Primary percutaneous coronary intervention in the Isfahan province, Iran; A situation analysis and needs assessment

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Original Article

Abstract

BACKGROUND: Primary percutaneous coronary intervention (PPCI) is considered as a choice of treatment in ST-elevation myocardial infarction (STEMI). PPCI has been performed in the Isfahan Province for several years. This study was performed to describe the situation, and determine in-hospital and early (30 days) clinical outcomes of the patients in order to provide sufficient evidence to evaluate and modify this treatment modality if necessary.

METHODS: All patients, who underwent PPCI for STEMI from July to December 2011 at Chamran and Saadi Hospitals (PPCI centers in the Isfahan Province), were included in this case series study. Premedication, angioplasty procedure, and post-procedural treatment were performed using standard protocols or techniques. All discharged patients were followed for 30 days by phone. Endpoints consisted of clinical success rate, and in-hospital and 30 day major adverse cardiac events (MACEs) (death, reinfarction, stroke, and target vessel revascularization).

RESULTS: 93 patients (83 (89.2%) at Chamran Hospital and 10 (10.8%) patients at Saadi Hospital) had PPCI. Mean Age of the patients was 59.60 ± 11.10 and M/F ratio was 3.89. From the 181 involved vessels (involved vessels/patient ratio = 1.97 ± 0.70), the treatment of 105 lesions (lesions/patient ratio = 1.13 ± 0.368) was attempted. The clinical success rate was 72%. Pain-to-door and door-to-balloon times were, respectively, 255.1 ± 221.4 and 148.9 ± 168.5 min. The reason for failure was impaired flow (n = 17 (18.3%)), failure to cross with a guidewire (n = 2 (2.2%)), suboptimal angiographic results (n = 2 (2.2%)), and death in one patient. The in-hospital and 30 days MACE rates were, respectively, 8.6% and 3.2%.

CONCLUSION: Low success rate in our series could be due to prolonged pain-to-door and door-to-balloon times and lack of an established, definite protocol to regularly perform PPCI in a timely fashion. We should resolve these problems and improve our techniques in order to prevent and treat slow/no-reflow phenomenon.

Keywords: Acute Coronary Syndrome, Myocardial Infarction, Percutaneous Transluminal Coronary Angioplasty, Cardiogenic Shock, No-Reflow Phenomenon

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Introduction

ST-elevation myocardial infarction (STEMI) is a dangerous manifestation of coronary artery disease (CAD) and continues to be a significant public health problem in industrialized and developing countries.[1,2]

The cornerstone of treatment of these patients is the rapid and effective restoration of blood flow with fibrinolytic therapy, and/or primary percutaneous coronary intervention (PPCI).[3] PPCI

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has been shown to be the superior strategy resulting in a markedly lower occurrence of short-term major adverse cardiac events (MACEs).[4-9]

Impaired or ceased flow in the absence of anatomical obstruction may occur after PPCIN; this can influence the prognosis negatively.[10,11] this event known as angiographic slow/no-reflow phenomenon is recognized angiographically in 5-20% of patients undergoing PPCI for acute myocardial infarction (AMI).[10,12,13]

A major disadvantage of PPCI is related to the availability of facility and an experienced team; PPCI is the treatment of choice for reperfusion therapy of STEMI whenever available and feasible.[14,15] Its golden time is within 90 min of admission to the hospital (door-to-balloon time 90 min) especially when thrombolytic therapy has failed (known as rescue PCI).[2,4,16]

In the Isfahan Province, PPCI has been performed since 2006. It was performed in Chamran Hospital for the first time, and has recently been performed in Saadi Hospital. However, after 6 years of experience of PPCI we could not find any study describing the situation, problems, and clinical outcomes of PPCI in Isfahan. Therefore, the objective of this study is to describe the situation and determine in-hospital and early (after discharge until 30 days) clinical outcomes of the patients who underwent primary or rescue PCI in the Isfahan Province. This study was done in order to provide sufficient evidence to evaluate and modify our system if necessary.

Materials and Methods

All patients who underwent primary or rescue PCI for the STEMI from July to December 2011 in the Isfahan Province (at Chamran and Saadi Hospitals) were included in this case series study.

All patients received orally 325 mg of chewable aspirin, and 600 mg of Plavix in the emergency room. After coronary angiography if the anatomy was eligible for PCI additional heparin (100 units/kg) was administered intravenously, and angioplasty procedure was performed using standard techniques.[2,16] However, strategic planning of the procedure and device selection were dependent on the operator's discretion.

After the angioplasty, patients received 325 mg of aspirin daily, beta-blockers, and angiotensin-converting enzyme inhibitors if not contraindicated. All patients (DES or BMS) received 75 mg of Plavix daily for the first month, and were suggested to continue using it for 12 months under the supervision of their physician.

Lesion types were noted according to the American College of Cardiology/American Heart Association's (ACC/AHA) lesion characteristics classification.[16]

All Patients who were discharged alive from hospitals were eligible to be followed by a phone survey for 30 days.

Definitions: Myocardial infarction (MI) was defined as Ischemic symptoms accompanied by at least one of the following criteria: positive cardiac enzymes, electrocardiographic changes (pathologic Q wave or new ST changes), and new cardiac motion abnormality on echocardiographic or radionuclide imaging.

Coronary blood flow after PPCI is graded on a scale of 0 through 3 depending on flow characteristics. Thrombolysis In myocardial infarction (TIMI) 0 is defined as no contrast flow beyond the site of occlusion (no perfusion), TIMI 1 as contrast flow beyond the site of occlusion but failing to opacify the entire artery (penetration with minimal perfusion), TIMI 2 is defined as contrast flow beyond the site of occlusion and opacification of the entire artery but at a rate slower than normal (partial reperfusion), and TIMI 3, known as normal flow, as opacification of the entire artery at a normal rate. No-reflow is traditionally defined as TIMI grade 0 or 1, and slow flow is defined as TIMI grade 2 in this scheme.[13]

Angiographic success was defined as post-procedure TIMI flow grade 3 and a residual stenosis of less than 20%.[2] The procedure was considered as successful if it was angiographically successful in all attempted lesions.

Clinical success was defined as a successful procedure in the absence of in-hospital major adverse cardiac events (MACEs: death, reinfarction, stroke and target vessel revascularization (TVR)) during hospitalization.[2,16] Reinfarction after PCI was defined as recurrent symptoms of ischemia with new electrocardiographic changes, and/or a rise in cardiac troponin more than twice the normal limits. Early MACEs were defined as the occurrence of mentioned events during the first 30 days after STEMI. TVR was defined as ischemia-driven repeat percutaneous intervention, or bypass surgery of the target vessel. Target lesion revascularization (TLR) was defined as ischemia-driven repeat percutaneous intervention, or bypass surgery for the target lesion. Other adverse events in this study included arrhythmia, congestive cardiac failure, allergy, access site complications, and bleeding.

The left ventricular ejection fraction was determined using either echocardiography, or contrast ventriculography during the procedure.

Data Collection and Management: The data were collected by specific data collection forms. Data entry was done using the forms designed in EPI Info™ 3.3.2 (Center for Disease Control and Prevention; Atlanta, GA). Moreover, data were analyzed using the Statistical Package for Social Sciences (SPSS) for Windows 15.0 (SPSS Inc., Chicago, IL, USA).

All the continuous data were expressed as mean ± SD or range (min-max) and categorical data were expressed as number, and percentages. After descriptive analyses, categorical variables were compared using the chi-square test (or Fisher's exact test if required), and continuous variables by using student's t-test or Mann-Whitney test. P values of less than 0.05 were considered as statistically significant.

Results

From July to December 2011, 83 (89.2%) patients at Chamran Hospital and 10 (10.8%) patients at Saadi Hospital (93 patients in total) underwent PPCI. Table 1 describes baseline characteristics of the patients at the time of reaching the hospital. Mean age of the patients was 59.60 ± 11.10, and M/F ratio was 3.89.

Table 2 reveals angiographic success, lesion characteristics, and treatment strategies of the patients. The interventionalists attempted to treat 105 lesions (lesions/patient ratio = 1.13 ± 0.368) of the 181 involved vessels (involved vessels/patient ratio = 1.97 ± 0.70) in our patients. In total 116 stents (62 BMS and 54 DES) were deployed in 98 lesions, and 4 lesions were treated only by balloon angioplasty. 3 lesions remained inaccessible during the PPCI.

83 of 105 lesions were treated successfully (angiographic success rate = 79.0%).

Procedural details are described in table 3. Pain-to-door (time from onset of symptoms to hospital admission and door-to-balloon time were 255.1 ± 221.4 and 148.9 ± 168.5 min, respectively. Their medians were 255.1 and 148.8 min, respectively.

Pain-to-door time was significantly different in primary and rescue PCI (207.9 ± 203.9 min vs. 396.3 ± 217.3 min, P < 0.001), but the door-to-balloon time was not (137.1 ± 150.9 min vs. 184.7 ± 217.3 min, P = 0.359).

Thrombectomy was used in 23 (24.7%) patients, and stents were deployed in lesions of 87 (93.5%) patients.

Table 1. Baseline characteristics of patients

Age	
Mean (years)	59.60 ± 11.10
Range (years)	33-86
Age ≥ 65 years	34 (36.6)
Gender, M/F ratio	74/19
MI location	
Anterior	58 (63)
Inferior	32 (34.8)
Other	2 (2.2)
Killip class	
1	72 (77.4)
2	12 (12.9)
3	4 (4.3)
Ischemic time (pain-to-door time)	
Mean (minutes)	255.1 ± 221.4
Range (minutes)	16-720
< 2 hr	29 (31.2)
≤ 2 hr - < 4 hr	21 (22.6)
≤ 4hr - < 6 hr	6 (6.5)
≤6hr - < 12 hr	30 (32.3)
Missed	7 (7.5)
Unconsciousness at admission	4 (4.3)
Cardiogenic shock at admission	9 (9.7)
Renal insufficiency(Cr > 1.5)	12 (12.9)
Smoker *	28 (30.1)
Diabetes mellitus	19 (20.4)
Hypertension†	24 (25.8)
Hyperlipidemia‡	18 (19.4)
Previous stroke	1 (1.1)
Previous CAD	25 (26.9)
EF	
Mean (%)	36.02 ± 11.58
Range (%)	15-60
Low EF (< 40%)	40 (43.0)

Categorical variables are expressed as n (%) and continuous variables are expressed as Mean ± SD or range (Min-Max).
M/F: Male/Female; MI: Myocardial infarction; SBP: Systolic blood pressure; CAD: Coronary artery disease; EF: Ejection fraction
*Smoker: a person who has smoked at least 1 cigarette (or cigar, pipe) in the last month.
†Hypertension: Systolic blood pressure > 140 mmHg; diastolic blood pressure > 90 mmHg; or taking hypertensive drugs
‡Hyperlipidemia: LDL cholesterol ≥ 130 mg/dl; triglycerides ≥150 mg/dl; and HDL ≤ 40 mg/dl; or on treatment of hyperlipidemia

Table 2. Basic angiographic success, lesion characteristics, and treatment strategies*

Attempted lesions	105 (100)
Left main	1 (1.0)
LAD	58 (55.2)
D1	5 (4.8)
LCX	9 (8.6)
OM1	4 (3.8)
RCA	25 (23.8)
PDA	2 (1.9)
Ramus	1 (1.0)
Lesion characteristics	
Mean preprocedural stenosis,%	96.19 ± 7.44
Total occlusion	61 (59.9)
Proximal location	44 (41.9)
Small vessels (RVD < 3mm)	23 (21.9)
Long (>10, < 20 mm)	52 (49.5)
Diffuse (≥ 20 mm)	49 (46.7)
Treatment strategy	
Predilation balloon	74 (70.5)
Stenting	98 (93.3)
Postdilation balloon	11 (10.5)
Thrombectomy	25 (23.8)
TIMI grade after procedure	
0–1	9 (8.6)
2	10 (9.5)
3	84 (80.0)
Angiographic success	83 (79.0)

Categorical variables are expressed as n (%) and continuous variables are expressed as mean ± SD.
LAD: Left anterior descending; D1: Diagonal1; LCX: Left circumflex artery; OM1: Obtuse marginal; RCA: Right coronary artery; PDA: Posterior descending artery; BMS: Bare metal stents; DES: Drug-eluting stents; BMS+DES: Combined DES and BMS stenting in a lesion, TIMI: Thrombolysis in myocardial infarction
*Lesion-based Analysis

The procedure failed due to impaired flow (n = 17 (18.3%)), failure to cross with a guide wire (n = 2 (2.2%)), suboptimal angiographic results (n = 2 (2.2%)), and death during procedure in one patient (procedural success rate = 76.3%). As mentioned above, impaired flow was the most frequent cause of failure. Slow flow (TIMI less than 3) was detected in 8 (47.1%) and no-reflow in 9 (52.9%) cases all of whom had been treated by stenting (BMS 9 (52.9%), DES 6 (35.3%), and combined stents 2 (11.8%)). This phenomenon was treated by intracoronary (IC) Integrilin in 12 cases (70.6%), IC epinephrine in 8 cases (47.1%), IC adenosine in 6 cases (35.3%), IABP in 3 cases (17.6%), and Nitrate in 3 cases (17.6%) in this series.

8 (8.6%) patients had MACEs during hospitalization which included 5 (5.4%) cases of in-hospital death (Figure 1). Of the five patients who died, 3 (60.0%) had cardiogenic shock, 3 (60%) had impaired flow. In-hospital mortality was significantly higher in the shock group (33.3% vs. 2.5%, P < 0.001), and in the older patients (over 65 years of age: 11.8% vs. 1.7%, P < 0.05). Successful PCI decreased in-hospital mortality significantly (33.3% vs 3.4%, P < 0.05) in our series.

PPCI was clinically successful in 67 (72.0%) patients. The response rate in the follow-up was 100%, and 3 other patients developed MACEs in this period (Figure 1). In total 11 (11.8%) patients had MACEs (combined MACEs) in our study. The rate of MACEs was significantly higher in the patients with impaired flow (29.4% vs. 7.0%, P = 0.009).

All of the PPCI failures and MACEs occurred in Chamran Hospital, but due to the small sample size at Saadi Hospital we could not compare clinical outcomes of the patients in these hospitals.

Table 3. Procedural details* and complications of primary percutaneous coronary interventions

SVD	24 (25.8)
Multivessel PCI‖	11 (11.8)
Primary	69 (74.2)
Rescue	24 (25.8)
Door-to-balloon time	
Mean (min)	148.9 ± 168.5
Range (min)	24-900
IABP	6 (6.5)
Arrhythmia	27 (29.0)
Procedure	
Plain old balloon angioplasty (POBA)	3 (4.3)
Guide wire cross failure	2 (2.2)
Cardiogenic shock, only IABP / discontinue procedure for CPR	1 (1.1)
Use of stent	87 (93.5)
Only BMS	42 (48.3)
Only DES	34 (39.1)
BMS+DES	11 (12.6)
Stent/patient ratio	1.31 ± 0.64
Procedural acute adverse events	
Impaired flow	17 (18.3)
Access site complications	7 (7.5)
Congestive cardiac failure	13 (14)
Bleeding	1 (1.1)
Procedural success rate	71 (76.3)

Categorical variables are expressed as n (%) and continuous variables are expressed as mean ± SD.
SVD: Single vessel disease; PCI: Percutaneous coronary intervention; IABP: Intra-aortic balloon pump; PVC: Premature ventricular contraction; VF: Ventricular fibrillation; VT: Ventricular Tachycardia; CPR: Cardiopulmonary resuscitation; LAD: Left anterior descending; LCX: Left circumflex artery; RCA: Right coronary artery
*Patient Based Analysis
‖Multivessel PCI: PCI on more than one lesion in one stage

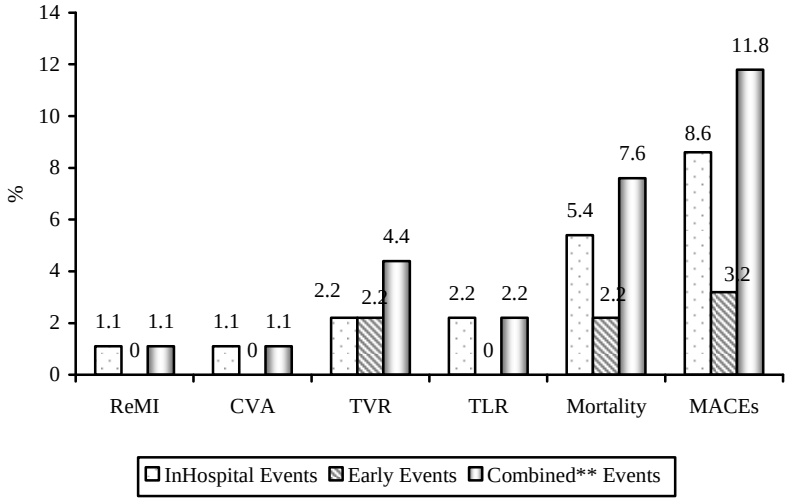

Figure 1. In-hospital and early* clinical outcome of the patients
*Early clinical outcome: after discharge until 30 days; **Combined: In-hospital and early clinical outcome
MACE: Major adverse cardiac events; ReMI: Repeated myocardial infarction; CVA: Cerebrovascular accident; TVR: Target vessel revascularization; TLR: Target lesion revascularization

Discussion

PPCI is considered to be a superior strategy in treatment of STEMI.[14,15] This procedure has been carried out for our patients since 2006, but, to our knowledge it has not yet been evaluated in any research project.

Our study revealed that procedural success rate was 76.3%, in-hospital MACEs was 8.6%, and combined MACEs was 11.8%. Alidoosti et al. described their experience of 83 primary angioplasty in STEMI based on their single center registry at Tehran Heart Center during a period of 2 years (2003-2005).[17] Their reported procedural success rate was 95%, both in-hospital MACEs and mortality were 8.4%, and MACEs after 9 months was 12%.[17] The results of our study are in accordance with that of the study by Alidoosti et al. regarding in-hospital MACEs, but are different in terms of success rates and in-hospital mortality. In comparison with other studies, although we reported lower success rates our patients' early clinical outcomes were in accordance with international data.[10,11,17] For instance, the in-hospital mortality, which was 5 (5.4%) cases, in our series of patients is comparable to international data, which showed in-hospital mortality of 5.2% in the second national registry of Myocardial infarction (NRMI2).[18]

In our study 9 patients had cardiogenic shock; 3 (33.3%) of them died, which is again in agreement with international data, which showed higher mortality in patients with cardiogenic shock (i.e. 32% in NRMI 2, 46.4% in shock registry, and 59.1% in American College of Cardiology-National Cardiovascular Data Registry (ACCNCDR).[18-20]

Poor angiographic and procedural results in our series were related to the most frequent cause of failure, which was impaired flow (18.3%). Although, the mechanisms of slow-flow and no-reflow phenomenon have been debated extensively, it has been proposed that obstruction of the myocardial microcirculation is a result of distal embolization or vasospasm.[12] Moreover, it was revealed that the degree of impaired flow is associated with the duration of the preceding myocardial ischemia, infarct size, procedural variables, and patient characteristics.[10]

Our study revealed that pain-to-door and door-to-balloon times had an extremely wide range of almost 12, and 14.5 hours, respectively. These wide ranges, which were observed both in primary and rescue PCI, demonstrated that PPCI was not performed in a timely fashion.

In Tehran, 88% of the patients arrived at the hospital in the first 6 hours.[17] 46% of our patients arrived during this time. This shows that our patients request medical help later. We think that this is a multifactorial issue (cultural, socioeconomic, political, and educational), which could be improved by intersectoral and cross-sectoral collaboration, and the contribution of all authorities of the province.

Door-to-balloon time is exclusively related to health management, and it is an important

determinant of the quality of care. The door-to-balloon time recommended by the American College of Cardiology (ACC)/American Heart Association (AHA) guidelines is 90 minutes.[2] However, achieving this time is only possible in an ideal world scenario. In developing countries financial constraints, insurance coverage problems, and delay in decision making due to lack of knowledge are the major obstacles in following door-to-balloon time recommendations. In Pakistan the median door-to-balloon time was reported to be 115 minutes with 40% of patients having PCI performed at or over 90 minutes.[3] In China the median door-to-balloon time was 132 min, and only 22% of patients had PCI performed in less than 90 minutes.[21] In Germany this time, from admission to start of PPCI, was 86 ± 42.[22] In Tehran door-to-balloon time was not reported.[17] Solving the Insurance problems, facilitating the process of admittance, discharge, and transfer, providing well-established protocols and an expert team, and informing the community could improve this Index.

Conclusion

The low success rate in our series could be due to prolonged pain-to-door time; community education is necessary to decrease this type of delay.

Long door-to-balloon time could be due to lack of a definite protocol to regularly perform PPCI in a timely fashion. We should define the duty and role of different components of the process of patient admission, transfer, and treatment to reduce door-to-balloon time.

Finally, we should improve our technique, especially to prevent and treat slow/no-reflow phenomena, in order to reach a better outcome after PPCI.

Conflict of Interests

Authors have no conflict of interests.

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