Immediate results and six-month outcomes after percutaneous coronary intervention in a referral heart center in Isfahan, Iran

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Abstract

BACKGROUND: There is a lack of data in our society on the outcomes, complications, and prognostic factors in patients with coronary artery disease who underwent percutaneous coronary intervention (PCI). We evaluated the success rate, early and late outcomes, and prognostic factors in a referral university center in Isfahan, IRAN.

METHODS: This prospective cohort study was conducted in Chamran University Hospital in Isfahan (IRAN) from March 2010 to February 2011. Patients consequently were included if they have the indication for emergent or elective PCI. Outcomes included procedural success, complications, and major adverse cardiovascular events (MACE) during hospitalization and 6 months follow-up.

RESULTS: A total of 282 patients (74.1% females) with mean age of 57.0±3.2 years were studied. Most of the patients (89.7%) underwent elective PCI. Angiographic and procedure success rates were 95.7% and 94.6%, respectively. In-hospital MACE included two cases of death (0.7%) and one MI (0.3%); 2/29 (6.9%) of the emergent PCI and 1/253 (0.4%) of the elective PCI cases. MACE during follow-up included three cases of death (1.0%) and two MI (0.7%); 2/252 (0.8%) of the elective PCI and 1/28 (3.5%) of the emergent PCI cases. The overall MACE was calculated as 8 cases (2.8%) which included 5/29 (17.2%) of the emergent and 3/253 (1.1%) of the elective cases; $P < 0.001$. In multivariate analysis, none of the factors including gender, age, emergency of the procedure, lesion type, number of stenotic vessels, or stent type were associated with total MACE ($P > 0.05$).

CONCLUSION: PCI is performed with an acceptable success rate in our center in Isfahan and mortality and complications are within the range reported by other highly specialized centers in IRAN. Further studies with larger sample size are needed to find predictive factors.

Keywords: Percutaneous Coronary Intervention, Myocardial Infarction, Acute Coronary Syndrome, Reperfusion Therapy, Outcome, Mortality.

ARYA Atherosclerosis 2011; 7(1): 24-30.

Date of submission: 28 Aug 2010, ***Date of acceptance:*** 8 Dec 2010

Introduction

Despite considerable ongoing improvements in preventive programs and access to the specialized medical care, atherosclerosis and its complications such as acute myocardial infarction (MI) are still regarded as the most important causes of death in developed as well as developing societies.[1,2] In Iran, coronary artery diseases (CAD) are yet the leading causes of death with up to 40% of all causes of death and also one of the leading causes of disability and morbidity.[3,4]

Since its development, reperfusion therapy has been a great improvement in the treatment of MI and significantly decreased the associated mortality and morbidity. Medical therapies (fibrinolytic agents) and surgical interventions (percutaneous coronary intervention (PCI) and coronary artery bypass surgery (CABG)) are available for the treatment of CAD patients. Patients with typical chest pain and electrocardiographic (ECG) evidence of an acute MI are candidates for either PCI or fibrinolytic therapy.[5] Coronary reperfusion with primary PCI or fibrinolytic

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therapy improves outcomes in patients with acute ST-segment elevation MI (STEMI) and if it was timely performed, primary PCI is the reperfusion therapy of choice compared to fibrinolysis, because it achieves significantly better outcomes and does not carry the risks that are associated with fibrinolytic therapy (e.g. intracranial hemorrhage).[6,7] Although evidence showed that, compared with PCI under stable angina and elective conditions, emergent PCI for patients with unstable angina has been associated with a slightly lower success rate and higher peri-procedural/in-hospital complications and higher re-stenosis, it is a widely administered treatment strategy for patients with non ST-segment elevation MI (NSEMI), as well.[8-10]

Several factors can affect the reperfusion therapy of choice. Besides characteristics such as patient age and general condition, kind and degree of the stenosis, patient and system delays, emergency of the condition, and patient preferences, specialized care facilities and high costs of the invasive procedures are also important.[11-13] It is of great importance for an interventionist to recognize the main predictors of such an invasive intervention outcomes and complications to efficiently decide about the treatment strategy. Although, several centers have described their experience with primary PCI during these years, concern persists as to whether the results of highly specialized centers could be generalized to clinical practice. There are some few published data on the outcomes, complications, and prognostic factors from centers in our society.[14-22] According to reports from Tehran Heart Center, success rate is up to 98%, mortality rate (including one year follow-up) from about 0.3% to 8.5%, and major complications from 1.6% to 19.2%.[14-17,20,21] Regarding the lack of data from our society in this regard, the object of this study was to determine the success rate of PCI, early and late outcomes, and prognostic factors in a referral university center in Isfahan, IRAN.

Materials and Methods

Patients and settings

This prospective cohort study was conducted in Chamran University Hospital in Isfahan (IRAN) from March 2010 to February 2011. Patients were included consequently if they have the indication for emergent or elective PCI; STEMI, NSTEMI, and unstable angina (UA). STEMI was defined as cases that referred within 12 hours from the symptom onset with a typical chest pain (lasting for more than 30 minutes) and have concomitant ECG changes; ST-segment elevation of ≥1 mm in at least two consecutive precordial/inferior leads or the presence of a left bundle branch block. Confirmation of MI was done according the elevation of cardiac enzymes of more than twice the normal of the upper range. UA was defined by the sudden appearance/worsening of angina, with more frequent and prolonged attacks occurring at rest or on efforts that were previously well tolerated. The ethics committee of Isfahan University of Medical Sciences approved the study and informed consent was obtained from the patients or relatives.

Angiographic characteristics, PCI procedures, and related care

Lesion morphology was classified according to the modified American Heart Association/ American College of Cardiology (AHA/ACC) classification taskforce. Reference vessel diameter, degree of stenosis, and lesion lengths were estimated visually, referencing the catheter or by aid of the device software. PCI procedures, technical details, and choice of stent were left to the operators' judgment. Unfractionated heparin (70-100 u/kg) was administered before guide-wire insertion to achieve a clotting time > 250 sec. All the patients were pretreated with clopidogrel (600 mg) and ASA (325 mg). A loading dose of 600 mg of clopidogrel was administered if the patient was not pretreated. Patients with acute MI and those with thrombosis in angiography received (/intravenous) glycoprotein IIb/IIIa receptor inhibitor during the procedure, as well. After the procedure, aspirin (325 mg/d) was continued for 1 months and then 80 mg/d indefinitely. Clopidogrel (75 mg/d) was administered for a period of 2 months after bare metal stent (BMS) implantation and 12 months in patient with ACS or after implantationof drug-eluting stent (DES), respectively. In patients without contraindications, beta-blockers, angiotensin-converting enzyme inhibitors, and stains were also administered. For all the patients, 12-lead electrocardiography was obtained prior and following intervention to detect procedure-related ischemic changes and or the appearance of a new pathologic Q wave on the surface electrocardiogram. After the procedure, all the patients were checked for creatine kinase MB (CK-MB) enzyme sampling at 8 and 16 hours.

Assessments

General characteristics included age, gender, and patients medical history including the following risk factors: smoking history; current smoker defined as patient who regularly smokes one or more times per day or has smoked in the 30 days prior to admission or quitted smoker defined as those who quitted smoking since 30 days before hospitalization, dyslipidemia; total cholesterol ≥ 200 mg/dL, HDL-

cholesterol ≤ 35 mg/dL, LDL-cholesterol ≥ 100 mg/dL, and/or triglycerides ≥ 200 mg/dL, hypertension; systolic blood pressure ≥140 mmHg and/or diastolic ≥90 mmHg and/or on anti-hypertensive treatment, and known diabetes mellitus.

Outcome

TIMI flow of the infarct-related arteries was determined before and after PCI. Angiographic success was defined as a TIMI-3 and < 20% residual stenosis and procedural success was defined as the angiographic success without major procedural or in-hospital complications (death, MI, emergent surgery, or repeated PCI). The no-reflow phenomenon was defined as TIMI < 3 after PCI in spite of residual stenosis <50%, absence of significant dissection, or visible thrombosis or spasm.

Major adverse cardiovascular events (MACE): in-hospital and six-month rates of death, MI, target vessel revascularization (TVR), and target lesion revascularization (TLR). Death was defined as mortality from any cause. Peri-procedural MI was defined by a rise in the CK-MB fraction of more than 5 times the upper limit of normal. TVR and TLR were defined as the revascularization of the vessel and target lesion, respectively, formerly treated by PCI during the index hospitalization by a repeat PCI or bypass surgery within 24 hours after the index PCI.

Follow-up

Each patient was followed-up for 6 months after the index procedure. Data of the early outcomes and occurrence of death, new MI, need for CABG, subsequent need for repeat PCI, and occurrence of angina were obtained by office visits or telephone interviews. Angiographic follow-up and repeat revascularization was only performed if clinically indicated by symptoms or documentation of myocardial ischemia in non-invasive tests.

Statistical analyses

Continuous variables are expressed as mean±SD, and dichotomous variables as frequencies. Categorical variables were compared using the chi-square test and continuous variables by using student t test. Univariate and multivariate logistic regression analyses were performed to identify the independent predictors of outcomes (showed in logistic regression tables). The odds ratio (OR) and its 95% confidence interval (CI) were computed for the outcome measures. A p value of less than 0.05 was considered statistically significant. The statistical analyses were performed with SPSS 16.0 software (SPSS Inc. Chicago, IL).

Results

The study population consisted of 73 males and 209 females with the mean age of 57.0±3.2. According to medical history, risk factors included hypertension (34.0%), dyslipidemia (28.0%), and DM (20.2%). Also, 19.8% of the patients were current smokers and 6.0% were quitted smokers.

Angiographic and lesion characteristics

Angiographic and lesion characteristics of the patients are presented in table 1. Most of the patients (89.7%) underwent elective PCI.

Table 1: Angiographic and lesion characteristics

		N = 282
Indication of PCI		
Emergent, n = 29 (10.2%)	1- STEMI/rescue	5 (2.2%)
	2- STEMI/Primary	10 (4.3%)
	5- UA	14 (6.1%)
Elective		253 (89.7%)
Direct/Secondary Stenting		121 (42.9%) / 161 (57.0%)
DES/Non-DES, n = 265		164 (58.1%) / 118 (41.8%)
RVD (mm)		2.36 ± 18.8 [SE = 1.1]
Lesion length (mm)		16.5 ± 11.5 [SE = 0.6]
Number of stenotic vessels		
SVD		140 (49.6%)
2VD		105 (37.2%)
3VD		27 (9.6%)
MVD		10 (3.5%)
Lesion Characteristics		
A		29 (10.3%)
B1		108 (38.3%)
B2		48 (17.0%)
C		97 (34.4%)
Data are presented as mean±SD or number (%)		

SVD = single vessel disease MVD = multi vessel disease

Procedural and early outcomes

Data regarding procedural characteristics and outcomes are presented in table 2. Angiographic and procedure success rates were 95.7% and 94.6%, respectively. Procedural related complications included dissection (3.5%), side branch occlusion (0.3%), and abrupt Closure (0.7%). In-hospital events and complications were two death (0.7%) including one case with emergent PCI (1/29, 3.4%) and one with elective PCI (1/253, 0.4%), one MI (0.3%), one cerebro-vascular attack (CVA) (0.3%), and one ventricular arrhythmia (0.3%). No one needed emergent surgical intervention. In overall, 3/282 (1%) of the cases experienced a major adverse cardiac event during hospitalization which included 2/29 (6.9%) of the emergent PCI and 1/253 (0.4%) of the elective PCI cases; P = 0.029.

Follow-up and late outcomes

Three patients (1.0%) died during follow-up; two of the elective PCI (2/252, 0.8%) and one of the emergent PCI cases (1/28, 3.5%), and two patients (emergent PCI cases) experienced MI (0.7%). MACE was therefore calculated as 1.7% (5/280) in all cases during follow-up. This included 3/252 (1.2%) of the elective PCI and 2/28 (7.1%) of the emergent PCI cases; P = 0.8. With regards to MACE during hospitalization, the overall MACE was calculated as 8 cases (2.8%) which included 5/29 (17.2%) of the emergent and 3/253 (1.1%) of the elective cases; P < 0.001.

Multivariate analysis

The logistic regression analysis was carried out considering all factors which might have an effect in MACE. The results showed that none of the factors including gender, age, emergency of the procedure, lesion type, number of stenotic vessels, or stent type were associated with total MACE (P > 0.05). (showed in logistic regression tables).

Table 2. Procedural and early outcomes

		N = 282
Preprocedural stenosis (%)		80.7 ± 29.3 [SE = 1.7]
Post procedural stenosis (%)		2.5 ± 8.0 [SE = 0.4]
Angiographic success		270 (95.7%)
Procedural success		267 (94.6%)
In-hospital Complications	Death	2 (0.7%)
	MI	1 (0.3%)
	Emergent CABG	0
	CVA	1 (0.3%)
	Arrhythmia	1 (0.3%)
Any In-Hospital MACE		3 (1.0%)

MACE = major adverse cardiac event CABG = coronary arthery bypass graft

Table 3. Follow-up and late outcomes

	N = 280
Death	3 (1.0%)
MI	2 (0.7%)
TVR/TLR	0
Repeated PCI/CABG	0
Any MACE at Follow	5 (1.7%)
Any MACE total	8 (2.8%)

MACE = major adverse cardiac event TVR = target vessel revascularization
TLR = target lesion revascularization

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Discussion

The purpose of the present study was to assess the early and late outcomes of patients with CAD after reperfusion therapy with PCI in a single university-affiliated tertiary medical center in Isfahan (IRAN), and compare it with the results reported from other centers in our country as well as other countries. We achieved an acceptable angiographic and procedural success rates of 95.7% and 94.6%, respectively, while the success rate reported from other centers in Iran and also other highly specialized centers is between 90% to 99%.[14-17,20,21,23] The variation between these reports can be related to the improving success overtime, differences in experience, different patient population, and differences in definition of procedural success. According to our study results, 1% of the patients experienced a major adverse cardiac event during hospitalization and 1.7% during 6-month follow-up; leading to a total MACE of 2.8%. This included total mortality rate of 6.9% in emergent and 1.2% in elective PCI cases. Available reports from Tehran Heart Center shows a mortality rate from about 0.3% to 8.5% and major complications from 1.6% to 19.2%.[14-17, 20, 21] Among the reports with large sample size, is the study by Alidoosti and colleagues on 1311 consecutive patients from 2003 to 2007 in Tehran Heart Center who underwent elective PCI using sirolimus/paclitaxel-eluting stents. Authors reported 0.15% in-hospital mortality and 0.76% total mortality rate and a total of 4.2% MACE. The only reported predictive factors in this study was the reference vessel diameter.[18] In another report from Alidoosti and colleagues from the same center, authors found that patients left ventricular dysfunction, as measured by ejection fraction, had higher rates of MACE and mortality.[20] In large series from experienced centers, mortality rate is ranged from 0.5% to 1.7%[24] and according to a report from the American College of Cardiology National Cardiovascular Data registry which included over 100,000 PCI procedures (between 1998 and 2000) the mortality rate was 1.4%.[25] The mortality rate in our patients with emergent PCI was 6.9%, higher than that of the elective PCI cases. Alidoosti and colleagues in a report of 83 patients with STEMI who underwent PCI between 2003 to 2005, found a 8.5% mortality rate.[21] Some evidence showed that mortality rate as well as complications are relatively more frequent in patients undergoing emergent PCI compared with elective PCI.[26] However, there are controversial results in this regard.[27] In our study, while MACE was significantly more prevalent in those who underwent emergent PCI, compared with elective PCI, multivariate analysis did not find an association which is probably due to the small sample size.

Several other factors are associated with mortality and complications during hospitalization and follow-up of patients who underwent reperfusion therapy with PCI. The time to the onset of reperfusion therapy is a critical determinant of outcome with both PCI and medical reperfusion therapies. Delay in reperfusion therapy can be divided into treatment delay (time between symptom onset and PCI), door-to-balloon time (DTB, time from hospital arrival to PCI), and patients delay (time from first contact with the healthcare system). In one study by Safi and colleagues in Tehran on patients who underwent primary PCI, authors found a significant association between DTB time and mortality rate; 67% in patients with DTB > 120 min vs. 4.6% in patients with DBT < 120 min.[16] While patient delay is not easily correctable by the healthcare system, strategies to shorten other delays are modifiable and can lead to a significant decrease in mortality and morbidity rates.[28] Another factors predicting the outcomes includes hospital performance (hospital and operator volume) and local expertise. Studies showed that the mortality rate after primary PCI is significantly lower in high-volume compared to lower-volume hospitals[29,30] and an inverse correlation exists between in-hospital MACE and operator volume quintile.[31,32] With regard to our center (Chamran Hospital) it must be noted that the center is located relatively far from the city center which increases delay of therapy, especially when patients with emergent condition are referred from other centers. However, it is the only university-affiliated referral center in the city with appropriate facilities (e.g. on-site surgery) for performing PCI. Other prognostic factors are angiographic characteristics and the kind of stent used. Suboptimal reperfusion, post-PCI TIMI flow grade, is an important determinant of prognosis after PCI. Lack of attainment of TIMI 3 flow is a significant independent predictor of mortality (adjusted hazard ratio 3.8, 95% CI 2.5-5.7).[33] In our study, 8 patients did not achieved TIMI 3 flow, but none of them died or experienced other MACE. Also, we didn't find association between lesion type and drug eluting versus non-drug eluting stents with MACE. It must be noted that the sample size of our study was small and precise investigation of predictive factors with multivariate analysis was not possible.

Conclusion

The results of the present study showed that PCI is

performed with an acceptable success rate in our center in Isfahan and mortality and complications are within the range reported by other highly specialized centers in IRAN. We found a trend toward worsened outcomes in patients who underwent emergent PCI compared to elective cases. However, further studies with larger sample size are needed to find predictive factors.

Acknowledgments

This study was supported by the Isfahan University of Medical Sciences (grant number). We are thankful to Chamran Hospital staff that helped us through the study.

Conflict of Interests

Authors have no conflict of interests.

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