In-hospital outcomes after primary percutaneous coronary intervention according to left ventricular ejection fraction

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Original Article

Abstract

BACKGROUND: The primary objective of primary percutaneous coronary intervention (pPCI) in patients with acute ST-segment elevation myocardial infarction (STEMI) is not only to restore the blood flow in the infarct-related artery, but also to save the patients' quality and duration of their life. Since left ventricular ejection fraction (LVEF) is a known predictor of clinical outcomes in STEMI patients, the possible association between characteristics of a large group of patients who undergo pPCI with LVEF and death was evaluated.

METHODS: This prospective cohort study included 304 patients who had undergone pPCI between 2009 and 2011. The association between LVEF and in-hospital outcomes of patients was assessed.

RESULTS: LVEF ≤ 25%, 25% < LVEF < 50%, and LVEF ≥ 50% were presented in 23 (7.6%), 150 (49.3%), and 128 (42.1%) of the patients, respectively. Three patients (0.01%) died before echocardiography. There was no significant difference among aforementioned three groups regarding baseline characteristics, except age (P = 0.012) and sex (P = 0.016). Cumulative number of cardiogenic shock and death were 7 (2.3%) and 22 (7.2%), respectively; with significant differences between three LVEF groups. Age more than 70 years old, pulmonary edema, systolic blood pressure < 100 mm Hg, shock, post-PCI thrombolysis in myocardial infarction (MI) flow grade, corrected thrombolysis in MI frame count, angiographic success and ST-segment resolution showed significant association with death (P < 0.050).

CONCLUSION: This study not only demonstrates that LVEF ≤ 50% is associated with a higher incidence of in-hospital adverse events, but also identifies characteristics that are strongly correlated with the risk of LVEF ≤ 50% and death after pPCI.

Keywords: Myocardial Infarction, Percutaneous Coronary Intervention, Ejection Fraction, Corrected Trombolysis in Myocardial Infarction

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Introduction

Primary angioplasty is the best-known therapy for patients with ST-segment elevation myocardial infarction (STEMI) and for saving lives.[1] Sizable advancements in interventional techniques, equipments, and drugs coupled with better triage of patients have led to significant improvement in short and long-term clinical outcomes of STEMI patients. However, risk prediction in these patients remains problematic. Thereby, a practical prognostic criterion is needed. Since left ventricular ejection fraction (LVEF) is a known predictor of clinical outcomes in STEMI patients, the purpose of this study was to evaluate the possible association between demographical, clinical, and paraclinical characteristics of a large group of patients who undergo primary percutaneous coronary intervention (pPCI) with LVEF. Similarly, the association between demographic, clinical, and paraclinical characteristics of STEMI patients who have been found death was also reported.

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Materials and Methods

Participants and study design

This is a prospective cohort study conducted in Modarres Hospital (Tehran, Iran). A total of 304 patients with STEMI who underwent primary angioplasty during 2009-2011 were enrolled. STEMI was defined by the presence of ischemic chest discomfort within 12 h before hospital admission lasting for at least 20 min and associated with electrocardiographic criteria for STEMI.[2] Patients with prior thrombolytic therapy were excluded. Informed consent was obtained from all patients.

Procedure and assessment of variables

A checklist was filled out for all patients regarding baseline characteristics [age, gender, family history of coronary artery disease (CAD), smoking, diabetes mellitus, hypertension, dyslipidemia, renal insufficiency, prior aspirin usage, and prior CAD], physical examination on admission (systolic and diastolic blood pressure, heart rate, cardiogenic shock, and pulmonary edema), location of myocardial infarction (MI) [anterior (Ant.) MI vs. non-Ant. MI], door-to-balloon time, angiographic results, angiographic success rate, thrombolysis in myocardial infarction (TIMI) flow grade, corrected TIMI frame count (CTFC), ST-segment resolution, EF at discharge, and in hospital adverse events. Door-to-balloon time was defined as the interval between arrival to the hospital and the use of a therapeutic device such as thrombectomy device, balloon, or stent. Coronary angioplasty was performed in accordance to American College of Cardiology/American Heart Association guidelines, using the femoral approach, approved devices and techniques and in the presence of reduced TIMI flow grade < 3, and/or a culprit lesion stenosis of > 50%. Only the culprit lesion was targeted, and left ventriculography was not performed in none of patients. All coronary angiograms were reviewed by two interventional cardiologists who were blinded to all data apart from the angiograms; and TIMI flow grades and CTFCs were determined. All angiograms were performed with 7F guiding catheters. TFC is the number of cine frames needed for contrast to reach a standardized distal coronary landmark in the culprit vessel. TFC was determined by Gibson et al. method.[3] The first frame is selected when the column of the contrast extends across > 70% of the arterial lumen with antegrade flow. The number is expressed based upon a cine filming rate of 30 frames/s. The last frame is that in which the contrast enters the distal landmark. Distal landmark in the right coronary artery (RCA) is the first branch of the posterolateral extension of the RCA after the origin of the posterior descending artery; in the circumflex artery, it is the most distal branch of the obtuse marginal branch which includes the culprit lesion; and in the left anterior descending artery, it is the distal bifurcation which usually places at the apex of the heart. The CTFC means that the TFC for left anterior descending (LAD) must be corrected due to the longer length of the LAD by dividing it into 1.7.

Advised medical treatments were 325 mg of aspirin, 600 mg of clopidogrel, heparin, 20 mg of pantoprazole, and 40 mg of atorvastatin for all patients. The use of glycoprotein IIb/IIIa inhibitors, beta-blockers, enalapril or losartan, thrombectomy, intra-aortic balloon pump, and bare-metal or drug-eluting stents were left to the decision of the operators. Successful angioplasty of the infarct-related artery (IRA) was defined as sustained patency of the infarct-related vessel with TIMI III flow and < 50% final stenosis.

Electrocardiograms were recorded on arrival and 60 min after pPCI. ST resolution was measured 60 min after primary angioplasty at the same lead with maximal ST elevation in pre-angioplasty electrocardiogram. ST resolution > 70% was considered as a good result.

In-hospital adverse clinical events were cardiogenic shock, reinfarction, stent thrombosis, urgent target vessel revascularization (repeat PCI or coronary artery bypass grafting), major bleeding, cerebrovascular accident, need to dialysis, and death. Shock was diagnosed as persistent hypotension (systolic blood pressure < 90 mmHg) and associated signs of low cardiac output unresponsive to treatment. Reinfarction was defined as recurrence of clinical symptoms or development of new electrocardiographic changes accompanied with new elevation of creatine kinase MB enzyme levels. Ischemia-driven target vessel revascularization was any repeat PCI or coronary artery bypass surgery of the IRA prompted by clinical symptoms or objective evidence of ischemia. Major bleeding was defined either as intracerebral hemorrhage, a drop in the hemoglobin greater than 3 mg/dl, need for blood transfusions, or local bleeding requiring surgical treatment.

LVEF was evaluated before discharge, by 2D echocardiography based on Simpson's method. The study population was divided into three groups of LVEF ≤ 25% (severe LV systolic dysfunction), 25% < LVEF < 50% (moderate or mild LV systolic dysfunction), and LVEF ≥ 50% (preserved or normal LV systolic function).

Statistical analysis

Baseline characteristics were reported as mean ± standard deviation for continuous variables or percentages for categorical variables. Normality of the data for continuous variables was evaluated by Kolmogorov-Smirnov test. Then, continuous variables were compared by using a series of tests including ANOVA, and post-hoc Tukey for variables with normal distribution, and Kruskal-Wallis and Mann-Whitney for those without normal distribution. Categorical variables were evaluated by the chi-square test (or Fisher's exact test as needed). The 95% confidence intervals (CIs) for the odds ratio (OR) using multivariate logistic regression were calculated to measure the association between the patients' characteristics and the risk of in-hospital death. All analyses were performed by using the SPSS for Windows (version 16.0; SPSS Inc., Chicago, IL, USA). The P-value of less than 0.05 was considered to be statistically significant.

Results

The mean age of study population was 57.6 ± 11.1 (27-90) years, and 238 (78.3%) of all patients were male. Three patients (0.01%) died before echocardiography. Table 1 represents baseline characteristics of the enrolled patients stratified into three groups of LVEF ≤ 25%, 25% < LVEF < 50%, and LVEF ≥ 50%. There was a significant difference between the LVEF groups regarding age (P = 0.012) and sex (P = 0.016), though Tukey test revealed that the statistically significant difference was just observed between the two groups with LVEF ≤ 25% and 50% ≤ LVEF regarding age (P = 0.010). There was no significant difference between three groups of LVEF concerning coronary risk factors such as family history of CAD, smoking, diabetes mellitus, hypertension, dyslipidemia, and renal insufficiency (P > 0.050). Similarly, there was not any significant difference between three LVEF groups regarding hemodynamic findings (systolic, diastolic blood pressure, fraction of patients with systolic blood pressure less than 100 mm Hg, and heart rate). The aforementioned groups had significant differences in location of MI (Ant. MI vs. non-Ant. MI), presence of pulmonary edema, and shock (P < 0.000). In addition, door-to-balloon time was less than 60 min for all patients that revealed no significant difference between groups (P > 0.050).

Table 1. Baseline characteristics of patients who underwent primary percutaneous coronary intervention stratified by left ventricular ejection fraction

Characteristics	Left ventricular ejection fraction			P
	≤ 25%	25% < LVEF < 50%	≥ 50%	
Number of patients	23	150	128	-
Age ≥ 75 (year)	6 (26.1)	26 (17.3)	11 (8.6)	0.028
Gender, male	15 (65.2)	127 (84.7)	93 (72.7)	0.016
Family history of CAD	1 (4.3)	33 (22.0)	28 (21.9)	0.134
Current smoking	10 (43.5)	67 (44.7)	56 (43.8)	0.986
Dyslipidemia	7 (30.4)	50 (33.3)	43 (33.6)	0.956
Diabetes mellitus	5 (21.7)	35 (23.3)	30 (23.4)	0.984
Hypertension	12 (52.2)	69 (46.0)	43 (33.6)	0.060
Ant. MI vs. non Ant. MI	19 (82.6)	97 (64.7)	48 (37.5)	< 0.001
Shock	4 (17.4)	3 (2.0)	0 (0.0)	< 0.001
Pulmonary edema	6 (26.1)	3 (2.0)	0 (0.0)	< 0.001
Renal insufficiency	2 (8.7)	6 (4.0)	3 (2.3)	0.311
SBP < 100 (mmHg)	3 (13.0)	7 (4.7)	4 (3.1)	0.115
Prior aspirin usage	5 (21.7)	43 (28.7)	34 (26.6)	0.765
Prior coronary artery disease	1 (4.3)	7 (4.7)	5 (3.9)	0.953
Hemoglobin (mg/dl) (mean ± SD)	12.5 ± 1.7	13.1 ± 1.6	13.0 ± 1.7	0.359
Serum Cr (mg/l) (mean ± SD)	1.4 ± 0.9	1.2 ± 1.0	1.1 ± 0.3	0.052*
LDL (mg/dl) (mean ± SD)	96.4 ± 30.5	105.9 ± 25.0	102.7 ± 25.9	0.210
DBP (mm Hg) (mean ± SD)	73.9 ± 11.2	74.3 ± 7.6	74.2 ± 7.1	0.978
Pulse (beats/min) (mean ± SD)	80.8 ± 16.2	77.8 ± 15.4	74.0 ± 8.7	0.110*
SBP (mm Hg) (mean ± SD)	129.6 ± 28.5	123.7 ± 21.0	123.2 ± 16.9	0.371
Age (year) (mean ± SD)	63.5 ± 12.6	58.0 ± 11.6	56.2 ± 10.0	0.012

Values are presented as n (%) unless otherwise expressed; LVEF: Left ventricular ejection fraction; CAD: Coronary artery disease; Ant.: Anterior; MI: Myocardial infarction; SBP: Systolic blood pressure; SD: Standard deviation; Cr: Creatine; LDL: Low-density lipoprotein; DBP: Diastolic blood pressure

* Abnormal distribution was determined using Kruskal-Wallis test

Table 2 compares angiographic results of patients who underwent pPCI and stratified by LVEF. According to the angiographic findings, the number of narrowed vessels among these three LVEF groups showed significant difference (P < 0.001). Most number of narrowed coronary arteries were three, two, and single vessels in groups with LVEF ≤ 25%, 25% < LVEF < 50%, and LVEF ≥ 50%), respectively. Furthermore, the IRA was significantly different between the three groups (P < 0.001). The most IRA in patients with LVEF ≤ 25% and 25% < LVEF < 50% was the LAD artery, while for patients with LVEF ≥ 50% it was the RCA. All three LVEF groups, had similar initial TIMI flow grades (P = 0.473), but post-PCI TIMI flow grade showed significant difference (P = 0.013). The CTFC values in three groups with LVEF ≤ 25%, 25% < LVEF < 50%, and LVEF ≥ 50%, were 36.5 ± 35.2, 20.1 ± 15.5, and 18.2 ± 14.0, respectively; which was statistically significant (P < 0.000). Similarly, Tukey test revealed that significant difference was between patients with LVEF ≤ 25% and two other groups with 25% < LVEF < 50% and LVEF ≥ 50% (P < 0.001).

The angiographic success rate of pPCI in the three groups of LVEF (LVEF ≤ 25%, 25% < LVEF < 50%, and LVEF ≥ 50%) were 65.2%, 84.7%, and 89.1%, respectively, which revealed significant difference between groups (P = 0.013). Absence of ST-segment resolution in the mentioned groups was 47.8%, 17.3%, and 1.6%; respectively, which showed significant difference (P ≤ 0.001).

Table 3 compares in-hospital adverse events of patients who underwent pPCI and stratified by LVEF. In-hospital adverse clinical events did not have significant difference between groups, except for the gastrointestinal bleeding and death. Death rate in groups with LVEF ≤ 25%, 25% < LVEF < 50%, and LVEF ≥ 50% was 30.4%, 7.3%, and 0.8%, respectively (P < 0.001).

Table 4 represents OR of patients' characteristics associated with the risk of in-hospital death in patients who underwent pPCI. Characteristics that showed significant association with death include age more than 70 years old, pulmonary edema, systolic blood pressure < 100 mmHg, shock, post-PCI TIMI flow grade, CTFC, angiographic success, and ST-segment resolution (P < 0.050).

Table 2. Angiographic results of patients who underwent primary percutaneous coronary intervention stratified by left ventricular ejection fraction

Characteristics	Left ventricular ejection fraction			P
	≤ 25%	25% < LVEF < 50%	≥ 50%	
Number of patients	23	150	128	-
Number of narrowed vessels	-	-	-	
One vessel disease	2 (8.7)	50 (33.3)	79 (61.7)	
Two vessel disease	8 (34.8)	66 (44.0)	42 (32.8)	< 0.001
Three vessel disease	13 (56.5)	32 (21.3)	6 (4.7)	
Left main involvement	0 (0.0)	2 (1.3)	1 (0.8)	
Infarct-related artery	-	-	-	
LAD	19 (82.6)	96 (64.0)	49 (38.3)	
RCA	4 (17.4)	41 (27.3)	69 (53.9)	< 0.001
LCX	0 (0.0)	13 (8.7)	10 (7.8)	
SVG	0 (0.0)	0 (0.0)	0 (0.0)	
Initial TIMI flow grade ≤ 1	23 (100.0)	141 (94.0)	120 (93.8)	0.473
Post-PCI TIMI flow grade < 3	8 (34.8)	23 (15.3)	14 (10.9)	0.013
CTFC > 20	11 (47.8)	46 (30.7)	31 (24.2)	0.062
Intra-aortic balloon pump	8 (34.8)	8 (5.3)	0 (0.0)	< 0.001
Angiographic success	15 (65.2)	127 (84.7)	114 (89.1)	0.013
Stent treatment	20 (87.0)	147 (98)	124 (96.9)	0.450
No ST-segment resolution	11 (47.8)	26 (17.3)	2 (1.6)	< 0.001
CTFC (mean ± SD)	36.5 ± 35.2	20.1 ± 15.5	18.2 ± 14.0	< 0.001
Contrast volume (ml) (mean ± SD)	345.7 ± 132.6	319.5 ± 75.1	311.6 ± 80.6	0.187

Values are presented as n (%) unless otherwise expressed; LVEF: Left ventricular ejection fraction; LAD: Left anterior descending LCX: Left circumflex; RCA: Right coronary artery; SVG: Saphenous vein graft; TIMI: Thrombolysis in myocardial infarction; CTFC: Corrected thrombolysis in myocardial infarction frame count

Table 3. In-hospital complications of patients who underwent primary percutaneous coronary intervention stratified by left ventricular ejection fraction

Characteristics	Left ventricular ejection fraction			P
	≤ 25%	25% < LVEF < 50%	≥ 50%	
Number of patients	23	150	128	-
Reinfarction	0 (0.0)	1 (0.7)	0 (0.0)	0.603
Stent thrombosis	0 (0.0)	0 (0.0)	0 (0.0)	-
Repeat PCI	1 (4.3)	3 (2.0)	0 (0.0)	0.147
CABG	1 (4.3)	6 (4.0)	0 (0.0)	0.070
Gastrointestinal bleeding	1 (4.3)	0 (0.0)	0 (0.0)	0.002
Dialysis	0 (0.0)	0 (0.0)	0 (0.0)	-
Cerebrovascular accident	0 (0.0)	0 (0.0)	0 (0.0)	-
Death	7 (30.4)	11 (7.3)	1 (0.8)	< 0.001
Hospital stay, days (mean ± SD)	6.3 ± 4.9	5.9 ± 0.2	5.9 ± 4.3	0.858

Values are presented as n (%) unless otherwise expressed; LVEF: Left ventricular ejection fraction; PCI: Percutaneous coronary intervention; CABG: Coronary artery bypass grafting

Table 4. Odds ratio of characteristics associated with the risk of death in patients who underwent primary percutaneous coronary intervention

Characteristics	Live	Death	Odds ratio	95% Confidence interval	P
Number of patients	282	22	-	-	-
Age ≥ 70 years	35 (12.4)	8 (36.4)	0.2	0.1-0.6	0.002
Gender, male	222 (78.7)	16 (72.7)	0.7	0.3-1.9	0.511
Hypertension	112 (39.7)	13 (59.1)	2.2	0.9-5.3	0.075
Diabetes mellitus	67 (23.8)	3 (13.6)	0.5	0.1-1.8	0.277
Pulmonary edema	3 (1.1)	6 (26.6)	34.9	8.0-152.4	< 0.001
Ant. MI vs. non-Ant. MI	151 (53.5)	15 (68.2)	1.9	0.7-4.7	0.184
LAD as IRA	154 (54.6)	12 (54.5)	1.0	0.4-2.4	0.995
SBP < 100 mmHg	7 (2.5)	8 (36.4)	16.0	5.1-50.0	< 0.001
Shock	2 (0.7)	5 (23.8)	41.2	7.4-228.0	< 0.001
Intra-aortic balloon pump	7 (2.5)	11 (50.0)	39.3	12.8-120.8	< 0.001
Initial TIMI flow grade ≤ 1	265 (94.0)	22 (100.0)	0.9	0.9-1.0	0.236
Post-PCI TIMI flow grade < 3	33 (11.7)	13 (59.1)	10.9	4.3-27.5	< 0.001
CTFC > 20	73 (25.9)	18 (81.8)	0.1	0.03-0.2	< 0.001
Angiographic success	249 (88.3)	9 (40.9)	10.9	4.3-27.5	< 0.001
No ST-segment resolution	28 (9.9)	13 (59.1)	0.1	0.03-0.2	< 0.001

Values are presented as n (%); Ant.: Anterior, MI: Myocardial infarction; LAD: Left anterior descending; IRA: Infarct-related artery; SBP: Systolic blood pressure; TIMI: Thrombolysis in myocardial infarction; CTFC: Corrected thrombolysis in myocardial infarction frame count

Discussion

The mean age of the overall study population was lower (< 60 years) than previous studies run in this area (> 60 years), whereas the percentage of patients who were older than 75 years old was high (14.1%).[4] The elderly patients (> 75 years old) with their higher mortality rate versus younger patients (18.6% vs. 5.4%, respectively), increased the rate of total mortality. The mortality rate in older patients was equal to studies from developed countries.[5] Other baseline characteristics of the enrolled patients were similar to previous studies.[6,7] Compatible with two new studies, sex showed significant difference between LVEF groups.[8,9] Though death rate in females and males was 9.1% and 6.7%, respectively; however, it was not statistically significant, which was probably due to insufficient number of patients.

Incidence of pulmonary edema was similar to recent studies and heart failure was a strong predictor of death in this study [OR: 34.9 (95% CI: 8.0-152.4), P < 0.001].[10]

Angiographic findings according to number of narrowed vessels, IRA, and initial TIMI flow grade ≤ 1 were similar to recent reports.[11,12]

The TIMI flow grading system is a qualitative method for evaluation of reperfusion. Furthermore, TIMI flow grade < 3 after pPCI is associated with increased incidence of major in-hospital adverse events.[13] The CTFC is a quantitative method for measuring reperfusion. The mean CTFC in the normal coronary arteries is 21.1 ± 1.5 for LAD,

22.2 ± 4.4 for left circumflex, 20.4 ± 3.3 for RCA.[3] The CTFC is an independent predictor of prognosis and death following STEMI. In our previous study, CTFC of the IRA did not have significant association with LVEF in STEMI patients who underwent pPCI.[14] However, current study with more enrolled patients showed significant association between CTFC values and LVEF. Although, the percentages of patients with CTFC > 20 did not have significant association with LVEF (P = 0.062), but a larger study population seems more suitable and necessary.

In patients with STEMI, ST-segment resolution results in a better global LVEF, which in turn leads to a survival benefit.[15]

Reported failure rate is 4-11% for pPCI.[16] Failure of PCI in STEMI patients is associated with poor outcomes.[17] In this study, angiographic success was associated with better LVEF and lower mortality rates.

The in-hospital mortality rate in this study was 7.2%, which was similar to a number of newer studies and less than older studies.[4,5,18,19] Death can be predicted from baseline, clinical, and angiographic characteristics of the patients. Hence, these high risk patients will be triaged for more intensive observation and treatment. Therefore, in order to achieve more sound decisions, every population in each country needs its own data for better judgments in clinical situations.

Study limitations

This study has some limitations. First, data was obtained from a single hospital, so external validation is necessary. Second, long-term follow-up data are needed for thorough analysis and post-discussions thereby the author(s) made their best to publish follow-up data in the second manuscript. Third, the repeat study including larger number of patients will help to better analysis and achievement of more reliable results. Overestimation of the ORs in this study with moderate sample size is probably.

Conclusion

LVEF is an independent predictor of all-cause death in patients who undergone pPCI. Patients with older age, female gender, anterior MI, higher heart rate, pulmonary edema, shock, need to IABP, post-PCI TIMI flow grade < 3, higher CTFC, and absent angiographic success or ST-segment resolution after pPCI had significantly higher rates of low LVEF. Awareness of these predictors may assist clinicians to make better clinical decisions for STEMI patients and to facilitate possible future research.

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Conflict of Interests

Authors have no conflict of interests.

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