list of PCI hospitals participat

Hospital	Province/Municipality/
Chizhou people's hospital	Anhui
Taihe County People's Hospital	Anhui
Anhui Provincial Hospital	Anhui
Maanshan Central Hospital	Anhui
Beijing Anzhen Hospital#	Beijing
Beijing Chao-Yang Hospital#	Beijing
Chinese PLA General Hospital ｜ Medical School of Chinese PLA*	Beijing
General Hospital of Armed Police Forces*	Beijing
General Hospital of Beijing Military Command of PLA*	Beijing
Navy General Hospital	Beijing
Peking University First Hospital#	Beijing
Peking University People's Hospital#	Beijing
Peking University Shougang Hospital#	Beijing
Peking University Third Hospital#	Beijing
The 306th Hospital of PLA	Beijing
The 309th Hospital of Chinese People's Liberation Army	Beijing
Daping Hospital,Research Institute of Surgery Third Military Medic	Chongqing
Southwest Hospital	Chongqing
Xinqiao Hospital,Research Institute of Surgery Third Military Medi	Chongqing
Fuzhou General Hospital of Nanjing Military Command	Fujian
Jiuquan people's Hospital of Gansu Province	Gansu
Lanzhou General Hospital of Lanzhou Military Command	Gansu
The First Hospital of Lanzhou University*	Gansu
The First Hospital of Tianshui	Gansu
Dongguan Kanghua Hospital	Guangdong
The Third People's Hospital of Dongguan	Guangdong
The First People's Hospital of Shunde	Guangdong
First Affiliated Hospital of Sun Yat-sen University#	Guangdong
General Hospital of Guangzhou Military Command of PLA	Guangdong
Guangdong General Hospital of Armed Police Force	Guangdong
Guangdong General Hospital*	Guangdong
Guangzhou Red Cross Hospital#	Guangdong
Nanfang Hospital	Guangdong
Wuhan General Hospital of Guangzhou Military Command	Guangdong
Maoming Hospital of TCM	Guangdong
Maoming People's Hospital	Guangdong
Qingyuan people's Hospital	Guangdong
Shantou Central Hospital	Guangdong
The First Affiliated Hospital of Shantou University Medical College	Guangdong
Yuebei People's Hospital	Guangdong
Shenzhen People's Hospital	Guangdong
Sun yat-sen Cardiovascular Hospital of Shenzhen*	Guangdong
The Fourth People's Hospital of Shenzhen	Guangdong
Affiliated Hospital of Guangdong Medical University	Guangdong
Danzhou People's Hospital	Hainan
Haikou people's Hospital	Hainan

Hainan General Hospital	Hainan
Hainan Provincial Nong Ken Hospital	Hainan
The First Affiliated Hospital of Hainan Medical University	Hainan
Hainan Branch of PLA General Hospital	Hainan
Hainan Third People's Hospital	Hainan
Sanya People's Hospital	Hainan
Affiliated Hospital of Hebei University	Hebei
Baoding Second Central Hospital	Hebei
the First Central Hospital of Baoding City	Hebei
Cangzhou Central Hospital*	Hebei
General Hospital of North China Petroleum Administration Bureau	Hebei
Affiliated Hospital of Chengde Medical College	Hebei
Chengde Central Hospital	Hebei
Handan Central Hospital	Hebei
Handan First Hospital	Hebei
Harrison international Heping Hospital	Hebei
Hengshui Cardiovascular Hospital	Hebei
Langfang Fourth People's Hospital	Hebei
Qinhuangdao First Hospital	Hebei
Bethune International Peace Hospital	Hebei
Hebei General Hospital	Hebei
The Second Hospital of Hebei Medical University*	Hebei
Kailuan General Hospital	Hebei
Tangshan Gongren Hospital*	Hebei
Xingtai People's Hospital	Hebei
Xingtai Third Hospital	Hebei
The Second Affiliated Hospital of Hebei North University	Hebei
Zhangjiakou First Hospital	Hebei
Zunhua people's Hospital	Hebei
The Fourth Hospital of Harbin Medical University*	Heilongjiang
The Second Affiliated Hospital of Harbin Medical University*	Heilongjiang
Daqing Oilfield General Hospital*	Heilongjiang
Longnan hospital in Daqing	Heilongjiang
Greater Khingan Mountains Aera People’s Hospital	Heilongjiang
Harbin First Hospital	Heilongjiang
The Central Hospital of Jiamusi City	Heilongjiang
Mudanjiang Cardiovascular Hospital	Heilongjiang
Mudanjiang City 2rd People’s Hospital	Heilongjiang
The 3rd Affiliated Hospital of Qiqihar Medical University	Heilongjiang
Tsitsihar First Hospital	Heilongjiang
Shuangyashan Coal General Hospital	Heilongjiang
The First Affiliated Hospital of Harbin Medical University#	Helongjiang
Anyang District Hospital	Henan
The People's Hospital of Hebi	Henan
Huaihe Hospital of Henan University	Henan
Kaifeng Central Hospital	Henan
Luohe Central Hospital	Henan
The First Affiliated Hospital of Henan University of Science and Te	Henan

The Second Affiliated Hospital of Henan University of Science and	Henan
Nanyang Central Hospital	Henan
the Second People's Hospital of Pingdingshan	Henan
Puyang Oilfield General Hospital	Henan
Puyang People's Hospital	Henan
First people's hospital of Shangqiu	Henan
Xinxiang Central Hospital	Henan
Xuchang Central Hospital	Henan
First Affiliated Hospital of Henan University of TCM	Henan
Henan Province People's Hospital*	Henan
Henan Provincial Chest Hospital	Henan
The 7th people's hospital of Zhengzhou	Henan
The First Affiliated Hospital of Zhengzhou University*	Henan
Zhengzhou first people's hospital	Henan
Zhumadian Central Hospital	Henan
Alxa League Central Hospital	Inner Mongolia
Baotou Central Hospital*	Inner Mongolia
The First Affiliated Hospital of Baotou Medical College	Inner Mongolia
Bayannur Hospital	Inner Mongolia
Chifeng Municipal Hospital	Inner Mongolia
The Affiliated Hospital of Chifeng University	Inner Mongolia
Inner Mongolia People's Hospital	Inner Mongolia
The Affiliated Hospital of Inner Mongolia Medical University	Inner Mongolia
Ordos Central Hosiptal	Inner Mongolia
Tong Liao City Hospital	Inner Mongolia
Ulanqab Central Hospital	Inner Mongolia
People’s Hospital Wuhai City	Inner Mongolia
Xilingol League Hospital	Inner Mongolia
Inner Mongolia Xing'an Meng People's Hospital	Inner Mongolia
Inner Mongolia Forestry General Hospital	Inner Mongolia
Ansteel Group Hospital	Liaoning
Dalian Municipal Central Hospital*	Liaoning
The First Affiliated Hospital of Dalian Medical University*	Liaoning
The Second Hospital of Dalian Medical University	Liaoning
Dandong Central Hospital	Liaoning
General Hospital Under The Fushun Mining Affairs Bureau	Liaoning
Fuxin Central Hospital	Liaoning
Huludao Central Hospital	Liaoning
Jinzhou Central Hospital	Liaoning
The First Affiliated Hospital of Liaoning Medical University*	Liaoning
Shengjing Hospital of China Medicine University#	Liaoning
The First Affiliated Hospital of Liaoning University of Traditional C	Liaoning
The First Hospital of China Medical University	Liaoning
The First Hospital of China Medical University	Liaoning
The Fourth Hospital of China Medical University*	Liaoning
The General Hospital of Shenyang Military	Liaoning
The People's Hospital of Liaoning Province*	Liaoning
The Second Affiliated Hospital of Shenyang Medical College	Liaoning

Tieling Central Hospital	Liaoning
Yingkou Central Hospital	Liaoning
Nanjing General Hospital	Nanjing
Dezhou People's Hospital	Shandong
Dongying People's Hospital	Shandong
Jinan Central Hospital	Shandong
Qianfo Hill Hospital	Shandong
Qilu Hospital of Shandong University*	Shandong
Shandong Provincial Hospital*	Shandong
The No.4 Hospital 1946 Jinan Shandong	Shandong
The Second Hospital of Shandong University	Shandong
Jining NO.1 People's Hospital	Shandong
The Affiliated Hospital of Jining Medical University*	Shandong
Liaocheng People's Hospital*	Shandong
The second People's Hospital Of Liaocheng	Shandong
Linyi People's Hospital	Shandong
Qingdao Central Hospital	Shandong
Qingdao Municipal Hospital	Shandong
The Affiliated Hospital of Qingdao University*	Shandong
Taian City Central Hospital	Shandong
The Affiliated Hospital of Taishan Medical University	Shandong
Tengzhou Central People's Hospital	Shandong
Anqiu City People's Hospital	Shandong
The Affiliated Hospital of Weifang Medical University	Shandong
Weifang People's Hospital	Shandong
Weifang Traditional Chinese Hospital	Shandong
Changhai Hospital	Shanghai
Jinshan Hospital of Fudan University	Shanghai
NO.3 People's Hospital Affiliated to Shanghai Jiao Tong University	Shanghai
Renji Hospital Affiliated to Shanghai Jiao Tong University School c	Shanghai
Ruijin Hospital, Shanghai Jiaotong University	Shanghai
Shanghai Changzheng Hospital	Shanghai
Shanghai Chest Hospital	Shanghai
Shanghai East Hospital	Shanghai
Shanghai Fengxian Central Hospital	Shanghai
Shanghai General Hospital	Shanghai
Shanghai Gongli Hospital	Shanghai
Shanghai Jiading District Central Hospital	Shanghai
Shanghai Jiao Tong University Affiliated Sixth People's Hospital	Shanghai
Shanghai Minhang Central Hospital	Shanghai
Shanghai ninth People's Hospital Affiliated to Shanghai Jiaotong Ur	Shanghai
Shanghai Pudong New Area People's Hospital	Shanghai
Shanghai Pudong New District Zhoupu Hospital	Shanghai
Shanghai Putuo District Central Hospital	Shanghai
The Fifth People's Affiliated Hospital of Fudan University	Shanghai
The Huashan Hospital of Fudan University	Shanghai
The Tenth People's Hospital of Tongji University*	Shanghai
Tong Ren Hospital, Shanghai Jiao Tong University School of Medic	Shanghai

Tongji Hospital	Shanghai
Xin Hua Hospital Affiliated to Shanghai Jiao Tong University Scho	Shanghai
Zhongshan Hospital*	Shanghai
General hospital of shanxi lu 'an mining (group) co., LTD	Shanxi
Shanxi Luan Mining (Group) Co., Ltd. General Hospital	Shanxi
With the Coal Group General Hospital*	Shanxi
Shanxi Fenyang Hospital	Shanxi
Shanxi Province Cardiovascular Disease Hospital*	Shanxi
Taiyuan Center Hospital	Shanxi
Taiyuan People's Hospital#	Shanxi
Tangdu Hospital, The Fourth Military Medical University	Shanxi
Xijing Hospital, The Fourth Military Medical University	Shanxi
The First People's Hospital of Yangquan	Shanxi
The First People's Hospital of JinZhong	Shanxi
General Hospital of Chengdu Military Command of PLA	Sichuan
Affiliated Hospital of Chinese People's Armed Police Force Logistic	Tianjin
TEDA International Cardiovascular Hospital*	Tianjin
The 254th Hospital of Chinese People's Liberation Army	Tianjin
The 254th Hospital of PLA	Tianjin
The Affiliated Hospital of Armed Police Medical College#	Tianjin
The Second Hospital of Tianjin Medical University*	Tianjin
Tianjin Baodi District People's Hospital	Tianjin
Tianjin Beichen Hospital	Tianjin
Tianjin Chest Hospital*	Tianjin
Tianjin Fifth Central Hospital	Tianjin
Tianjin First Central Hospital	Tianjin
Tianjin Fourth Central Hospital	Tianjin
Tianjin Jinghai hospital	Tianjin
Tianjin Jixain People's Hospital	Tianjin
Tianjin Medical University General Hospital*	Tianjin
Tianjin People's Hospital*	Tianjin
Tianjin Third Central Hospital	Tianjin
Tianjin Xiqing Hospital	Tianjin
The First Affiliated Hospital of the Medical College,Shihezi Univer	Xinjiang
People's Hospital of Xinjiang Uygur Autonomous Region*	Xinjiang
The First Affiliated Hospital of Xinjiang Medical University*	Xinjiang
The Second Affiliated Hospital of Xinjiang Medical University	Xinjiang
The Xinjiang Uygur Autonomous Region Hospital of traditional Ch	Xinjiang
Xinjiang Cardio-Cerebrovascular Disease Hospital	Xinjiang
Urumqi General Hospital of Lanzhou Military Area Command	Xinjiang
Kunming General Hospital of Chengdu Military Command of PLA	Yunnan
Hangzhou First People's Hospital	ZheJiang
Sir Run Run Shaw Hospital of ZheJiang University School of Medi	ZheJiang
The Affiliated Hospital of Hangzhou Normal University	ZheJiang
The First Affiliated Hospital ZheJiang University*	ZheJiang
The Second Affiliated Hospital of ZheJiang University School of M	ZheJiang
ZheJiang Provincial Hospital of TCM	ZheJiang
ZheJiang Provincial People's Hospital	ZheJiang

Jiaxing First Hospital	ZheJiang
Jiaxing Second Hospital	ZheJiang
Jinhua Central Hospital	ZheJiang
Lishui Central Hospital	ZheJiang
Ningbo City Medical Treatment Center Lihuili Hospital	ZheJiang
Ningbo First Hospital	ZheJiang
Ningbo No.2 Hospital	ZheJiang
Quzhou People's Hospital of ZheJiang Province	ZheJiang
Shaoxing Second Hospital	ZheJiang
Taizhou Central Hospital	ZheJiang
Taizhou Hospital of ZheJiang Province	ZheJiang
People's Hospital of Wenzhou City	ZheJiang
The First Affiliated Hospital of Wenzhou Medical University	ZheJiang
The Second Affiliated Hospital and Yuying Children's Hospital of W	ZheJiang
Zhuji People's Hospital of ZheJiang Province	ZheJiang

ting in CSCAP-1 and CSCAP-2

City
Chizhou
Fuyang
Hefei
Maanshan
Beijing
Beijing
Beijing
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Jiuquan
Lanzhou
Lanzhou
Tianshui
Dongguan
Dongguan
Foshan
Guangzhou
Guangzhou
Guangzhou
Guangzhou
Guangzhou
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Maoming
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Qingyuan
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Shenzhen
Zhanjiang
Danzhou
Haikou

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Hengshui
Hengshui
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Qinghuangdao
Shijiazhuang
Shijiazhuang
Shijiazhuang
Tangshan
Tangshan
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Xingtai
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Zhangjiakou
Zunhua
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Daqing
Greater Khingan
Harbin
Jiamusi
Mudanjiang
Mudanjiang
Qiqihar
Qiqihar
Shuangyashan
Harbin
Anyang
Hebi
Kaifeng
Kaifeng
Luohe
Luoyang

Luoyang
Nanyang
Pingdingshan
Puyang
Puyang
Shangqiu
Xinxiang
Xuchang
Zhengzhou
Zhengzhou
Zhengzhou
Zhengzhou
Zhengzhou
Zhengzhou
Zhumadian
Alxa League
Baotou
Baotou
Bayannur
Chifeng
Chifeng
Huhehaote
Huhehaote
Ordos
Tongliao
Ulanqab
Wuhai
Xilinhaote
Xing'an Meng
Yakeshi
Anshan
Dalian
Dalian
Dalian
Dandong
Fushun
Fuxin
Huludao
Jinzhou
Jinzhou
Shenyang
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Shenyang
Shenyang

Tieling
Yingkou
Nanjing
Dezhou
Dongying
Jinan
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Jining
Jining
Liaocheng
Liaocheng
Linyi
Qingdao
Qingdao
Qingdao
Taian
Taian
Tengzhou
Weifang
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Taiyuan
Taiyuan
Taiyuan
Xi'an
Xi'an
Yangquan
Yuci
Chengdu
Tianjin
Tianjin
Tianjin
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Shihezi
Urumchi
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Urumqi
Kunming
Hangzhou
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Jiaxing
Jiaxing
Jinhua
Lishui
Ningbo
Ningbo
Ningbo
Quzhou
Shaoxing
Taizhou
Taizhou
Wenzhou
Wenzhou
Wenzhou
Zhuji

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Protocol of the China STEMI Care Project (CSCAP): a 10-year project to improve quality of care by building up a regional STEMI care network

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	Huo, Yong ; Peking University First Hospital,
Primary Subject Heading:	Evidence based practice
Secondary Subject Heading:	Medical management
Keywords:	Accreditation, chest pain center, network, reperfusion, ST-elevation myocardial infarction

Protocol of the China STEMI Care Project (CSCAP): a 10-year project to improve quality of care by building up a regional STEMI care network

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Date:

This study was initiated in 2011 and will be completed in 2021. Phase 1 (CSCAP-1) is conducted from 2011 to 2013, Phase 2 (CSCAP-2) is conducted from 2015 to 2018, and Phase 3 (CSCAP-3) is conducted from 2018 to 2021, respectively.

Abstract

Introduction: Successful ST-segment elevation myocardial infarction (STEMI) management is time-sensitive and is based on prompt reperfusion mainly to reduce patient mortality. It has evolved from a single hospital care to an integrated regional network approach over the last decades. This prospective study, named the China STEMI Care Project (CSCAP), aims to show how implementation of different types of integrated regional STEMI care networks can improve the reperfusion treatment rate, shorten the total duration of myocardial ischemia, and lead to mortality reduction step by step.

Methods and analysis: The CSCAP is a prospective, multicenter registry involving 3 phases. A total of 18 provinces, 4 municipalities and 2 autonomous regions in China were included. Patients who met with the third universal definition of myocardial infarction and the Chinese STEMI diagnosis and treatment guidelines were enrolled. Phase 1 (CSCAP-1) focused on the in-hospital process optimization of primary percutaneous coronary intervention (PPCI) hospitals, phase 2 (CSCAP-2) focused on the PPCI hospital-based regional STEMI carenetwork construction together with emergency medical services and adjacent non-PPCI hospitals, and phase 3 (CSCAP-3) focused on the whole-city STEMI care network construction by promoting chest pain center accreditation. Systematic data collection, key performance index assessment and subsequent improvement were implemented throughout the project to continuously improve the quality of STEMI care.

Ethics and dissemination: The study has been reviewed and approved by the Ethics

Committee of Peking University First Hospital. Ranking reports of quality of care will be generated available to all participant affiliations. Results will be disseminated via peer-reviewed scientific journals and presentations at congresses.

Trial registration number: NCT03821012

Strengths and limitations of this study

- CSCAP is the first project focused on establishing an integrated regional STEMI care network in China through in-hospital process optimization, PPCI hospital-based regional STEMI care network construction and whole-city STEMI care network construction step by step, which will help to understand the situations extensively and then improve accordingly.
- Evaluation, feedback and improvement system will be established, aiming to provide a tailored and continuous quality of care improvement plan based on the conditions of different regions to further integrate the STEMI care network nationwide.
- Hospitals are not randomly selected in CSCAP which might be lead to the lack of representatives to some degree. However, these hospitals are at a high level in their region which is suitable to be core centers for regional network construction. Their experiences could be valuable for hospitals in the same region but outside this study.

Introduction

The burden of cardiovascular diseases is increasing and posing a major public health issue worldwide. The number of new onset of myocardial infarction will be tremendous in China in the next 15 years with the increasing risk factors and aging population [1]. The Chinese cardiovascular report in 2017 showed an increase in both the percentage of hospitalization and mortality of acute myocardial infarction (AMI) over the years. The trends of fast growth nationwide as well as higher in rural areas in AMI mortality were observed since 2005 and 2013, respectively [2].

ST-elevation myocardial infarction (STEMI), mainly caused by a sudden obstruction of the coronary artery with thrombus, benefits from both increasing reperfusion rate and shortening of the duration from the symptom occurrence to the opening of the target vessel [3 4]. Although implementing an evidence-based medicine significantly improves the prognosis of patients with STEMI, the gap of the translational application is still large in real-world settings [5]. A majority of Chinese STEMI patients miss the optimal treatment timing due to restrictions from both patients and medical services [6 7]. Additionally, the ratio of significant deficiency in STEMI reperfusion treatment remained at the level of around 55% in the last decade. Hence, the in-hospital mortality has not changed significantly yet [7].

Successful treatment of STEMI is a systemic issue, and the solution is neither a novel thrombolytic drug nor an intervention device. It can be brought about by comprehensive factors, including patient health awareness, physician level, physician–patient relationship, medical reimbursement system, prehospital emergency

system, in-hospital treatment, connection mechanism between prehospital and in-hospital care, and posthospital management. Experiences from both the American Lifeline program and the European Stent – Save a Life can be used for reference. The quality of medical service can be significantly improved by establishing a regional STEMI care network through close collaboration with different levels of hospitals and the emergency medical system (EMS) [8 9].

Although large-scale studies have been conducted in China, such as Clinical Pathways for Acute Coronary Syndromes in China (CPACS) focusing on the ACS clinical pathway, Cardiovascular Disease in China (CCC) focusing on the in-hospital treatment of acute coronary syndrome (ACS), China Acute Myocardial Infarction (CAMI) Registry focusing on the management of both STEMI and non-STEMI, and China Patient-centered Evaluative Assessment of Cardiac Events Retrospective Study of Acute Myocardial Infarction (China PEACE-Retrospective AMI Study), none of them focused on establishing a regional STEMI care network [7 10-12]. Serial documents issued by the National Health Commission of China provide favorable government support and further emphasize the importance of administrative departments of health care at all levels in strengthening the construction of regional emergency medical treatment system [13-15].

China has gradually increased the input of medical expense in the last few decades. However, there are several types of medical insurances with different reimbursement rate in China. The impacts of medical insurance policy coverage as well as geographical and humanistic factors on STEMI management need to be discussed.

Objectives

The 10-year project, named as China STEMI Care Project (CSCAP), aims to show how implementation of different types of integrated regional STEMI care networks can improve the reperfusion treatment rate, shorten the total duration of myocardial ischemia, and lead to mortality reduction step by step. It will also provide useful information when building up a STEMI care network in other similar regions. In details, CSCAP focuses on improving the awareness of health and emergency treatment for STEMI patients, increasing the ratio of reperfusion treatment, shortening the overall duration of myocardial ischemia, and implementing standard secondary prevention to improve the long-term prognosis by establishing and optimizing medical care evaluation, feedback and improvement system with data support.

Methods and analysis

Study design

CSCAP is a prospective multicenter registry containing 3 phases. Phase 1 of CSCAP (CSCAP-1) focused on the in-hospital process optimization of primary percutaneous coronary intervention (PPCI) hospitals. Phase 2 of CSCAP (CSCAP-2) focused on the PPCI hospital-based regional STEMI care network construction with their adjacent non-PPCI hospitals and EMS. Phase 3 of CSCAP (CSCAP-3) focused on the whole-city STEMI care network construction by promoting chest pain center (CPC) accreditation (Fig. 1). Systematic data collection, assessment of quality of care and subsequent improvement were implemented throughout this study to continuously

improve the quality of care.

Organizational framework

CSCAP was established by the Chinese Medical Doctor Association and supported by the National Health Commission of China in 2011. After collaborating with the European Stent – Save a Life in CSCAP-3, China became its member country in 2017. The project office, executive committee and steering committee were set up for the purpose of management, implementation and academic support. Data management and statistical analyses were conducted by the School of Public Health of Peking University.

Site selection

CSCAP included 18 provinces (Anhui, Fujian, Gansu, Guangdong, Guangxi, Hainan, Hebei, Heilongjiang, Henan, Hubei, Jiangsu, Liaoning, Shandong, Shanxi, Shaanxi, Sichuan, Yunnan, and Zhejiang), 4 municipalities (Beijing, Chongqing, Shanghai, and Tianjin) and 2 autonomous regions (Inner Mongolia and Xinjiang) in China when considering incidence of STEMI, logistic as well as economic issues (Fig. 2).

A total of 53 tertiary hospitals qualified for PPCI in 14 provinces, municipalities or autonomous regions of China were enrolled in CSCAP-1. The qualification of these selected hospitals is based on the numbers of PCI cases and cardiovascular interventionists extracted from the national PCI registry database. Moreover, all of them are able to provide 24/7 PPCI service. These hospitals were selected because they were at the top level in their city and potentially a hub for regional network construction in CSCAP-2. A total of 244 PCI hospitals with adjunct non-PCI hospitals

from 24 provinces, municipalities and autonomous regions were selected to build up the regional STEMI care network in CSCAP-2. A total of 7 cities (Harbin, Hangzhou, Nanning, Qingdao, Shenzhen, Suzhou, and Taiyuan) from 7 provinces with different EMS types were selected to build up the whole-city STEMI care network in CSCAP-3 (Fig. 2).

Patient enrollment

Patients who met with the third universal definition of myocardial infarction and the Chinese STEMI diagnosis and treatment guidelines were enrolled [16 17]. STEMI patients with late admission to hospitals were also considered for the purpose of exploring optimal methods to shorten total ischemic time containing both patient delay and system delay issues. All patients received routine clinical assessments and treatments without any experimental intervention. The updated guideline-directed management such as reperfusion, auxiliary device implementation, elective revascularization, medications and therapeutic lifestyle change will be implemented during the whole study period.

In CSCAP-1, a total of 4,191 hospitalized patients, with symptom onset within 12 h regardless of whether receiving reperfusion or symptom onset within 12–24 h of needing PPCI, were enrolled consecutively in 2012. In CSCAP-2, a total of 20,799 patients with STEMI occurrence within 30 days regardless of reperfusion were enrolled consecutively from PPCI hospitals 3 times at a 6-month interval from 2015 to 2017. In CSCAP-3, a total of 30 hospitalized STEMI patients with symptom onset within 30 days will be enrolled consecutively from both PCI and non-PCI hospitals in

the whole-city network every 3 months. Those patients who survived after hospital discharge will be followed up for 1 year.

Regional network construction

An integrated regional network contains PCI hospitals, non-PCI hospitals and EMS. There are 3 major types of EMS exist in China: (1) independent-type EMS, which has its own ambulances; (2) command-type EMS, which does not have its own ambulances and uses local hospital ambulances; and (3) affiliate-type EMS, which is based in hospitals and uses its ambulances. On the basis of these comprehensive situations, patients may not be transported to optimal hospitals to receive effective treatment in the shortest period because of incomplete communication [18]. Thus, prehospital information transmission should be considered accordingly for hospital alert and rapid and accurate transfer.

Although PPCI is the most effective treatment for STEMI, it is difficult to be implemented in most of the primary hospitals, as they are limited by medical condition, geographic location and techniques. Early thrombolysis and/or transfer PCI strategy are the priority in most of these hospitals. Therefore, rapid identification of STEMI and referral to a hospital with PPCI ability are extremely important components in establishing a regional STEMI care network in China.

Optimizing the in-hospital green channel can significantly shorten the door-to-balloon (D2B) time and door-to-needle (D2N) time while establishing a CPC to integrate multiple resources is one of the most important methods [19 20]. Traditional CPC focuses on the optimization and integration of the in-hospital sources

aimed to shorten the process. The medical system and patient factors together determine the delay in STEMI emergency treatment [21]. The concept of a modern CPC expands to establish an effective regional network aiming to shorten the total ischemia duration, thereby maximizing the advantage of reperfusion therapy. The CPC independent accreditation in China was initiated in 2013 and 2 types accreditation standards were developed according to PPCI ability [22 23].

Procedures

The treatment process of the patients suffered STEMI was based on the STEMI protocol in the Announcement of Improving Medical Emergency Treatment Performance of Acute Cardiovascular and Cerebrovascular Diseases issued by the National Health Commission of China in 2015 [15]. Briefly, this flow chart included 1 center (EMS), 2 types of hospitals (PCI and non-PCI), 3 types of transfer methods [EMS transfer to hospital, bypass emergency department (ED) and inter-hospital transfer], and 11 clinical pathways. Different clinical pathways were selected to execute the optimal emergency treatment based on the visiting time, approaching method and hospital ability (Fig. 3). In addition, the procedures should be launched without results of myocardial biomarkers according to typical ischemic symptoms and electrocardiogram (ECG).

Data collection and management

Data of all treatment process were collected, including patient general information, prehospital treatment, in-hospital management and follow-up management (Table 1). Considering the real situation in ED, many time points could not be recorded

manually on time which might lead to missing and inaccurate data. Mobile device app could record these time variables through a simple click and complete the prehospital ECG transmission. The technique of data auto-capture becomes more and more popular at present and should resolve this issue. All of these methods are considered gradually in this study.

Data were inputted into a self-built electronic database together with two existing databases of both CPC accreditation and national PCI registry by trained clinical research coordinators and clinicians in each hospital. The quality of the data was monitored and suspicious contents with missing, outlier and logical errors were reviewed mainly. When all problems are resolved, the database is then locked for statistical analysis.

The describing method was used in CSCAP to mainly rank data quality and medical quality. Continuous variables were described as mean (standard deviation) or median (interquartile range), while categorical variables were described as a percentage. The multivariate regression model was used to evaluate the factors related to the assessment of medical quality. The Cox model was used to analyze the association between exposures and medical outcomes. A P value < 0.05 was defined as a significant difference. All analyses were performed using R (http://www.R-project.org).

Key performance index

The National Cardiovascular Data Registry (NCDR), established since 1997, has become the basis for project implementation and quality evaluation as well as

research center medical quality improvement in the United States. It has a positive impact on clinical practice, medical payment, clinical research and government decision-making [24 25]. The present study referred to the NCDR model to optimize the STEMI quality of care and established an evaluation, feedback and improvement system for primary key performance indexes (KPIs). For KPI selection, PPCI hospitals focused on the improvement in the PPCI capacity and efficiency, non-PPCI hospitals focused on the improvement in rapid diagnosis, thrombolysis and referral capacity to PPCI hospitals, and EMS focused on the improvement in information transmission to alert hospitals early for the purpose of rapid and accurate transfer.

A total of 13 primary KPIs were selected for medical quality evaluation based on different roles of EMS and hospitals in STEMI management (Table 2). These KPIs are different in each phase but have internal logic. Except reperfusion rate, method and cardiovascular outcomes, different treatment delay indexes are selected in different phases which will shift to others step by step according to the progress of network construction. D2N and D2B time, defined as from in-hospital FMC to target vessel open, were used to evaluate in-hospital delay in CSCAP-1. First medical contact-to-balloon time (FMC2B) and first medical contact-to-needle time (FMC2N) time, defined as FMC by emergency system or hospital to target vessel open, were used to evaluate the whole medical system delay in CSCAP-2. Total ischemic time, defined as from symptom onset to target vessel open, is used in CSCAP-3 to add the information of patient delay.

The circular enrollment–evaluation–feedback-improvement method will be

implemented in both CSCAP-2 and CSCAP-3. The quality feedback report contains each KPI of the affiliation and its ranking within its regional network and among all affiliations. Comparison of KPIs with itself and those of others was analyzed for tailed improvements.

Patient and public involvement

The development of the research questions and outcome measures was informed by the current situations of lacking of the integrated regional STEMI care network in China. Patients were not offered the opportunity to participate in the study design. They will obtain the information related to the study via public media as well as academic publications.

Ethics and dissemination

The study was conducted in accordance with Declaration of Helsinki. The study protocol was approved by the Ethics Committee of Peking University First Hospital. Ranking reports of quality of care will be made available to all participant affiliations. Results will be disseminated at international conferences and published in peer-reviewed scientific journals or public media.

Discussion

The integration and optimization of an integrated regional network with government support are urgent issues of STEMI care especially in China. CSCAP is the first prospective registry study focused on regional network construction and will help

extensively understand the basic situations and the differences with other countries, which leading to optimized clinical practice and problem-guided improvement. It will provide important information for the network construction shifting from the PPCI hospital-centered regional network to the whole-city network step by step so as to create an optimal integrate STEMI care system in China.

Contributions Yan Zhang coordinated the study, assisted with data collection, performed data analysis, and drafted the manuscript. Bo Yu, Yaling Han, Jianan Wang, Lixia Yang, Zheng Wan, Zheng Zhang, Yuguo Chen, Xianghua Fu, Chuanyu Gao, Bao Li, Jiyan Chen, Ming Wu, Yitong Ma, Xingsheng Zhao, Yundai Chen, Hongbing Yan, Dingcheng Xiang, Weiyi Fang, and Junbo Ge carried out the data collection and helped draft the manuscript. Sameer Mehta and Christoph K Naber participated in the design and helped draft the manuscript. Yong Huo, principal investigator of the project, conceived and designed the project, helped collect data and draft the manuscript. All authors reviewed the results and approved the final version of the manuscript.

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Competing interest None declared.

Patient consent for publication Not required.

Ethics approval This study was reviewed and approved by the Ethics Committees at Peking University First Hospital.

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Table 1. CSCAP data elements

Category	Example elements
Patient baseline information	Demographics (age, sex, ethnicity, occupation, marriage status, and medical insurance type) Risk factors (smoking status, BMI, hypertension, diabetes, dyslipidemia, peripheral artery disease, MI history, stroke history, and prior revascularization) Clinical presentation (blood pressure, heart rate, and cardiac function classification)
Prehospital information	Patient (symptoms, symptom onset time, and hospital approaching method) EMS (response time, transfer process, first ECG time, ECG transmission ratio, and bypass ED ratio) Non-PCI hospital (hospital approaching method, first medical contact time, admission time, first ECG time, diagnosis time, consent time, reperfusion and other treatment, DI-DO time, and transfer process)
PCI hospital information	Reperfusion (methods, indication and contraindication, and nonreperfusion reasons) Treatment delay (hospital approaching method, first medical contact time, bypass ED ratio, admission time, first ECG time, catheter lab ready time, consent time, D2B, D2N, FMC2B,

	FMC2N, total ischemic time, and reasons of delay) PCI procedures (operative route, coronary angiography results, aspiration, culprit vessels, stent, and elective PCI) Thrombolytic procedures (thrombolytic agent, dose, and outcome) Medications (loading dose DAPT and statin, antiplatelets, β-blockers, statin, ACEI/ARB, GP IIb/IIIa inhibitor, and anticoagulant with dose and contraindication information) Laboratory results (troponin, CK-MB, creatinine, hemoglobin, HbA1c, fasting glucose, BNP or NT-proBNP, lipid profiles, ECG, and UCG) Discharge (diagnosis, in-hospital duration, expense, and medications) Outcomes (death, non-fatal reinfarction, nonfatal stroke, revascularization, mechanical complication, and bleeding)
Follow-up and management	Presentation status (symptom, cardiac function classification, blood pressure, heart rate, and follow-up on-time ratio) Laboratory results (lipid profiles, glucose traits, HbA1c, creatinine, hemoglobin, BNP or NT-proBNP, ECG, and UCG) Medications (antiplatelets, β-blockers, statin, and ACEI/ARB) Risk factor control rate (Blood pressure, lipid, glucose, and

	smoking cessation)
	Outcomes (death, nonfatal reinfarction, stroke, revascularization, rehospitalization due to unstable angina pectoris, heart failure or other cardiovascular reasons, and bleeding)

ACEI, Angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; BMI, body mass index; BNP, brain natriuretic peptide; CK-MB, creatine kinase MB isoenzyme; DAPT, dual antiplatelet therapy; D2B, door to balloon; D2N, door to needle; DI–DO, door in–door out; ECG, electrocardiograph; ED, emergency department; EMS, emergency medical service; FMC2B, first medical contact to balloon; FMC2N, first medical contact to needle injection; GP IIb/IIIa, glycoprotein IIb/IIIa; HbA1c, glycosylated hemoglobin A1c; MI, myocardial infarction; NT-ProBNP, N-terminal pro–brain natriuretic peptide; PCI, percutaneous coronary intervention; UCG, ultrasound cardiogram.

Table 2. Primary performance measures for evaluating medical care quality

Primary performance measures
Prehospital care
Symptom onset to arrival in hospital (min)
Hospital admission ratio via ambulance (%)
Prehospital ECG transmission ratio (%)
Bypass ED ratio in patients with symptom onset within 12 h (%)
Reperfusion
Overall reperfusion ratio (%)
Thrombolysis ratio in patients with symptom onset within 12 h (%)
Primary PCI ratio in patients with symptom onset within 12 h (%)
D2B in patients with symptom onset within 12 h (min)
D2N in patients with symptom onset within 12 h (min)
Discharge
Usage of both DAPT, statin, β blocker, and ACEI/ARB in patients without contraindication (%)
Outcomes
In-hospital mortality (%)
Follow-up and management
1-Year on-time follow-up ratio (%)
1-Year MACE (%), including mortality, non-fatal myocardial infarction, non-fatal stroke, and hospitalization due to heart failure or acute coronary syndrome

ACEI, Angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker;

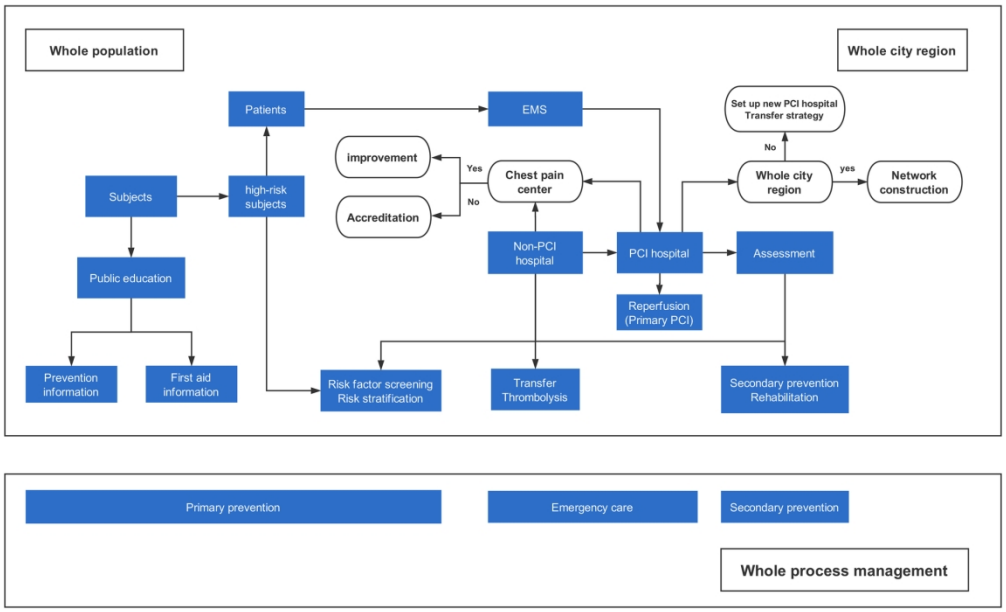
DAPT, dual antiplatelet therapy; D2B, door to balloon; D2N, door to needle; ECG, electrocardiogram; ED, emergency department; PCI, percutaneous coronary intervention; MACE, major adverse cardiovascular event.

Figure legends

Figure 1. CSCAP whole-city STEMI care network construction.

Figure 2. Geographic distribution of CSCAP.

Figure 3. CSCAP STEMI emergency care flow chart.



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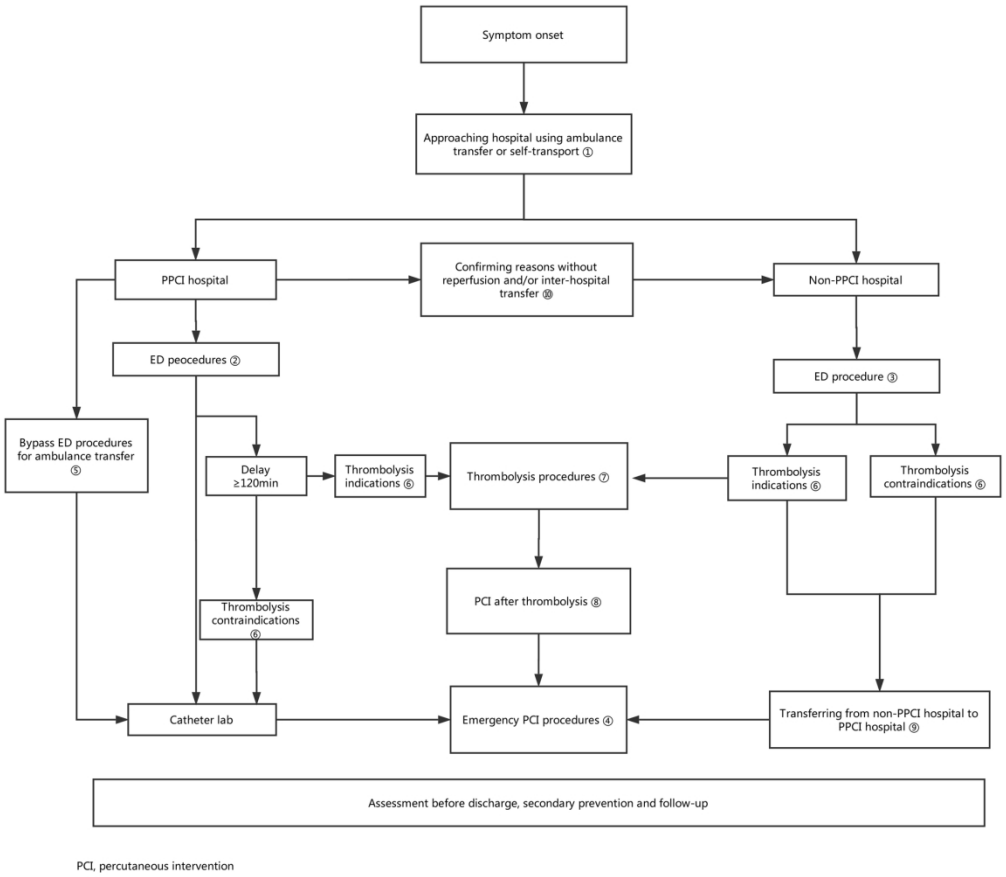

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Protocol of the China ST-segment elevation myocardial infarction (STEMI) Care Project (CSCAP): a 10-year project to improve quality of care by building up a regional STEMI care network

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Primary Subject Heading:	Evidence based practice
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Protocol of the China ST-segment elevation myocardial infarction (STEMI) Care Project (CSCAP): a 10-year project to improve quality of care by building up a regional STEMI care network

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This study was initiated in 2011 and will be completed in 2021. Phase 1 (CSCAP-1) is conducted from 2011 to 2013, Phase 2 (CSCAP-2) is conducted from 2015 to 2018, and Phase 3 (CSCAP-3) is conducted from 2018 to 2021, respectively.

Abstract

Introduction: Successful ST-segment elevation myocardial infarction (STEMI) management is time-sensitive and is based on prompt reperfusion mainly to reduce patient mortality. It has evolved from a single hospital care to an integrated regional network approach over the last decades. This prospective study, named the China STEMI Care Project (CSCAP), aims to show how implementation of different types of integrated regional STEMI care networks can improve the reperfusion treatment rate, shorten the total duration of myocardial ischemia, and lead to mortality reduction step by step.

Methods and analysis: The CSCAP is a prospective, multicenter registry study of 3 phases. A total of 18 provinces, 4 municipalities and 2 autonomous regions in China were included. Patients who meet the third universal definition of myocardial infarction and the Chinese STEMI diagnosis and treatment guidelines are enrolled. Phase 1 (CSCAP-1) focuses on the in-hospital process optimization of primary percutaneous coronary intervention (PPCI) hospitals, phase 2 (CSCAP-2) focuses on the PPCI hospital-based regional STEMI care network construction together with emergency medical services and adjacent non-PPCI hospitals, while phase 3 (CSCAP-3) focuses on the whole-city STEMI care network construction by promoting chest pain center accreditation. Systematic data collection, key performance index assessment and subsequent improvement are implemented throughout the project to continuously improve the quality of STEMI care.

Ethics and dissemination: The study has been reviewed and approved by the Ethics

Committee of Peking University First Hospital. Ranking reports of quality of care will be generated available to all participant affiliations. Results will be disseminated via peer-reviewed scientific journals and presentations at congresses.

Trial registration number: NCT03821012

Strengths and limitations of this study

- CSCAP is the first project focuses on establishing an integrated regional STEMI care network in China through in-hospital process optimization, PPCI hospital-based regional STEMI care network construction and whole-city STEMI care network construction step by step, which will help us to understand the situations extensively and then improve accordingly.
- Evaluation, feedback and improvement system will be established, aiming to provide a tailored and continuous quality of care improvement plan based on the conditions of different regions to further integrate the STEMI care network nationwide.
- Hospitals are not randomly selected in CSCAP which might be lead to lack of representatives to some degree. However, these hospitals are at a high level in their region which is suitable to be core centers for regional network construction. Their experiences could be valuable for hospitals in the same region but not in this study.

Introduction

The burden of cardiovascular diseases is increasing and posing a major public health issue worldwide. The number of new onset of myocardial infarction will be tremendous in China in the next 15 years with the increasing risk factors and aging population [1]. The Chinese cardiovascular report in 2017 has shown an increase in both the percentage of hospitalization and mortality of acute myocardial infarction (AMI) over the years. The trends of fast growth nationwide as well as higher AMI mortality in rural areas in were observed since 2005 and 2013, respectively [2].

ST-elevation myocardial infarction (STEMI), mainly caused by a sudden obstruction of the coronary artery with thrombus, benefits from both increasing reperfusion rate and shortening of the duration from the symptom occurrence to the opening of the target vessel [3 4]. Although implementing an evidence-based medicine significantly improves the prognosis of patients with STEMI, the gap of clinical application is still large in real-world settings [5]. A majority of Chinese STEMI patients miss the optimal treatment timing due to restrictions from both patients and medical services [6 7]. Additionally, the ratio of STEMI reperfusion treatment remained at the level of around 55% in the last decade. Hence, the in-hospital mortality has not changed significantly yet [7].

Successful treatment of STEMI is a systemic issue, and the solution is neither a novel thrombolytic drug nor an intervention device. It can be brought about by comprehensive factors, including the patients' health awareness, physician's skill, physician–patient's relationship, medical reimbursement system, prehospital

emergency medical system (EMS), in-hospital treatment, connection mechanism between prehospital and in-hospital care, and posthospital management. Experiences from both the American Lifeline program and the European Stent – Save a Life can be used for reference. The quality of medical care can be significantly improved by establishing a regional STEMI care network through close collaboration between hospitals of different levels and EMS [8 9].

Although large-scale studies have been conducted in China, such as Clinical Pathways for Acute Coronary Syndromes in China (CPACS) focusing on the ACS clinical pathway, Cardiovascular Disease in China (CCC) focusing on the in-hospital treatment of acute coronary syndrome (ACS), China Acute Myocardial Infarction (CAMI) Registry focusing on the management of both STEMI and non-STEMI, and China Patient-centered Evaluative Assessment of Cardiac Events Retrospective Study of Acute Myocardial Infarction (China PEACE-Retrospective AMI Study), none of them focused on establishing a regional STEMI care network [7 10-12]. Serial documents issued by the National Health Commission of China provide favorable government supports and further emphasize the important rolls of administrative departments of health care at all levels in strengthening the construction of regional emergency care network [13-15].

China has gradually increased the input of medical expense in the last few decades. However, there are several types of medical insurances with different reimbursement policy in China. The impacts of health economic factors as well as geographical and humanistic factors on quality of STEMI care need to be discussed either.

Objectives

The 10-year project, named as China STEMI Care Project (CSCAP), aims to show how implementation of different types of integrated regional STEMI care networks can improve the reperfusion treatment rate, shorten the total duration of myocardial ischemia, and lead to mortality reduction step by step. It will also provide useful information when building up a STEMI care network in other similar regions. In details, CSCAP focuses on improving the awareness of health and emergency treatment for STEMI patients, increasing the ratio of reperfusion treatment, shortening the overall duration of myocardial ischemia, and implementing standard secondary prevention to improve the long-term prognosis by establishing and optimizing medical care evaluation, feedback and improvement system with data support.

Methods and analysis

Study design

CSCAP is a prospective multicenter registry containing 3 phases. Phase 1 of CSCAP (CSCAP-1) focuses on the in-hospital process optimization of primary percutaneous coronary intervention (PPCI) hospitals. Phase 2 of CSCAP (CSCAP-2) focuses on the PPCI hospital-based regional STEMI care network construction with their adjacent non-PPCI hospitals and EMS. Phase 3 of CSCAP (CSCAP-3) focuses on the whole-city STEMI care network construction by promoting chest pain center (CPC) accreditation (Fig. 1). Systematic data collection, assessment of quality of care and subsequent improvement are implemented throughout this study to continuously

improve the quality of care.

Organizational framework

CSCAP was established by the Chinese Medical Doctor Association and supported by the National Health Commission of China in 2011. After collaborating with the European Stent – Save a Life in CSCAP-3, China became its member country in 2017. The project office, executive committee and steering committee were set up for the purposes of management, implementation and academic support. Data management and statistical analyses were conducted by the School of Public Health of Peking University.

Site selection

CSCAP included 18 provinces (Anhui, Fujian, Gansu, Guangdong, Guangxi, Hainan, Hebei, Heilongjiang, Henan, Hubei, Jiangsu, Liaoning, Shandong, Shanxi, Shaanxi?, Sichuan, Yunnan, and Zhejiang), 4 municipalities (Beijing, Chongqing, Shanghai, and Tianjin) and 2 autonomous regions (Inner Mongolia and Xinjiang) in China when considering incidence of STEMI, logistic as well as economic issues.

A total of 53 tertiary hospitals qualified for PPCI in 10 provinces, 2 municipalities and 2 autonomous regions of China were enrolled in CSCAP-1. The qualification of these selected hospitals was based on the numbers of PCI cases and cardiovascular interventionists extracted from the national PCI registry database. Moreover, all of them are able to provide 24/7 PPCI service. These hospitals were selected because they were at the top level in their city and potentially a hub for regional network construction in CSCAP-2. A total of 244 PCI hospitals with adjunct non-PCI hospitals

from 18 provinces, 4 municipalities and 2 autonomous regions were selected to build up the regional STEMI care network in CSCAP-2. A total of 7 cities (Harbin, Hangzhou, Nanning, Qingdao, Shenzhen, Suzhou, and Taiyuan) from 6 provinces and 1 autonomous region with different EMS types were selected to build up the whole-city STEMI care network in CSCAP-3.

Patient enrollment

Patients who met with the third universal definition of myocardial infarction and the Chinese STEMI diagnosis and treatment guidelines were enrolled [16 17]. STEMI patients with late admission to hospitals were also considered for the purpose of exploring optimal methods to shorten total ischemic time causing by both patient and system delay. All patients received routine clinical assessments and treatments without any experimental intervention. The updated guideline-directed management such as reperfusion, auxiliary device implementation, elective revascularization, medications and therapeutic lifestyle change will be implemented during the whole study period.

In CSCAP-1, a total of 4,191 hospitalized patients, with symptom onset within 12 h regardless of whether receiving reperfusion or symptom onset within 12–24 h but still need PPCI, were enrolled consecutively in 2012. In CSCAP-2, a total of 20,799 patients with STEMI occurrence within 30 days regardless of reperfusion were enrolled consecutively from PPCI hospitals 3 times at a 6-month interval from 2015 to 2017. In CSCAP-3, a total of 30 hospitalized STEMI patients with symptom onset within 30 days will be enrolled consecutively from both PCI and non-PCI hospitals in

the whole-city network every 3 months. Those patients who survived after hospital discharge will be followed up for 1 year.

Regional network construction

An integrated regional network contains PCI hospitals, non-PCI hospitals and EMS. There are 3 major types of EMS in China: (1) independent EMS, which has its own ambulances; (2) commanding EMS, which does not have its own ambulances and uses hospital ambulances; and (3) affiliated EMS, which is based in hospitals and uses their ambulances. Due to these comprehensive situations, patients may not be transported to optimal hospitals to receive effective treatment in the shortest period because of incomplete communication [18]. Thus, prehospital information transmission should be considered accordingly for hospital alert and rapid and accurate transfer.

Although PPCI is the most effective treatment for STEMI, it is difficult to be implemented in most of the primary hospitals, as they are limited by medical condition, geographic location and techniques. Early thrombolysis and/or transfer PCI strategy are the priority in these hospitals. Therefore, rapid identification of STEMI and referral to a hospital with PPCI ability are extremely important components in establishing a regional STEMI care network in China.

Optimizing the in-hospital green channel can significantly shorten the door-to-balloon (D2B) time and door-to-needle (D2N) time, while establishing a CPC to integrate multiple resources is one of the most important methods [19 20]. Traditional CPC focuses on the optimization and integration of the in-hospital sources

aiming to shorten the time of the process. The medical system and patient factors together determine the delay in STEMI emergency treatment [21]. The concept of a modern CPC expands to establishing an effective regional network aiming to shorten the total ischemia duration, thereby maximizing the advantage of reperfusion therapy. The CPC independent accreditation in China was initiated in 2013 and 2 types accreditation standards were developed according to PPCI ability [22 23].

Procedures

The treatment process of patients suffered STEMI was based on the STEMI protocol in the Announcement of Improving Medical Emergency Treatment Performance of Acute Cardiovascular and Cerebrovascular Diseases issued by the National Health Commission of China in 2015 [15]. Briefly, this flow chart included 1 center (EMS), 2 types of hospitals (PCI and non-PCI), 3 types of transfer methods (EMS transfer to hospital, bypass emergency department (ED) and inter-hospital transfer), and 11 clinical pathways. Different clinical pathways were selected to execute the optimal emergency treatment based on the approaching time, method and hospital ability (Fig. 2). In addition, the procedures should be launched without results of myocardial biomarkers according to typical ischemic symptoms and electrocardiogram (ECG).

Data collection and management

Data of all treatment process were collected, including patient general information, prehospital treatment, in-hospital management and follow-up management (Table 1). Considering the real situation in ED, many time points could not be recorded manually on time which might lead to missing and inaccurate data. Mobile device app

can record these time variables through a simple click and complete the prehospital ECG transmission. In addition, the technique of data auto-capture becomes more and more popular at present and should resolve this issue. All of these methods are considered gradually in this study.

Data were inputted into a self-built electronic database together with two existing databases of both CPC accreditation and national PCI registry by trained clinical research coordinators and clinicians in each hospital. The quality of the data was monitored and suspicious contents with missing, outlier and logical errors were mainly reviewed. When all problems are resolved, the database is then locked for statistical analysis.

The describing method was used in CSCAP to mainly rank data quality and medical quality. Continuous variables were described as mean (standard deviation) or median (interquartile range), while categorical variables were described as a percentage. Multivariate regression model was used to evaluate the factors related to the assessment of medical quality. The Cox model was used to analyze the association between exposures and medical outcomes. A P value < 0.05 was defined as a significant difference. All analyses were performed using R (http://www.R-project.org).

Key performance index

The National Cardiovascular Data Registry (NCDR), established since 1997, has become the basis for project implementation and quality evaluation as well as medical quality improvement of research centers in the United States. It has a positive impact

on clinical practice, medical payment, clinical research and government decision-making [24 25]. The present study referred to the NCDR model to optimize the STEMI quality of care and established an evaluation, feedback and improvement system for primary key performance indexes (KPIs). For KPI selection, PPCI hospitals focused on the improvement in the PPCI capacity and efficiency, non-PPCI hospitals focused on the improvement in rapid diagnosis, thrombolysis and referral capacity to PPCI hospitals, and EMS focused on the improvement in information transmission to alert hospitals early for rapid and accurate transfer.

A total of 13 primary KPIs were selected for medical quality evaluation based on different roles of EMS and hospitals in STEMI management (Table 2). However, different treatment delay indexes were used in different phases according to the progress of network construction. D2N and D2B time, defined as in-hospital FMC to target vessel open, were used to evaluate in-hospital delay in CSCAP-1. First medical contact-to-balloon (FMC2B) time and first medical contact-to-needle (FMC2N) time, defined as FMC by emergency system or hospital to target vessel open, were used to evaluate the whole medical system delay in CSCAP-2. Total ischemic time, defined as symptom onset to target vessel open, is used in CSCAP-3 to add the information of patient delay.

The circular enrollment–evaluation–feedback-improvement method will be implemented in both CSCAP-2 and CSCAP-3. The quality feedback report contains each KPI of the affiliation and its ranking within its regional network and among all affiliations. Comparisons of KPIs with itself and those of others are analyzed for

tailed improvements.

Patient and public involvement

Public education of first aid and health care will be performed during the project implementation. Patients were not offered the opportunity to participate in the study design. They will obtain the information related to the study via public media as well as academic publications.

Ethics and dissemination

The study was conducted in accordance with Declaration of Helsinki. The study protocol was approved by the Ethics Committee of Peking University First Hospital. Ranking reports of quality of care will be made available to all participant affiliations. Results will be disseminated at international conferences and published in peer-reviewed scientific journals or public media.

Discussion

The integration and optimization of an integrated regional network with government support are urgent issues of STEMI care, especially in China. CSCAP is the first prospective registry study focused on regional network construction and will help to understand the current situations and the differences with other countries extensively, which leading to optimized clinical practice and problem-guided improvement. It will provide important information for the network construction shifting from the PPCI hospital-centered regional network to the whole-city network step by step, so as to

create an optimal integrate STEMI care system in China.

Contributions Yan Zhang coordinated the study, assisted with data collection, performed data analysis, and drafted the manuscript. Bo Yu, Yaling Han, Jianan Wang, Lixia Yang, Zheng Wan, Zheng Zhang, Yuguo Chen, Xianghua Fu, Chuanyu Gao, Bao Li, Jiyan Chen, Ming Wu, Yitong Ma, Xingsheng Zhao, Yundai Chen, Hongbing Yan, Dingcheng Xiang, Weiyi Fang, and Junbo Ge carried out the data collection and helped draft the manuscript. Sameer Mehta and Christoph K Naber participated in the design and helped draft the manuscript. Yong Huo, principal investigator of the project, conceived and designed the project, helped collect data and draft the manuscript. All authors reviewed the results and approved the final version of the manuscript.

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Competing interests None declared.

Patient consent for publication Not required.

Ethics approval This study was reviewed and approved by the Ethics Committees at Peking University First Hospital.

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Table 1. CSCAP data elements

Category	Example elements
Patient baseline information	Demographics (age, sex, ethnicity, region, occupation, marriage status, and medical insurance type) Risk factors (smoking status, BMI, hypertension, diabetes, dyslipidemia, chronic kidney disease, peripheral artery disease, MI history, stroke history, and prior revascularization) Clinical presentation (blood pressure, heart rate, and cardiac function classification)
Prehospital information	Patient (symptoms, symptom onset time, and hospital approaching method) EMS (response time, transfer process, first ECG time, ECG transmission ratio, and bypass ED ratio) Non-PCI hospital (hospital approaching method, first medical contact time, admission time, first ECG time, diagnosis time, consent time, reperfusion and other treatment, DI-DO time, and transfer process)
PCI hospital information	Reperfusion (methods, indication and contraindication, and nonreperfusion reasons) Treatment delay (hospital approaching method, first medical contact time, bypass ED ratio, admission time, first ECG time,

	catheter lab ready time, consent time, D2B, D2N, FMC2B, FMC2N, total ischemic time, and reasons of delay) PCI procedures (operative route, coronary angiography results, aspiration, culprit vessels, stent, and elective PCI) Thrombolytic procedures (thrombolytic agent, dose, and outcome) Medications (loading dose DAPT and statin, antiplatelets, β-blockers, statin, ACEI/ARB, GP IIb/IIIa inhibitor, and anticoagulant with dose and contraindication information) Laboratory results (troponin, CK-MB, creatinine, HbA1c, fasting glucose, BNP or NT-proBNP, lipid profiles, ECG, and UCG) Discharge (diagnosis, in-hospital duration, expense, and medications) Outcomes (death, non-fatal reinfarction, nonfatal stroke, revascularization, mechanical complication, and bleeding)
Follow-up and management	Presentation status (symptom, cardiac function classification, blood pressure, heart rate, and follow-up on-time ratio) Laboratory results (lipid profiles, glucose traits, HbA1c, creatinine, hemoglobin, BNP or NT-proBNP, ECG, and UCG) Medications (antiplatelets, β-blockers, statin, and ACEI/ARB)

	Risk factor control rate (Blood pressure, lipid, glucose, and smoking cessation)
	Outcomes (death, nonfatal reinfarction, stroke, revascularization, rehospitalization due to unstable angina pectoris, heart failure or other cardiovascular reasons, and bleeding)

ACEI, Angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; BMI, body mass index; BNP, brain natriuretic peptide; CK-MB, creatine kinase MB isoenzyme; DAPT, dual antiplatelet therapy; D2B, door to balloon; D2N, door to needle; DI–DO, door in–door out; ECG, electrocardiograph; ED, emergency department; EMS, emergency medical service; FMC2B, first medical contact to balloon; FMC2N, first medical contact to needle injection; GP IIb/IIIa, glycoprotein IIb/IIIa; HbA1c, glycosylated hemoglobin A1c; MI, myocardial infarction; NT-ProBNP, N-terminal pro–brain natriuretic peptide; PCI, percutaneous coronary intervention; UCG, ultrasound cardiogram.

Table 2. Primary performance measures for evaluating medical care quality

Primary performance measures
Prehospital care
Symptom onset to arrival in hospital (min)
Hospital admission ratio via ambulance (%)
Prehospital ECG transmission ratio (%)
Bypass ED ratio in patients with symptom onset within 12 h (%)
Reperfusion
Overall reperfusion ratio (%)
Thrombolysis ratio in patients with symptom onset within 12 h (%)
Primary PCI ratio in patients with symptom onset within 12 h (%)
D2B in patients with symptom onset within 12 h (min)
D2N in patients with symptom onset within 12 h (min)
Discharge
Usage of both DAPT, statin, β blocker, and ACEI/ARB in patients without contraindication (%)
Outcomes
In-hospital mortality (%)
Follow-up and management
1-Year on-time follow-up ratio (%)
1-Year MACE (%), including mortality, non-fatal myocardial infarction, non-fatal stroke, and hospitalization due to heart failure or acute coronary syndrome

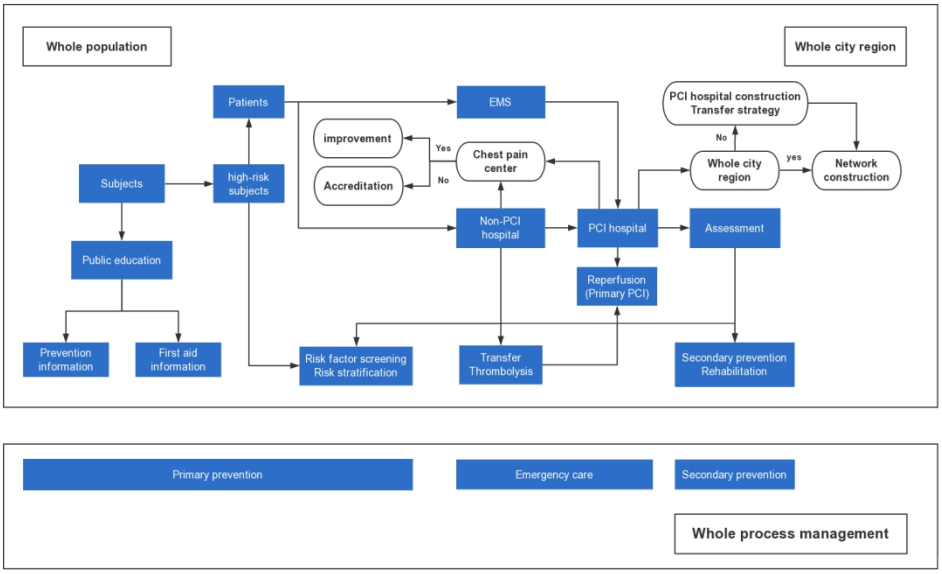
ACEI, Angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker;

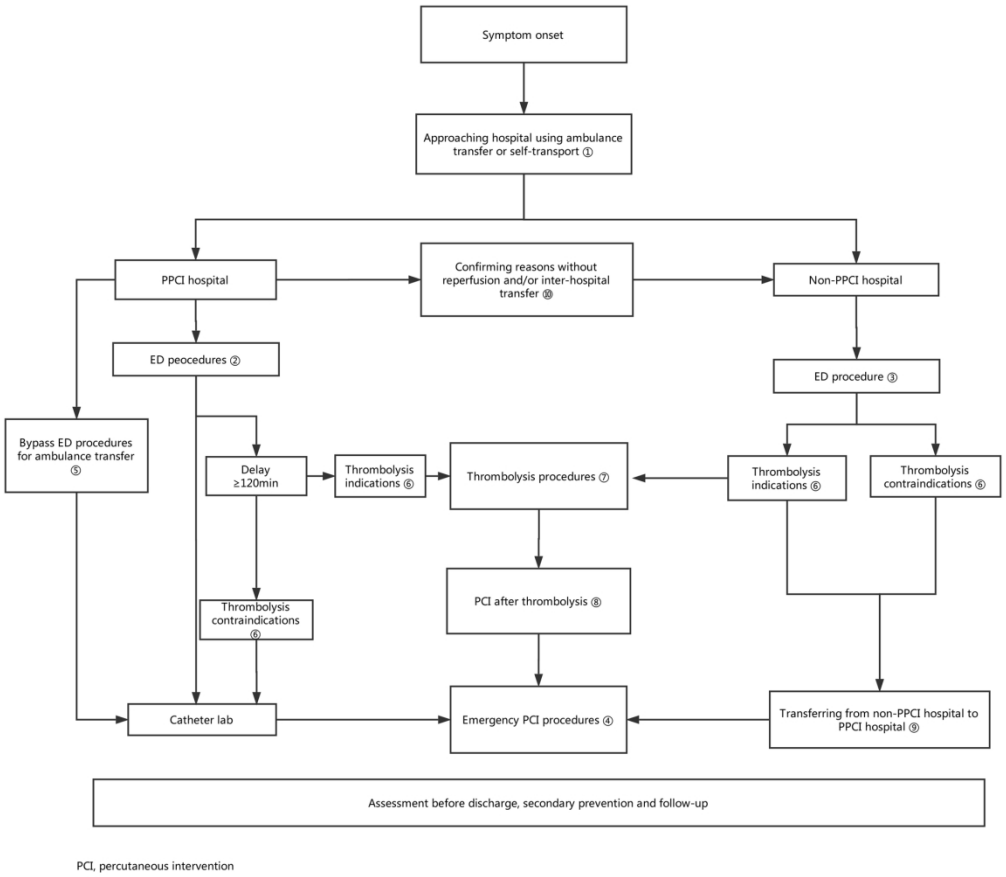
DAPT, dual antiplatelet therapy; D2B, door to balloon; D2N, door to needle; ECG, electrocardiogram; ED, emergency department; PCI, percutaneous coronary intervention; MACE, major adverse cardiovascular event.

Figure legends

Figure 1. CSCAP whole-city STEMI care network construction.

Figure 2. CSCAP STEMI emergency care flow chart.


Whole population
Whole city region
Patients
EMS
PCI hospital construction
Transfer strategy
No
improvement
Yes
Chest pain center
Whole city region
yes
Network construction
Subjects
high-risk subjects
Accreditation
No
Non-PCI hospital
PCI hospital
Assessment
Public education
Reperfusion (Primary PCI)
Prevention information
First aid information
Risk factor screening
Risk stratification
Transfer Thrombolysis
Secondary prevention
Rehabilitation
Primary prevention
Emergency care
Secondary prevention
Whole process management



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