Effects of streptokinase on reflow in rescue percutaneous coronary intervention

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Original Article

Abstract

BACKGROUND: Primary percutaneous coronary intervention (PPCI) is the preferred treatment method for ST elevation myocardial infarction (STEMI). However, the required equipments are not available in all hospitals. Thus, due to shortage of time, some patients receive thrombolysis therapy first. Patients with chest pain and/or persistent ST segment elevation will then undergo rescue percutaneous coronary intervention (PCI). The present study evaluated and compared the frequency of no-reflow phenomenon and 24-hour complications after PCI among patients who underwent PPCI or rescue PCI.

METHODS: This cross-sectional study assessed no-reflow phenomenon, 24-hour complications, and thrombolysis in myocardial infarction (TIMI) flow in patients admitted to Chamran Hospital (Isfahan, Iran) with a diagnosis of STEMI during March-September, 2011. Subjects underwent PPCI if they had received eptifibatide. Rescue PCI was performed if patients had chest pain and/or persistent ST segment elevation despite receiving streptokinase (SK). Demographic characteristics, history of diseases, medicine, angiography findings, PCI type, and complications during the first 24 hours following PCI were collected. Data was then analyzed by Student's t-test, chi-square test, and logistic regression analysis.

RESULTS: A total number of 143 individuals, including 67 PPCI cases (46.9%) and 76 cases of rescue PCI (53.1%), were evaluated. The mean age of the participants was 58.92 ± 11.16 years old. Females constituted 18.2% (n = 26) of the whole population. No-reflow phenomenon was observed in 51 subjects (37.1%). Although 9 patients (6.3%) died during the first 24 hours after PCI, neither the crude nor the model adjusted for age and gender revealed significant relations between rescue PCI and death or no-reflow phenomenon. Rescue PCI and no-reflow phenomenon were not significantly correlated even after adjustments for age, gender, history of diabetes, hypertension, hyperlipidemia, coronary artery disease, smoking, platelets number, myocardial infarction level, the extent of stenosis, and the involved artery.

CONCLUSION: According to the present study, although SK is more effective than eptifibatide in resolution of thrombosis and clots, rescue PCI did not differ from PPCI in terms of the incidence of no-reflow phenomenon or short-term complications.

Keywords: Primary Percutaneous Coronary Intervention, Rescue Percutaneous Coronary Intervention, No-Reflow Phenomenon

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Introduction

Primary percutaneous coronary intervention (PPCI) is suggested for treating ST elevation myocardial infarction (STEMI).[1] Rescue percutaneous coronary intervention (PCI) is also recommended in patients under fibrinolysis without electrocardiographic (ECG) improvements.[2] Reductions in short-term and 30-day mortality after PPCI have been found by a number of meta-analyses.[3-5]

An important factor in determining the success of reperfusion therapy (RT) is the comparison of thrombolysis in myocardial infarction (TIMI) flow before and after treatment. TIMI flow is of high value in prognosis of patients.[6,7] This semi-

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quantitative scale divides patients into three categories among which the best prognosis belongs to the TIMI3. Compared to other two groups, patients with TIMI3 present better local and general improvements in left ventricular perfusion and performance, enzyme level reductions, and overall morbidity and mortality.[8]

RT is considered as successful if no-reflow phenomenon does not occur. Kloner et al. defined no-reflow as reduced coronary reperfusion without any arterial obstruction, dissection, or spasm in angiography.[9] However, the prevalence of no-reflow phenomenon has been reported as high as 20% in PPCI.[10]

Although PPCI is the preferred treatment for patients with STEMI, its successful implementation depends on available facilities and circumstances. An appropriate hospital, availability of an angioplasty department with an experienced cardiologist, as well as accessibility to the equipments and the staff at any time are among the most important factors affecting the success of the treatment. Thus, absence of any of the above-mentioned factors would make PPCI problematic.[11] In such cases, patients do not have much time and are often suggested to undergo intravascular thrombolysis. If the patient does not respond to the treatment, PCI would also be applied. This procedure is called rescue PCI.[2]

On the other hand, some studies have indicated that even a successful PCI cannot guarantee the perfusion in all parts of myocardium. In fact, the existing thromboemboli may interfere with perfusion and even lead to clotting in capillaries.[12,13] Therefore, some researchers have recommended facilitated PCI which consists of thrombolytic treatment prior to PCI. However, contrastive results have been reported for this treatment method, i.e. although some studies indicated PCI after thrombolytic treatment to have negative outcomes, others considered it as efficient.[11]

The high incidence of coronary artery disease (CAD) in Iran[14] has increased the need to implement PPCI. However, absence of necessary facilities for PPCI in villages and small towns makes thrombolytic treatment the first choice management in many cases. Streptokinase (SK) is more effective than eptifibatide in resolution of thrombosis and risk of bleeding. The present study compared the prevalence of complications among patients who received SK prior to PCI (Rescue PCI) and those who received eptifibatide during PPCI.

Materials and Methods

In a cross-sectional study, the short-term complications, incidence of no-reflow phenomenon, and TIMI flow grades were assessed in patients who underwent PPCI in Chamran Hospital (Isfahan, Iran) during March-September, 2011. Using census sampling method, all hospitalized patients who had undergone PPCI due to a diagnosis of STEMI and consented to participate were included. A sample size of 140 patients was calculated based on the ratio comparison formula and considering the incidence of no-reflow among individuals who receive eptifibatide (6%[15]) and SK (21.8%[16]).

In the beginning, the subjects were explained about the study procedure and informed consents were obtained. Then, a questionnaire containing demographic data (age and gender), history of diseases (diabetes mellitus, stroke, hypertension, CAD, and hyperlipidemia), smoking, medicines [aspirin, heparin, Plavix, eptifibatide, adenosine, adrenaline, beta-blockers, SK, and angiotensin-converting enzyme (ACE) inhibitors], and MI level was completed.

SK was prescribed if the patient had not received thrombolysis treatment with SK, the symptoms had started less than 12 hours before, and the angiography ward was not ready. However, patients were not prescribed with SK if they had cardiogenic shock or were categorized in class 3 or 4 of heart failure.

In case the angiography ward was ready, the subjects underwent angiography and were then prepared for PPCI. In order to perform angiography, Seldinger method was applied by 6 French catheter. The results of angiography including the involved artery and the position and extent of stenosis were recorded for each patient.

After receiving a 70 IU/kg dose of stat heparin, PCI was applied using Seldinger method by a 7 French catheter. In patients who did not receive SK, 10 mg eptifibatide was injected into the coronary artery candidate for PCI immediately after catheter insertion. The interventionist selected the stent based on the involved artery and plaque length and diameter. The size of catheter balloon was determined by a skilled operator who simultaneously viewed a cineangiogram. Ballooning and stenting were applied according to the involved artery and the extent of obstruction. Angiography was performed after PCI to assess TIMI and no-reflow phenomenon and the results were recorded for all patients.

Patients were transferred to coronary care unit (CCU)

after PCI. Individuals who had received eptifibatide during PCI were kept under treatment with 75 mg eptifibatide infusions by a micro-set for about 18 hours.

In addition, all patients received 600 mg clopidogrel and 325 mg aspirin stat prior to PCI. They were also prescribed with 325 mg aspirin and 75-150 mg clopidogrel daily following PCI. Any observed complications, including death, reinfarction, bleeding, arrhythmia, and repeated PCI, during or 24 hours after PCI were recorded.

In order to analyze the collected data, descriptive statistics (frequency and mean) was applied. PPCI and rescue PCI groups (that had received eptifibatide and SK, respectively) were compared in terms of complications, incidence of no-reflow phenomenon, and TIMI flow using chi-square test. The effects of SK on any of the complications were determined by logistic regression. After evaluating the crude relations, the effects of age, gender, medicines, MI levels, and history of diseases on no reflow phenomenon were adjusted by multivariate logistic regression. Moreover, the model was adjusted based on sex and age (by multivariate logistic regression) to assess the effects of rescue PCI on 24-hour death. P values less than 0.05 were considered statistically significant. All analyses were performed in SPSS for Windows 19.0 (SPSS Inc., Chicago, IL, USA).

Results

A total number of 143 individuals with a mean age of 58.92 ± 11.16 years old were studied. Females constituted 18.2% (n = 26) of the whole population. PPCI and rescue PCI were performed for 67 (46.9%) and 76 (53.1%) subjects, respectively. No-reflow phenomenon was observed in 51 cases (37.1%). During the first 24 hours after PCI, 9 individuals died and arrhythmia, allergy, reinfarction, and bleeding occurred in 6 (4.02%), 1 (0.7%), 1 (0.7%), and 0 (0%) participants, respectively.

Table 1. The demographic characteristics and history of diseases in the rescue and facilitated percutaneous coronary intervention (PCI) groups

	Primary PCI (n = 67)	Rescue PCI (n = 76)	P
Age	57.01 ± 11.49	60.61 ± 10.66	0.055
Sex (female)	15 (22.4)	11 (14.5)	0.221
Diabetes	45 (68.2)	54 (72.0)	0.621
Hypertension	41 (63.1)	50 (66.7)	0.657
Previous CAD	55 (83.3)	64 (85.3)	0.744
Smoking	45 (68.2)	49 (65.3)	0.720
Hyperlipidemia	42 (64.6)	45 (60.0)	0.574
SBP	121.89 ± 20.38	121.99 ± 22.60	0.980
DBP	73.28 ± 13.37	78.20 ± 21.43	0.115
RBC	4.55 ± 0.43	4.52 ± 10.72	< 0.001
HCT	42.68 ± 3.53	41.02 ± 0.60	0.726
Platelet	2198356 ± 51062	193460 ± 48415	< 0.001
LVEF	38.76 ± 11.00	40.77 ± 9.47	0.259
Anterior MI	40 (59.7)	40 (52.6)	0.395
Inferior MI	16 (23.9)	22 (28.9)	0.494
Posterior MI	0	0	
RV MI	0	0	
Lateral MI	2 (3.0)	0 (0)	0.218
Posterior-inferior MI	2 (3.0)	8 (10.5)	0.106
Anterolateral MI	7 (10.4)	5 (6.6)	0.405
Aspirin	66 (98.5)	76 (100)	0.469
Plavix	66 (98.5)	76 (100)	0.469
Heparin	64 (95.5)	75 (98.7)	0.341
Beta-blocker	60 (89.6)	71 (93.4)	0.405
Statin	66 (98.5)	73 (96.1)	0.623
ACE	59 (88.1)	70 (92.1)	0.417
TNG	21 (31.3)	31 (40.8)	0.425

CAD: Coronary artery disease; SBP: Systolic blood pressure; DBP: Diastolic blood pressure; RBC: Red blood cell count; HCT: Hematocrit; LVEF: Left ventricular ejection fraction; MI: Myocardial infarction; RV: Right ventricular; ACE: Angiotensin-converting enzyme; TNG: Nitroglycerin
Data is presented as mean ± SD or number (%)

Table 2. Angiographic and percutaneous coronary intervention (PCI)-related data in rescue and facilitated PCI groups

	Primary PCI (n = 67)	Rescue PCI (n = 76)	P
Stenosis			
Cut-off	30 (44.8)	46 (60.5)	0.600
90-99	28 (41.8)	23 (30.3)	0.151
70-90	9 (13.4)	8 (10.5)	0.592
LAD stent number			
0	1 (2.0)	0 (0)	
1	43 (86.0)	30 (68.2)	< 0.001
2	5 (10.0)	13 (29.5)	
3	1 (2.0)	1 (2.3)	
RCA stent number			
0			
1	14 (93.3)	23 (85.2)	0.639
2	1 (6.7)	4 (14.8)	
3	0	0	
LCX stent	1	3	0.165
Complications			
CVA	0 (0.0)	0 (0.0)	1.000
Death	5 (7.5)	4 (5.3)	0.734
Arrhythmia	3 (4.5)	3 (3.9)	1.000
Bleeding	0 (0.0)	0 (0.0)	
Reinfarction	1 (1.5)	0 (0.0)	0.469
No-reflow phenomenon	23 (34.3)	30 (39.5)	0.525
TIMI flow			
1	8 (11.9)	5 (6.6)	0.266
2	12 (17.9)	21 (27.6)	0.169
3	43 (64.2)	45 (59.2)	0.542

LAD: Left anterior descending artery; RCA: Right coronary artery; LCX: Left circumflex artery; CVA: Cardiovascular arrest; TIMI: Thrombolysis in myocardial infarction
Data is presented as number (%)

Table 3. Odds ratio of streptokinase for no-reflow phenomenon and 24-hour death

	Odds ratio	95% confidence interval	P
No-reflow phenomenon			
Crude model	1.240	0.630-2.469	0.525
Model 2	1.200	0.595-2.428	0.607
Model 3	0.925	0.409-2.093	0.852
24-hour mortality			
Crude model	0.689	0.177-2.678	0.591
Model 2	0.846	0.202-3.542	0.891

Crude model: The effects of streptokinase or eptifibatide on dependent variables
Model 2: Adjusted based on age and sex
Model 3: Adjusted based on age, sex, history of diabetes, hypertension, hyperlipidemia, coronary artery disease, smoking, platelets, myocardial infarction level, vascular involvement (cutoff: 90-99 and 70-99) and the involved artery

Table 1 summarizes the demographic data, history of diseases, medicines intake, medical tests, MI type, and left ventricular ejection fraction (LVEF) of subjects in the PPCI and rescue PCI groups. As it is seen, the two groups were only significantly different in terms of red blood cell count (RBC) and platelets.

The two groups were not significantly different in vascular involvements. However, a significant difference in the number of left anterior descending artery (LAD) stents was observed, i.e. 31.8% of the cases in the rescue PCI group had more than 2 stents. The incidences of no-reflow phenomenon or complications were not significantly different between the two groups (Table 2).

Table 3 presents the effects of PCI type on

no-reflow phenomenon and mortality. In order to evaluate the effects of SK, 3 models of crude, adjusted for age and sex, and adjusted for age, sex, history of diabetes, hypertension, hyperlipidemia, CAD, smoking, platelets, MI level, vascular involvement (cutoff: 90-99 and 70-99), and the involved artery were used. The effects of PCI type on mortality were assessed in the crude model and the model adjusted for age and sex. Due to small sample size, adjustment for other factors did not result in an appropriate model for mortality. As Table 3 shows, PCI type did not affect no-reflow phenomenon and 24-hour death in either crude or adjusted models.

Discussion

In this study, the two groups were not significantly different in terms of 24-hour mortality and complications or no-reflow phenomenon. The frequency of no-reflow phenomenon among the PPCI group was 34.3%. Palomo Villada et al. found no-reflow phenomenon to occur in 21.8% of 32 cases of rescue PCI.[16] However, their mortality rate was much higher than ours (18.7% vs. 7.5%) which might have been the result of higher ages of their participants.

Steg et al. followed 362 patients with STEMI for 10 years. They reported the in-hospital death rate among the 91 individuals who underwent PCI after angiography as 5.5%. In addition, 1.6% of the same patients experienced intracerebral hemorrhage and 2.8% suffered from bleeding in other organs.[17] In our study, however, despite the higher in-hospital death rate, brain damage and bleeding were not observed probably due to not using heparin after PCI.

In a study on 109 patients with STEMI who underwent rescue PCI after unsuccessful thrombolysis, Balachandran et al. reported the in-hospital death rate as 9%.[18] Perez-Berbel et al. evaluated 361 similar patients and observed no-reflow phenomenon in 73 individuals (20.2%). Moreover, 33 subjects (10.4%) died throughout their study.[19] Interestingly, Perez-Berbel et al. used abciximab, a glycoprotein (GP) IIb/IIIa inhibitor, during the PCI procedure[19] which makes their groups comparable to ours.

In a multi-country, double-blind, placebo-controlled clinical trial, Ellis et al. compared the efficacy of reteplase plus abciximab (combination-facilitated PCI) with abciximab-facilitated PCI and PPCI in patients whose ischemic signs initiated at most 6 hours before and who qualified for undergoing fibrinolysis or PCI. A total number of 2452 patients were randomized into three groups of PPCI (n = 806), abciximab-facilitated PCI (n = 818) and combination-facilitated PCI (n = 828). Mortality rates in the three mentioned groups were not significantly different (4.5%, 5.5%, and 5.2%, respectively).[20] The mortality rate among the patients treated by facilitated PCI with eptifibatide was 5.3% in the present study. In contrast to Ellis et al., we performed either rescue PCI on patients who had received SK followed by PCI or PPCI on individuals who had received eptifibatide.[20] Furthermore, in our cross-sectional study, no placebo group was included and the interventionist decided to conduct PCI according to the conditions of the patients.

Another clinical trial was conducted by Kanakakis et al. to measure the effects of facilitated PCI on patients with STEMI. Patients were included if STEMI symptoms had started not more than 6 hours earlier. They were then randomly allocated to two groups of facilitated PCI with tenecteplase or PPCI (control group). The mortality in the two groups was not significantly different (6% vs. 3.5%).[21]

Likewise, in a randomized clinical trial, Le May et al. divided 400 patients with STEMI into two groups of PCI with eptifibatide or PPCI and evaluated death and major complications during a 30-day period following PCI. Although bleeding was increased in the first group, they did not report any significant differences in the outcomes between the two groups.[22] However, the present study could not make such a comparison since it did not assess the long-term outcomes. In addition, PCI was not performed without eptifibatide or SK to compare the efficacy of the two medicines.

Vienna STEMI Registry was a study to investigate STEMI treatment in five hospitals in Vienna. It included 1053 individuals. PPCI with eptifibatide and abciximab was conducted on 631 patients. However, 281 cases first underwent thrombolysis with tenecteplase (TT). They were then transferred to hospitals equipped with angioplasty wards where PCI was performed. The remaining 141 individuals did not receive PCI at all. The total in-hospital death rate and the rates in the PPCI and TT groups were not significantly different (9.5%, 8.1%, and 8.2%, respectively). However, in the no reperfusion group, 18.4% of the subjects died.[23]

Although the present study could not determine factors related with no-reflow phenomenon among the two groups of rescue PCI and PPCI with

eptifibatide, various studies have shown the phenomenon to have negative effects on clinical outcomes of patients with STEMI. Resnic et al. reported an odds ratio (OR) of 3.6 when the effects of no-reflow phenomenon on mortality and MI was concerned among 4264 patients who had experienced PCI ($P < 0.001$).[24] Similarly, Morishima et al. followed 120 patients with STEMI who had undergone PCI for five years. No-reflow phenomenon occurred in 25% of the subjects. They suggested the phenomenon to be an independent risk factor for cardiac arrest [OR: 5.25; 95% confidence interval (CI): 1.79-7.69].[25] No-reflow phenomenon was also considered as an independent risk factor for death during the first year after PCI [hazard ratio (HR): 3.35; 95% CI: 1.97-5.69] by Ndrepepa et al. who observed the complication in 9.5% of the studied patients with STEMI.[9] Therefore, identification and prevention of contributing factors to no-reflow phenomenon might lead to reduced complications and mortality following PCI.

The present study could not evaluate effective factors on death since it aimed to determine in-hospital complications and thus followed the patients for a short period. According to the obtained results, however, the mortality rates, in either the primary or rescue PCI groups, did not seem different from the studies in other countries. It can therefore be concluded that thrombolytic therapy and RT for patients with STEMI in Iran follow standards similar to other countries and cause the same short-term complications.

Ethical considerations imposed a limitation on the present study. In fact, we could not perform a double-blind randomized clinical trial. In addition, due to the short follow-up period, long-term complications of the two methods could not have been compared with previous researches. Another limitation was the absence of a control group for making appropriate comparisons. A clinical trial model with completely aware and consented patients is suggested for better evaluation of the outcomes. Moreover, long-term follow-up may find the best treatment method applicable by the interventionists in the country.

Overall, the present study suggested thrombolytic therapy (when angioplasty is not accessible) not to significantly differ from PCI with eptifibatide in terms of no-reflow phenomenon and short-term complications. Thrombolytic therapy is thus recommended in all hospitals lacking an angioplasty ward. However, the patient must be quickly transferred to a fully equipped hospital for PCI afterwards.

Conflict of Interests

Authors have no conflict of interests.

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