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Background and design of a 5-year ST Elevation Myocardial Infarction Cohort in Isfahan, Iran: SEMI-CI study

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Original Article

Abstract

BACKGROUND: Cardiovascular disease (CVD) is one of the most important causes of mortality and morbidity in Iran. Secondary prevention of acute myocardial infarction (AMI) is necessary. The main aim of this cohort is evaluating clinical, paraclinical, management, and 5-year major events of the participants in Isfahan, Iran.

METHODS: All consecutive patients with AMI hospitalized in Chamran Hospital, Isfahan, during 1 year from march 2015 were recruited and followed for 5 years. ST-Elevation Myocardial Infarction Cohort Study (SEMI-CI) has been initiated as a longitudinal study to evaluate course of patients with AMI in Iran, adherence to evidence-based secondary prevention drug, and five-year events such as death, re-myocardial infarction (REMI), re-hospitalization, congestive heart failure (CHF), and referring to another procedure [percutaneous coronary intervention (PCI), coronary artery bypass graft (CABG), and resynchronization therapy].

RESULTS: A total of 867 patients with ST-elevation myocardial infarction (STEMI) with mean age of 60.91 ± 12.76 years were recruited. 705 (81.3%) subjects were men with mean age of 59.63 ± 12.59 years. 470 (54.2%) patients had anterior AMI (ant-AMI) and the rest had other types of AMI. The ejection fraction (EF) mean was 37.80 ± 11.74 percent. A total of 30 (3.5%) cases of AMI had not received reperfusion. 445 (51.4%) had primary PCI and 392 (45.2%) had thrombolysis at first revascularization strategy. In-hospital death occurred in 72 participants (8.3%). Drug during hospital included: at discharge, 767 (88.5%) received aspirin, 787 (90.7%) statin, 697 (80.4%) beta-blocker, and 480 (55.4%) angiotensin-converting enzyme (ACE) inhibitor.

CONCLUSION: According to the best of our knowledge, it is among few cohorts in Eastern Mediterranean Region (EMR) in patients with AMI. This paper showed methodology of this study in patients with STEMI and its follow-up protocol. We can use this result in policy-making for improving secondary prevention strategies.

Keywords: Myocardial Infarction; Cohort Study; Secondary Prevention; Death

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Introduction

Non-communicable diseases (NCDs) kill 41 million people each year, equivalent to 71% of all deaths globally.[1] Cardiovascular diseases (CVDs) account for decreased quality of life (QOL) in recent decades which creates an enormous burden for people, communities, and healthcare providers and systems.[2-4]

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CVD was the first leading cause of a million disability adjusted life years (DALYs) which led to 46% of all deaths and 20%-23% of the burden of disease in Iran.[5]

To strengthen national efforts, the World Health Organization (WHO) Global Action Plan for the Prevention and Control of NCDs 2013-2020 has been conducted.[6] There is still not much information about this global and highly prevalent health concern. Data registration may cause better improvements in this field. Poor registration of disease-related information leads to poor public health policies; thus, related guidelines are not applicable for doctors and other health departments; along these lines, inaccurate information can lead to poor choices in health investments.

Achieving the best evidence is possible through randomized controlled trials (RCTs), but this design is not always possible, because of the potential harm of the intervention like smoking or obesity. The next best evidence is then from observational cohort studies.[7] Well-designed longitudinal cohort studies are needed to update our knowledge considering the epidemiology of CVDs and known risk factors.[8] Reliable information about the distribution of known risk factors, how they change with time, and how they relate to cardiovascular outcomes is of major importance but still lacking in some developing countries.[9] The cross-sectional studies conducted in some developing countries did not give the expected policies against CVD.[10] This is because such studies offer a snapshot of a single moment in time; they do not consider what happens before or after the snapshot is taken, which highlights the importance of more sensitive evidence on CVD risk factors in longitudinal studies.[8] Without such reliable data, it is impossible to devise effective long-term disease-prevention strategies to combat the double burden.

In Iran, like other developing countries, lack of data registration has caused poor health policies. Thus, a number of cohort studies have been designed, such as the Isfahan Cohort Study (ICS),[11] the Prospective Epidemiological Research Studies in Iran (the PERSIAN Cohort Study),[12] Shahroud Cohort Study,[13] Tehran Lipid and Glucose Study (TLGS),[14] and the Golestan Cohort Study[15] which is currently in the enrollment phase as a primary-preventive cohort study on a large normal population in Iran. In the field of secondary-prevention on patients involved, there are not many studies in Iran.

According to the best of our knowledge, there is not a long-term follow-up of Acute coronary syndrome (ACS) cohort in EMR.

The ST-Elevation Myocardial Infarction Cohort Study (SEMI-CI) is a longitudinal study, conducted from September 2015, for at least 5 years, recruiting individuals with acute myocardial infarction (AMI) in the largest single cardiac center, Chamran Hospital, Isfahan, Iran. It is one of the large-scale cohort studies in EMR, which aims to determine CVD risk chart, the incidence of CVD events including fatal and non-fatal myocardial infarction (MI), fatal and non-fatal stroke and sudden cardiac death, heart failure (HF), re-hospitalization, recurrent percutaneous coronary intervention (PCI), coronary artery bypass graft (CABG), implantable cardioverter defibrillator (ICD), secondary prevention evidence-based drug use, and related risk factors in patients with ST-elevation myocardial infarction (STEMI). Here, we present the goals, design, and methodology of the SEMI-CI, the ongoing cohort study in patients with STEMI.

Materials and Methods

This study started from March 2015 to March 2016 for the consecutive patients in recruitment period as part of the Persian Registry of Cardiovascular Disease (PROVE) Study. Methodology of this study was published before.[16]

The main objective in this study (SEMI-CI) is preparing five-year risk chart for re-hospitalization and major adverse cardiac events (MACE) in patients with STEMI in a sample population in the Middle East. Moreover, we will show therapeutic pattern of patients with STEMI during follow-up and adherence to secondary prevention evidence-based drugs.

For one year, all the patients admitted with diagnosis of STEMI during past 24 hours in Chamran Hospital were recruited. If patients presented by new left bundle branch block (LBBB) with typical angina and rising in cardiac isoenzyme, they were also defined as having AMI. Exclusion criteria was non-diagnosis of AMI/STEMI or not willing to participate.

At the first encounter, all participants filled an informed consent. If they had loss of consciousness, the first relatives signed the form.

All participants' data were filled in hard sheets, then entered in Encapsulated PostScript Interchange (EPI) format.

For more confidentiality, all forms had a registration code, national code, besides their first and family names. Number of patient record in hospital was also noted. Home address of patients,

two phone numbers, date of birth, marital status, and type of insurance were also recorded.

Trained nurses filled the checklists. The nurses chosen to collect the data received ten initial training courses of 1.5-hour length and monthly one gathering of reeducation.

The research had four data-gathering phases:

Phase I: Pre-hospital, including pre-hospital diagnosis, symptom onset time and duration, admission process, transfer route to emergency room, place of patient referral (office, outpatient clinic, general hospital), drugs consumption and prescription, and pre-admission cardioversion

Phase II: Hospital phase, including first electrocardiography (ECG) diagnosis for AMI time, AMI site, blood pressure (BP) and heart rate (HR) during admission, past history of patients [including history of hypertension (HTN), diabetes, hyperlipidemia, atrial fibrillation (AF), cigarette smoking, stroke, previous ischemic heart disease (IHD)], opium and hookah use, psychological evaluation, angiographic and angioplasty data in detail, reperfusion therapy, ejection fraction (EF) before discharge, laboratory data [hemoglobin (Hb), creatinine, low-density lipoprotein cholesterol (LDL-C), blood glucose], rhythm and hemodynamic complications, and drugs' order during hospitalization.

Drugs were recorded during hospital and at discharge time in detail. Drug subtype was antiplatelet (aspirin, Plavix, ticlopidin, and prasugrel), anticoagulants (heparin, warfarin, and enoxaparin), beta-blockers (metoral, atenolol, carvedilol, and propranolol), angiotensin-converting enzyme (ACE) inhibitors (captopril, enalapril, and lisinopril), angiotensin receptor blockers (ARBs) (losartan and valsartan), aldosterone receptor antagonist (spirinolactane and eplerenone), diuretics (lasix, hydrochlorothiazide, and triamterene-H), statin type and dose (atorvastatin, lovastatin, rosuvastatin, and simvastatin), other lipid-lowering drugs (fibrates and ezetimibe), and other drugs.

The case report forms (CRFs) during hospital and follow-up also described additional planned procedures [recurrent PCI, CABG, intra-aortic balloon pump (IABP), and pacemaker].

Phase III: Discharge phase, including final diagnosis, drug prescription, referral to another hospital, AF in the last day

Phase IV: Yearly follow-up for 5 years, including adherence of secondary prevention drug consumption, MACE containing death (cardiovascular or all causes), stent thrombosis, re-hospitalization, congestive HF (CHF), electrical disturbance, and referring to another procedure (PCI, CABG). The long-standing annual follow-up of the patients was finalized over the phone and in person in the case of events. A trained nurse phoned all the patients to do this. In the event that patients came to our centers, we checked BP and serum lipids. If patients experienced MACE, they would be invited to hospital for exact diagnosis with their hospital record. In case of death, verbal autopsy and death certificate were evaluated. Verbal autopsy was done by a trained physician. All forms of event were reviewed by two expert cardiologists for accuracy of events.

All records had internal and external quality control for accurateness and validity of the files, as well as comparability and comprehensiveness of information.

Quality control (QC) measures taken were as follows: setting a list of minimum required information to enter into the registry, ensuring that the forms used to enter the data are user-friendly, providing a complete and easy-to-use protocol with a related glossary to be used in case of ambiguity, reviewing the data entry to ensure the quality, training all personnel responsible for data collection, ensuring that the data are collected with the highest quality and least missing info, visual inspection of the forms, and regular interim analysis.

Moreover, the QC committee ensured: 1) the timeliness of the data by registering the PROVE data in a preset time period, i.e., within two weeks of generating the medical record of a new patient at the target hospital and up to nine months, depending on the type of the disease, 2) the accuracy and validity of the data by accurately registering the data with no errors, and 3) the completeness of data by achieving the ultimate goal and by registering 90% of the admitted patients in hospitals, with any type of diseases. A second expert also reviewed the diagnostic accuracy.

Statistical analysis: Descriptive statistics were used to report the summary of data. Quantitative variables were expressed as mean ± standard deviation (SD), and qualitative variables were expressed as number (percent). Data were analyzed by SPSS software (version 22.0, IBM Corporation, Armonk, NY, USA).

Results

In this study, a total of 867 patients with STEMI with mean age of 60.91 ± 12.76 years were recruited. 705 (81.3%) were men with mean age of

59.63 ± 12.59 years and 162 (18.1%) were women with mean age of 66.00 ± 11.92 years.

342 (39.4%) patients with AMI were current smoker, 255 (29.4%) were diabetic, 255 (29.4%) had hypercholesterolemia, 9 (1.0%) had AF, 51 (5.9%) had prior stroke, 95 (11.0%) had prior PCI, and 295 participants (34.0%) were hypertensive. In-hospital death occurred in 72 participants (8.3%).

In 211 (24.4%) subjects, firs medical contact was by general physician, 190 (21.9%) were transferred by ambulance, and 446 (51.5%) by emergency room personnel.

470 (54.2%) patients had anterior AMI (ant-AMI) and the rest had other types of AMI. A total of 30 (3.5%) cases of AMI had not received reperfusion. 445 (51.4%) had primary PCI and 392 (45.2%) had thrombolysis at first revascularization strategy. The EF mean was 37.80 ± 11.74 percent.

Hospital complications were 2 (0.2%) cerebrovascular accidents (CVA), 7 (0.8%) CABG, 1 (0.1%) recurrent AMI, 2 (0.2%) mechanical complication, 1 (0.1%) tamponade, 108 (12.5%) clinical CHF, and 20 (2.3%) AF.

Drug during hospital included: At discharge, 767 (88.5%) patients received aspirin, 787 (90.7%) statin, 697 (80.4%) beta-blocker, and 480 (55.4%) ACE inhibitor/ARB (Table 1).

Discussion

According to the best of our knowledge, this longitudinal cohort study is a unique study for risk stratification of AMI in Middle East. SEMI-CI study was designed for knowledge about our situation in secondary prevention of patients with AMI and how our patients and physicians did new guideline in routine practice.

CVDs, especially AMI, is a leading cause of mortality and morbidity in Iran, and we must try to reduce their re-occurrence. Iranian Ministry of Health and Education had several fact sheets and seminars for physicians, nurses, and cardiologist for improving them in patient care, while our patients had some re-admission and discontinuation of drugs.

In recent years, with interventional therapy, CABG, and device implementation, the patient's length of life increased; thus, we need for more complementary drug and non-drug therapy strategies for prevention of disability and more effective years of life.[17]

As prevalence and incidence of risk factors and variable trend of recurrent ischemia after first AMI is different between societies and, on the other hand, life style of different communities varies, this factor implicates the risk factors, disease, and recurrent diseases. Finally, we need knowledge about our risk chart in secondary prevention study such as SEMI-CI.

The study by Khot et al. followed patients with AMI until one year; readmission of patients in this study was divided into three times including first peak (first 15 days), middles period (months 1-4), and ending period (> 4 months). The risk of readmission of patients after AMI was 5% until one year and also the risk of readmission in the first peak and middle period was more than ending peak.[18] Besides, in the United States (US), the incidence of readmission after 30 days of AMI was between 10% to 20%.[19]

In the study by Nakatani et al. on 7870 patients who had STEMI, in which patients were followed on average until 3.9 years after MI, 4.5% of patients experienced re-MI and 7 of them died until 30 days. Moreover, 2.6% of patients experienced re-MI after one year and incidence of re-MI was 0.91% to 1.42% until 5 years. Some risk factors including diabetics mellitus (DM), history of MI, and older age had significant effect on re-MI. The incidence of mortality in patients with re-MI was significantly higher than patients without re-MI. In addition, in patients treated with PCI after MI, the risk of re-MI was low compared with those without.[20] In the current study, hospital complications included CVA (0.1%), CABG (0.8%), recurrent AMI (0.1%), mechanical complication (0.2%), tamponade (0.1%), clinical CHF (12.5%), and AF (2.3%).

Incidence of early re-MI (one month) in STEMI occurred in 2.1% of patients; moreover, early re-MI was an uncommon complication in patients under primary PCI and re-MI was also an independent factor for death and ischemic target vessel revascularization. Some independent factors had significant effect on re-MI, including admission Killip class > 1 and left ventricular systolic dysfunction (LVSD).[21] In the current study, 50.9% of patients underwent PCI; 45.2% underwent thrombolysis and rescue PCI; instead, 0.1% of patients had recurrent MI.

In the other study that was done on AMI, 14% had re-MI; these patients were at advanced aged and most of them were men; also, these patients had more comorbidities and underlying diseases such as HTN and dyslipidemia. The Killip class III/IV was more frequent in the patients with re-MI and these patients were less likely to receive evidence-based treatment for management of MI.[22]

Table 1. Basic characteristics of study population

Variable	[n (%)] or Mean ± SD	Range
Demographic characteristics		
Gender (men)	705 (81.30)	
Age (year)	60.91 ± 12.76	18.0-94.0
Presentation and initial assessment		
SBP at entry (mmHg)	126.91 ± 27.25	50.0-230.0
HR at entry	79.42 ± 21.31	30.0-188.0
Paraclinical data		
EF at discharge (%)	37.80 ± 11.74	10.0-65.0
LDL-C (mg/dl)	111.22 ± 39.94	22.0-349
Creatinine (mg/dl)	1.22 ± 0.44	0.6-6.1
Blood sugar (mg/dl)	169.47 ± 80.82	64.0-491
Hb level (mg/dl)	14.31 ± 1.86	6.4-20.3
TIMI culprit vessel before PCI	1.07 ± 1.24	0-3
TIMI culprit vessel after PCI	2.63 ± 0.63	0-3
Past clinical history		
Previous MI	112 (12.90)	
Previous angina	133 (15.30)	
Previous stroke/TIA	51 (5.90)	
Previous PCI	95 (11.00)	
Risk factors		
Current smoker	342 (39.40)	
DM	255 (29.04)	
Hypercholesterolemia	255 (29.04)	
HTN	295 (34.00)	
Overweight and obesity	336 (59.50)	
Admission process (type of first medical contact)		
General practitioners	211 (24.40)	
Medical ambulance	190 (21.90)	
Paramedical ambulance	3 (0.04)	
Emergency room staff	446 (51.50)	
Others	16 (1.80)	
Intended treatment		
No reperfusion	30 (3.50)	
Primary PCI	445 (51.40)	
Thrombolysis	392 (45.20)	
Details of coronary anatomy and PCI procedure		
Number of epicardial territories with stenosis > 50%		
0	11 (1.50)	
1	318 (42.70)	
2	237 (31.80)	
3	179 (24.00)	
In-hospital complication		
Death	72 (8.30)	
CVA	2 (0.20)	
Stent thrombosis	1 (0.10)	
Re-MI	1 (0.10)	
Mechanical complications (tamponade/VSD/free wall rapture)	2 (0.20)	
HF	108 (12.50)	
AF at discharge	20 (2.30)	
Medication at discharge		
Aspirin	767 (88.50)	
Statins	787 (90.60)	
Beta-blockers	697 (80.40)	
ACE inhibitors/ARB	480 (55.40)	

Data are presented as mean ± standard deviation (SD) or number and percentage

SD: Standard deviation; SBP: Systolic blood pressure; HR: Heart rate; EF: Ejection fraction; LDL-C: Low-density lipoprotein cholesterol; Hb: Hemoglobin; TIMI: Thrombolysis in myocardial infarction; PCI: Percutaneous coronary intervention; MI: Myocardial infarction; TIA: Transient ischemic attack; DM: Diabetes mellitus; HTN: Hypertension; CVA: Cerebrovascular accident; AF: Atrial fibrillation; VSD: Ventricular septal defect; HF: Heart failure; ACE: Angiotensin-converting enzyme; ARB: Angiotensin receptor blockers

Conclusion

This study will plan to know situation of patients with STEMI during a 5-year follow-up. Short- and long-term management and complication of patients with AMI should be considered for improvement of health system and prediction and prevention of re-hospitalization and MACE in patients with STEMI. Besides, knowledge of use of secondary prevention evidence-based drug is useful for continuous education of our medical doctors and specialists for better long-term management of patients with AMI.

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Conflict of Interests

Authors have no conflict of interests.

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