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The Primary Angioplasty Registry of Sina (PARS); A Brief Report of Design and Rationale

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Abstract

Cardiovascular diseases, especially ST-elevation myocardial infarction (STEMI), are among the major health concerns in Iran. Although primary percutaneous coronary intervention (pPCI) is performed as the treatment of choice in Iranian hospitals, there is limited data on its efficacy, safety, procedural variations, and clinical outcomes after implementation of the new Protocol-247, which transfers patients with STEMI directly to pPCI-capable hospitals. The Primary Angioplasty Registry of Sina (PARS) is an ongoing prospective hospital-based registry enrolling patient with STEMI undergoing pPCI in Sina Hospital, which is a high-volume referral PCI-capable general hospital in Tehran, Iran. This registry aims to gather high-quality data on patient characteristics, hospital-based quality of care, coronary interventions, and in-hospital as well as long-term clinical outcomes of patients undergoing pPCI due to STEMI. In addition, the findings will be used to identify independent predictors of mortality and adverse events and form the basis of future clinical trials and quality improvement strategies.

Key words: Myocardial Infarction; Percutaneous Coronary Intervention; Registries; ST Elevation Myocardial Infarction

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INTRODUCTION

Cardiovascular diseases, especially myocardial infarction, are the leading cause of mortality and responsible for one-third of all deaths worldwide (1). Recent epidemiological studies have shown an increasing trend of myocardial infarction in the Iranian population with the highest in-hospital mortality reported in patients with ST-elevation myocardial infarction (STEMI) (2, 3). Multiple guidelines have been implemented to reduce mortality in these patients, including performing primary percutaneous coronary intervention (pPCI) and reducing ischemic time.

Project-247, referring to availability of this service 24 hours a day, 7 days a week (24/7), was initiated by the national committee for myocardial infarction under supervision of Iranian Ministry of Health and Medical Education in 2015 (October), with the goal of out-of-hospital diagnosis of STEMI patients and direct transfer to nearest PCI-capable hospitals across Iran. In this project an on-site electrocardiogram (ECG) is recorded from patients with complaint of chest pain by paramedics, which is then electronically assessed by the resident cardiologist at "Tehran's Emergency Dispatch Center". In case of possible diagnosis of STEMI, the patient is transferred to the nearest pPCI center. At the same time, Aspirin and Clopidogrel are given to patients in the ambulance and the on-call team of cardiac interventionists and nurses are informed to be ready to perform PCI upon arrival of the patient. With implementation of Project-247, there is an urgent need for a prospective registry to analyze the efficacy of pPCI, patient characteristics, compliance with guideline recommendations and predictors of mortality and adverse outcomes in patients undergoing pPCI.

Sina Hospital is the first modern-day hospital of Iran, which was built in the heart of Tehran's (Capital of Iran) historical district in 1837. It is a general hospital affiliated with Tehran University of Medical Sciences and now the primary high-volume referral PCI-capable hospital in south Tehran. The Primary Angioplasty Registry of Sina hospital (PARS) is an ongoing prospective longitudinal hospital-based registry of patients undergoing pPCI for STEMI.

Methods

Registry design

The Primary Angioplasty Registry of Sina hospital (PARS), an ongoing prospective registry of patients with STEMI undergoing pPCI, commenced patient enrollment from November 2016. In this registry, patients are directed to the pPCI unit through Project-247, emergency department, or transfer from other regional hospitals. The Primary Angioplasty Registry of Sina hospital is designed to comply with the reporting standards of STROBE guidelines (4) and was approved by the ethics committee of Tehran University of Medical Sciences (IR.TUMS.MEDICINE.REC.1398.244).

Inclusion criteria

All patients aged more than 18 years, who presented with STEMI of <12h duration and underwent pPCI were included in the study. Patients with STEMI presenting 12–24h after pain onset were also included in case of clinical and/or electrocardiographic evidence of ongoing ischemia. STEMI was diagnosed by the rise and/or fall of cardiac biomarkers with at least one value above the 99th percentile upper reference limit accompanied by electrocardiographic features of STEMI. ST-elevation was defined as elevation in the J point in two or more contiguous leads of >2.5mm in men younger than 40 years old, >2mm in men older than 40 years old or >1.5mm in women in leads V2-V3 and/or ≥1mm in other contiguous leads. New or supposedly new left bundle branch block was also considered equivalent to STEMI.

Exclusion criteria

We excluded patients under 18 years old, individuals presenting with STEMI >24h of pain onset, those presenting between 12-24h with no clinical and/or electrocardiographic evidence of ongoing ischemia, non-STEMI, unstable angina, and patients who had undergone thrombolytic therapy. It should be mentioned that thrombolytic administration in acute myocardial infarction is forbidden in the hospitals participating in the Project-247 and is performed only in cases of lack of angioplasty facilities. Patients for whom pPCI was not performed or other diagnoses such as Takotsubo were suggested were also excluded.

Data collection and quality assurance

Data collection was performed by designated staff members at different stages, while efforts were made to achieve real-time data collection (Table 1). If the patient was transferred to the catheterization laboratory immediately, missing data in the previous stage were also completed. Demographic, laboratory, echocardiographic, and angiographic features of patients are recorded on a completely web-based standardized electronic form in addition to paper-based medical records. Before the discharge of each patient, a trained research nurse checks the paper-based medical record to fill missing data on the electronic database. In addition, an independent researcher randomly checks and evaluates the accuracy of data entry.

Demographic data and risk factors

Baseline demographic data, educational status, occupational status, and mode of transfer to catheterization laboratory are obtained. All patients are evaluated for the presence of atherosclerotic cardiovascular disease risk factors through detailed interviews, previous medical records, and/or laboratory studies. Risk factors are

Table 1: Stages and personnel in charge of data entry

Location	Staff	Entered data
Emergency room	Admitting physician/ Staff	Demographic data Risk factors Drug history Time from pain-onset to first medical contact
Catheterization laboratory	Interventional cardiologists	Door to device time Time from first medical contact to device Hemodynamic parameters Angiographic features Coronary interventions Complications
Coronary care unit (CCU)	Cardiologist/ Nursing staff	Laboratory studies Echocardiographic features Medications
Ward	Cardiologist/ Nursing staff	Discharge medications In-hospital adverse events Discharge status
Outpatient clinic	Cardiologist/ Research nurse	Medication adherence Laboratory studies Follow-up adverse events Mortality

defined using the current guideline recommendations. Hypertension is defined as systolic blood pressure ≥130mmHg, diastolic blood pressure ≥80mmHg or previous diagnosis/treatment of hypertension. Diabetes is defined as fasting blood sugar ≥126mg/dL, glycated hemoglobin (HbA1c) ≥6.5% or previous diagnosis/treatment for diabetes. Chronic kidney disease is defined as an estimated glomerular filtration rate of less than 60mL/min/1.73m^2 or previous diagnosis of chronic kidney disease or dialysis.

Hospital course and diagnostic evaluations

Upon presentation, data on time from pain onset to PCI, pain onset to first medical contact, and hemodynamic parameters are recorded. Patients are scheduled for echocardiography on the day after pPCI. During hospitalization, data on medical interventions, diagnostic testing, laboratory studies, in-hospital events, and discharge status are recorded. Data of medications used on presentation, in the hospital, and after discharge will be collected, prospectively. In-hospital events and complications are recorded by staff physicians and further reviewed by expert cardiologists. These include all-cause mortality, cardiac arrest, conduction blocks, atrial fibrillation, ventricular tachycardia or ventricular fibrillation, cardiogenic shock, hemodynamic support interventions, recurrent MI, stent thrombosis, bleeding events, stroke, and contrast-induced nephropathy. Standard definitions are used to identify the mentioned complications and outcomes (5, 6).

Objectives and follow-up

All study participants will be followed at 30 days, 6 months, 1 year and then annually after the index hospitalization. The follow-up will be prospectively performed, using outpatient visits and telephone calls. At each visit, vital signs, adherence to guideline-directed medications, laboratory studies and occurrence of all-cause mortality and adverse events will be assessed through a detailed interview with the patient or immediate caregiver. The vital status of patients who are presumed to be lost to follow-up is assessed by contacting the designated contact number.

The purpose of PARS study is to assess baseline characteristics, risk factors, angiographic features, coronary interventions, and adherence to guideline-directed recommendations in patients with STEMI undergoing pPCI in a tertiary center. This study yields valuable information to determine independent predictors of in-hospital, short-term and long-term all-cause mortality and adverse cardiovascular events. In addition, we tend to evaluate the role of different procedural interventions on angiographic features of revascularization and patient-oriented outcomes.

Discussion

Multiple registries around the world have assessed the characteristics and outcomes of patients presenting with acute myocardial infarction (7-9). These registries report variations in patient characteristics, revascularization strategies, and clinical outcomes. However, most of these studies enrolled an unselected group of patients presenting with STEMI, Non-STEMI, and unstable angina. Besides, these studies included a heterogeneous group of patients regarding treatment strategy (pPCI vs. thrombolytic therapy). Hence, this might confound conclusions regarding efficacy, safety, and predictors of adverse clinical outcomes in patients with STEMI undergoing pPCI.

Recent guidelines have suggested that performing pPCI in a timely manner is the best treatment option for patients with STEMI (10, 11). Ever since, healthcare systems have increased PCI-capable centers to provide larger availability of pPCI. However, patient characteristics, delay to catheterization, quality of care, and outcomes differ between patients undergoing pPCI from different regions. Successful revascularization in STEMI patients undergoing pPCI requires a multidisciplinary approach from local systems of care including patient transfer protocols, guideline-directed pharmacotherapy, coronary intervention techniques, hemodynamic support, and intensive care.

Therefore, the PARS, a prospective hospital-based registry aims to identify variations in patient characteristics, delays to catheterization, and quality of care, as well as different predictors of mortality and adverse outcome in patients with STEMI undergoing pPCI to reach a conclusion regarding safety, efficacy, and effectiveness of therapeutic interventions.

Conclusions

The Primary Angioplasty Registry of Sina (PARS) hospital, a prospective hospital-based registry of individuals undergoing pPCI for STEMI, aims to gather high-quality data on patient characteristics, quality of care, coronary interventions, and short-term as well as long-term adverse clinical outcomes. Moreover, this study will be used to identify independent predictors of mortality and adverse events and form the basis of future clinical trials and quality improvement strategies.

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AUTHORS' CONTRIBUTION
All the authors met the standard criteria of authorship based on the recommendation of International Committee of Medical Journal Editors.

CONFLICT OF INTEREST
The authors declare that there is no conflict of interest regarding the present study.

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