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Original Article

Comparison of the 3-Month Outcome Between Primary PCI and Thrombolytic Therapy Concerning the Left Ventricular Ejection Fraction of STEMI Patients at 90-Minute Intervals

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ABSTRACT

Background: Standard treatment in patients with ST-elevation myocardial infarction (STEMI) is the reperfusion therapy of coronary arteries with the most appropriate therapeutic method. The purpose of the present study was to compare the 3-month outcome between primary percutaneous coronary intervention (P-PCI) and thrombolytic therapy regarding the ejection fraction (EF) of patients with STEMI who were referred to 2 hospitals in Tehran with the same door-to-balloon and door-to-needle times (≈90 min).

Methods: This cohort study enrolled 43 patients referred to Taleghani Hospital and Labbafinejad Hospital, affiliated with Shahid Beheshti University of Medical Sciences, in Tehran, Iran. Based on a researcher-made questionnaire, the initial and the 3-month EFs in the P-PCI group (n=19) and the thrombolytic therapy group (n=24) were determined and compared.

Results: No significant differences were found in demographic variables between the 2 therapeutic methods. Most participants were aged 60 years or older and male. The outcome of P-PCI and thrombolytic therapy in terms of the EF showed no significant differences at baseline (41% vs 42.6%) and 3 months' follow-up (50.2% vs 50.3%) (P>0.05). Additionally, the mortality and rehospitalization rates were the same in both groups (P>0.05).

Conclusions: No significant differences were observed in the 3-month outcome between P-PCI and thrombolytic therapy at 90-minute treatment intervals concerning the EF of patients with STEMI. Thus, either one may be used based on access to the Cath Lab and the patient's situation. ***(Iranian Heart Journal 2021; 22(4): 45-53)***

KEYWORDS: Primary PCI, Thrombolytic therapy, STEMI

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In the last decades, cardiovascular diseases have been the leading cause of death, and they have become epidemic around the world.[1,2] Meanwhile, coronary artery disease, which is the most common heart disease in adults[2,3] and a major cause of death and disability, is of great importance.[4] The most serious and life-threatening manifestation of acute coronary syndromes is acute myocardial infarction (MI), which is associated with an elevated ST segment in the electrocardiogram (ECG) and called "ST-elevation myocardial infarction" (STEMI).[2] According to the latest global statistics, STEMI accounts for approximately 25% to 40% of heart attacks.[3,5] Therefore, due to the high prevalence of these heart attacks and their complications and mortality, faster treatment of patients with a standard method that has not only the fewest complications and the most long-term benefits for patients but also improves the quality of life is mandatory. The standard treatment for STEMI is reperfusion therapy, considered to be the fast, complete, and stable establishment of the coronary blood flow in occluded arteries and in the necrotic tissue to prevent progressive loss in myocyte cell function.[1,3]

Reperfusion in the treatment of STEMI is performed by fibrinolytic therapy and primary percutaneous coronary intervention (P-PCI).[6] The earliest possible establishment of reperfusion plays the main role in reducing mortality, preventing a drop in the ejection fraction (EF), maintaining the quality of life, and diminishing possible MI complications, including cardiogenic shocks, malignant dysrhythmias, and heart failure.[5,7]

The first developed treatment for reperfusion in STEMI is the use of thrombolytic drugs. If prescribed in the early hours after an acute MI, thrombolytics will reduce patient mortality.[8,9] Nonetheless, the limited effects of this method on a complete and stable coronary artery blood flow, the possibility of recurrent infarctions, and the risk of hemorrhagic events as some of the most important possible complications of thrombolytic therapy have restricted the use of this method.[1,3,8]

Over time, as the complications and limitations of thrombolytic therapy became apparent, the use of P-PCI was preferred to it and was considered as the first choice of treatment in coronary artery reperfusion in MI.[6,8] Accordingly, many studies argue that if angioplasty is performed, there is almost no indication for thrombolytic therapy to re-establish the coronary artery blood flow in STEMI.[5,7,10] Despite the significant use of primary angioplasty, the need for an equipped Cath Lab and a specialized team to maintain the minimum door-to-balloon time with a view to increasing the effectiveness of this method as well as the high initial cost of angioplasty compared with thrombolytic therapy, the decision to prefer P-PCI in the treatment of acute MI is implicated, which is a major obstacle to the routine use of this method.[6,8]

Nevertheless, angiography and elective PCI are done after thrombolytic therapy in stable patients in many medical centers in Iran. This delay in performing angioplasty may further damage the myocardial tissue, reduce the EF, and increase medical costs and occupied hospital beds.[8,11]

Moreover, with the widespread use of P-PCI for patients with STEMI in most centers, the need to transfer patients from the non-capable hospitals to these centers and maintain the minimum door-to-balloon time to augment the effectiveness of this method is challenging compared with thrombolytic therapy. On the other hand, intra-city transportation problems may delay the procedure and increase complications such as heart failure and malignant arrhythmias.[4] Consequently, it is necessary to find the most appropriate treatment method in Iran to increase the quality of life and life

expectancy in these patients. Although numerous studies in Iran have compared the 2 methods of fibrinolytic therapy and P-PCI in terms of complications, treatment costs, and the quality of life,[4,8] the only study that has compared angioplasty and thrombolytic therapy in patients with STEMI by examining the EF was conducted by Safi et al[12] (2009). In their study, the door-to-balloon time in P-PCI was different from the door-to-needle time in angioplasty. Moreover, only the therapeutic effects of the 2 methods during hospitalization were investigated.

Therefore, in the present study, we compared the 3-month outcome between P-PCI and thrombolytic therapy in terms of the left ventricular EF among patients with acute STEMI in Taleghani Hospital and Labbafinejad Hospital, affiliated with Shahid Beheshti University of Medical Sciences, Tehran, Iran, with the same door-to-balloon and door-to-needle times of 90 minutes. We also assessed the risk factors involved in EF reduction.

METHODS

The present research was a cohort study to compare the 3-month outcome between P-PCI and thrombolytic therapy with regard to the left ventricular EF of patients with acute STEMI at Taleghani Hospital and Labbafinejad Hospital, affiliated with Shahid Beheshti University of Medical Sciences, Tehran, Iran, with the same door-to-balloon and door-to-needle times of 90 minutes in the autumn of 2017 and the winter and spring of 2018. This study was conducted after approval by the National Committee on Ethics in Biomedical Research (IR.SBMU.MSP.REC.1398.092).

The inclusion criteria were composed of patients with STEMI referred to the emergency department of Taleghani and Labbafinejad hospitals within 90 minutes of the onset of symptoms, having the opportunity to complete the follow-up, and undergoing echocardiography 3 months after admission. The exclusion criteria consisted of patients who were referred outside the defined time frame, patients who were treated with methods other than P-PCI or thrombolytic therapy, and patients who received both treatments such as rescue PCI or facilitated PCI.

The sample size in this study was determined to be 43 patients by considering a 5% α and a 20% β (80% power). The study patients were selected from among the patients with STEMI referred to our medical centers by the convenience sampling method. Ultimately, the study population was comprised of 24 patients under thrombolytic therapy and 19 patients under P-PCI treatment. The criterion for selecting P-PCI or thrombolytic therapy was whether the medical centers were equipped with P-PCI facilities. Accordingly, thrombolytic therapy was performed on the patients referred to Labbafinejad Hospital, and P-PCI was applied for the patients in Taleghani Hospital.

After STEMI diagnosis by ECG and history taking in the emergency department, the patients, who fulfilled the inclusion criteria and provided written informed consent, were subjected to echocardiography at the time of admission to the emergency department on the first day. Their EF levels were measured by M-Mode and eyeball estimation.

At the beginning of patient admission, the researcher questionnaire, including basic information, was completed. The data gathered included the patients' age, sex, blood pressure, the lipid profile, history of smoking, underlying diseases (eg, diabetes, previous history of MI, and positive family history of MI), the admission time, the number of involved vessels, heart vessel territories, and the EF. Then, based on the presence or absence of P-PCI facilities in the relevant medical centers, the patients

underwent P-PCI or thrombolytic therapy for 90 minutes during the door-to-balloon time or the door-to-needle time.

Patients with a good general condition were discharged after either P-PCI or thrombolytic therapy as well as the stabilization of their clinical condition. During the discharge, the patients and their companions were interviewed to assist in the follow-up of patients after discharge. The patients were asked to return for echocardiography 3 months after discharge. They were also asked to refer to the emergency room of the relevant medical center in the event of any signs of danger during this period.

At the end of the first 3-month after the intervention, the mortality rate of the patients and the rate of rehospitalization were reassessed through telephone calls with the patients' companions. Additionally, during the patients' re-examinations 3 months after discharge, the EF was measured with the same echo machine and also by the same cardiologist via the M-Mode and eyeball methods. The SPSS statistical software, version 25, was used to analyze the obtained data.

The results were expressed as the mean ± the standard deviation (SD) for quantitative variables and frequencies and percentages for qualitative variables. The χ^2, Fisher, and independent *t* tests were used to analyze the data. Moreover, the level of significance for interpreting the relationships between the variables was considered 0.05.

RESULTS

Out of the 43 patients with STEMI participating in the present study, 24 patients underwent thrombolytic therapy and 19 patients underwent coronary artery reperfusion therapy by P-PCI. One patient in the thrombolytic therapy group and 2 patients in the P-PCI group died during the study. According to Table 1, 28 patients in both groups were over 60 years of age. Eight participants in the 2 groups were female. Only 8 patients had no underlying diseases. The rest of the demographic characteristics are presented in Table 1. No significant differences in the demographic variables were observed between the 2 groups in the 2 treatment methods (P>0.05).

The results of our study showed no significant differences between the 2 groups apropos of the EF at the time of arrival and 3 months later based on demographic variables, MI areas, culprit lesions, the number of involved vessels, and rehospitalization (P>0.05).

According to Table 2, the 2 methods of reperfusion therapy had no statistically significant differences regarding MI areas, culprit lesions, the number of involved vessels, and rehospitalization (P>0.05). According to this table, 2.4% of the patients in the thrombolytic therapy group and 1.21% in the P-PCI group needed to be readmitted within 3 months after reperfusion therapy. Moreover, the highest frequencies in both groups in terms of MI areas, culprit lesions, and the number of involved vessels were associated with multivessel disease, proximal left anterior descending artery, and single-vessel disease, respectively.

According to Table 3, which shows the results of treatment based on the EF in the 2 groups, the mean 3-month EF in thrombolytic therapy and P-PCI was 50.17% and 50.26%, respectively. Therefore, there was no significant difference concerning the mean EF at arrival and 3 months later between the 2 methods of reperfusion therapy (P>0.05).

Table 1. Frequency distribution of the study patients' demographic characteristics

Treatment Method Demographic Characteristics	Thrombolytic Therapy	P-PCI	*P*-value	
Age, y	> 60	14 (58.3%)	14 (73.7%)	*P*=0.76
	< 60	10 (41.7%)	5 (26.3%)	
Sex	Female	4 (16.7%)	4 (21.1%)	*P*=0.55
	Male	20 (83.3%)	15 (78.9%)	
Background Diseases	Negative	4 (16.7%)	4 (21.1%)	*P*=0.81
	Hyperlipidemia	1 (42.0%)	2 (10.5%)	
	Diabetes	3 (12.5%)	3 (15.8%)	
	MI family history	1 (4.2%)	1 (5.3%)	
	Having more than 1 disease	9 (37.5%)	5 (26.3%)	
	Undiagnosed diseases	6 (25.0%)	4 (21.1%)	
	Hypertension	12 (50.0%)	8 (42.11%)	
Smoking	No	21 (87.5%)	15 (78.9%)	*P*=0.65
	Yes	3 (12.5%)	4 (21.1%)	
Previous MI History	No	18 (75.0%)	16 (84.2%)	*P*=0.21
	Yes	6 (25.0%)	3 (15.8%)	

P-PCI, Percutaneous coronary intervention; MI, Myocardial infarction

Table 2. Frequency distributions of MI areas, culprit lesions, the number of involved vessels, and rehospitalization in the patients in the 2 methods of thrombolytic therapy and P-PCI

Treatment Method Variables	Thrombolytic Therapy	P-PCI	*P*-value	
MI Area	Anterior	4 (16.7%)	4 (21.1%)	*P*=0.72
	Inferior	4 (16.7%)	2 (10.5%)	
	Right ventricle	1 (4.2%)	1 (5.3%)	
	Extensive	3 (12.5%)	3 (15.8%)	
	Multivessel disease	12 (50.0%)	9 (47.4%)	
Culprit Lesion	Distal LAD	1 (4.2%)	1 (5.3%)	*P*=0.97
	Distal RCA	2 (8.3%)	1 (5.3%)	
	Mid LAD	3 (12.5%)	5 (3.26%)	
	Mid LCX	1 (4.2%)	0 (0.0%)	
	Mid RCA	2 (8.3%)	1 (5.3%)	
	Proximal LAD	7 (29.2%)	7 (36.8%)	
	Proximal RCA	6 (25.0%)	4 (21.1%)	
	OM	2 (8.3%)	0 (0.0%)	
Number of Involved Vessels	LMD	3 (12.5%)	1 (5.3%)	*P*=0.65
	SVD	8 (33.3%)	11 (57.9%)	
	2 VD	5 (20.8%)	4 (21.1%)	
	3 VD	8 (33.3%)	3 (15.8%)	
Rehospitalization	Yes	1 (4.2%)	4 (21.1%)	*P*=0.28
	No	23 (95.8%)	15 (78.9%)	

P-PCI, Percutaneous coronary intervention; MI, Myocardial infarction; LAD, Left anterior descending artery; RCA, Right coronary artery; LCX, Left circumflex artery; OM, Obtuse marginal; LMD, Left min disease; SVD, Single-vessel disease; VD, Vessel disease.

Table 3. Results of the treatment based on the EF in the 2 methods of thrombolytic therapy and P-PCI

Treatment Method Treatment Result		Thrombolytic Therapy	P-PCI	*P*-value
EF	Initial EF	41.04±9.09	42.58±11.63	0.84
	EF 3 months later	50/17±6.25	50.26±9.37	0.67

P-PCI, Percutaneous coronary intervention EF, Ejection fraction

DISCUSSION

The results of the present study showed no significant differences between the 2 treatment methods of reperfusion therapy in terms of demographic variables. Most of our patients were over 60 years of age. The majority of the patients were men in the 2 groups, and they had a history of at least 1 underlying disease, which is consistent with studies by Dryja et al[13] (2006) and Safi et al[12] (2009), although they did not mention a history of smoking and previous MI in their investigations. The highest frequency in both of our groups in terms of MI was related to multi-vessel disease, while the highest frequency concerning MI in the study by Safi et al[12] (2009) was reported to be anterior (42.6% of the patients).

In recent years, performing P-PCI has been the preferred treatment in the literature[14] because it leads to a rapid return of blood supply to the heart muscle[15] to the extent that it is advised to refuse reperfusion therapy with fibrinolytic drugs in the case of the availability of P-PCI equipment.[5,7,10] Nonetheless, in the present study, there was no significant difference regarding the mean EF at arrival and 3 months later between the thrombolytic therapy group and the P-PCI group, nor were there any statistically significant differences between the 2 groups in terms of the EF at arrival and 3 months later according to any of the demographic variables, MI areas, culprit lesions, the number of involved vessels, and rehospitalization. The difference between the results of the present study and other studies can be attributed to differences in lifestyle, personality and stress characteristics, education level, income level, geographical conditions, religion, ethnicity and race, clinical skills and hospital equipment, type of medication in fibrinolytic therapy, and examination time of the treatment methods.

Safi et al[12] (2009) reported 50% resolution of the ST segment and EF improvement and concluded that P-PCI was more effective than thrombolytic therapy. Nevertheless, similar to our study, they did not report a significant difference in the EF in terms of MI and age. This difference between the 2 studies could be due to the difference in the number of samples or the time considered for the assessment of the effects of treatment methods, which was 3 months after admission in our study and during hospitalization in theirs.

Dryja et al[13] (2006) compared thrombolytic therapy and P-PCI and found no significant differences between the 2 methods. However, in their study, this comparison was based on mortality, while we based this comparison on the mean EF measured by echocardiography.

Rahnama et al[4] (2014) compared the 2 methods of reperfusion therapy based on the quality of life of patients 2 months after treatment. They reported no differences between the 2 methods of thrombolytic therapy and P-PCI.

Salem et al[16] (2015) studied the long-term effects of P-PCI and drug therapy in 60 STEMI patients in Egypt. The EF of the patients treated with P-PCI was significantly higher than that in the other patients. The differences between the results of the 2 studies can be justified by the differences in lifestyle, personality traits, geographical conditions, medications used in fibrinolytic therapy, and hospital equipment for P-PCI.

Consistent with this study, Wallace et al[17] (2013) also showed that there was no significant difference in the EF at the time of discharge between the 2 methods of fibrinolytic therapy and P-PCI (42.5±11.0 vs 44.3±13.1). [17] In the study by Wallace and colleagues, the patients' EF was assessed during discharge, while we measured the effects of reperfusion therapy in the long term.

Itoh et al[18] (2010) stated that although the effects of thrombolytic therapy on major adverse cardiac events were significantly lower than those of P-PCI, a long-term follow-up (6 mon) revealed that primary angioplasty was preferable to fibrinolytic therapy in STEMI patients. They, however, indicated that if thrombolytic therapy was performed before P-PCI, it would be more effective than P-PCI alone. Differences in the number of samples, follow-up duration (3 mon vs 6 mon), and clinical skills for P-PCI may be the reason for the differences between the results of the study by Itoh and colleagues and the present study.

In the present study, the door-to-balloon time in P-PCI was considered equal to the door-to-needle time in fibrinolytic therapy so that the results of these 2 methods could be compared, and this time was 90 minutes. This comes from clinical guidelines recommending that patients with STEMI have a door-to-balloon time of 90 minutes in the P-PCI method and warn that any delay increases the mortality of patients.[19] Still, in the study by Safi et al[12] (2009), the door-to-needle time was 1 hour, while angioplasty was performed after the initial evaluation and preparation of the patients, which caused a longer door-to-balloon time.

Although no statistically significant differences were observed between the 2 methods of reperfusion therapy over 3 months, a higher mortality rate was reported in the angioplasty method than in fibrinolytic therapy (10.5% vs 4.2%, respectively). In line with the present study, Wallace et al[17] (2013) stated that the mortality rate in the P-PCI method was statistically significantly higher (10 out of 82 patients in P-PCI vs 1 out of 27 patients in fibrinolytic therapy). The reason for this difference may be due to the smaller number of samples in the present study. However, the results of the investigation by Dryja et al[13] (2006) showed that patients treated with P-PCI had less mortality than those treated with thrombolytic therapy (5.5% vs 7.9%). This difference may be due to dissimilarities in the type of drug used in fibrinolytic therapy, differences in the skills of the treatment staff and hospital equipment to perform P-PCI, differences in the door-to-balloon time and the door-to-needle time, or the number of samples in the 2 studies.

In the present study, the need for rehospitalization over 3 months was higher in the P-PCI group than the thrombolytic therapy group (4 patients vs 1 patient), but this difference was not significant. In contrast, Salem et al[16] (2015) stated that STEMI patients treated with P-PCI required less hospitalization within 30 days (30%) and 6 months (13%) after the initiation of treatment. Differences in drug use in fibrinolytic therapy and hospital equipment, different geographical conditions, different lifestyles, and different personality traits of patients in the 2 countries may have led to differences in the results of the 2 studies.

Given that a short follow-up is the major limitation of this study, we recommend conducting a study with the same structure over 6 months and 1 year after treatment with a larger study population. Moreover, due to differences in terms of equipment and medical supplies between cities and towns, it is necessary to conduct similar research in other cities.

CONCLUSIONS

In this study, conducted on patients with STEMI, there were no significant differences in the 3-month outcome between the 2 methods of reperfusion therapy in terms of the EF, the door-to-balloon time, and the door-to-needle time. Be that as it may, thrombolytic therapy seems to be a more suitable and affordable option under time pressure in centers equipped with angioplasty facilities because it confers faster coronary artery reperfusion.

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