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Ultra Early Routine Post-Fibrinolysis Angioplasty Benefits More Patients with Acute ST-Elevation Myocardial Infarction

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Abstract

Objective: Evaluate whether early routine post-fibrinolysis angioplasty represents a reasonable reperfusion option for victims of ST-elevation myocardial infarction (STEMI), so that these patients could benefit more. Methods: A total of 936 STEMI patients were enrolled in this study to full Urokinase within 3 hours (h) followed by stenting within 3 - 12 h (Ultra early routine post-fibrinolysis angioplasty; 472 patients), or primary stenting within 12 h (primary angioplasty; 464 patints). The primary endpoints were the reperfusion time within 3 h and the incidence of no-reflow or slow-reflow. The secondary endpoints were the acute incidence of bleeding, the extent of myocardial damage, determined by the 6-month left ventricular function and the 3-year composite incidence of death, reinfarction, stroke, or revascularization. Results: Ultra early routine post-fibrinolysis angioplasty significantly increased the percentage of reperfusion treatment within 3 hours ($P < 0.01$). The primary angioplasty group resulted in higher frequency of no-reflow or slow-reflow ($P < 0.01$). Both groups were similar regarding major bleeding ($P > 0.05$). The 6-month left ventricular function of early routine post-fibrinolysis angioplasty group was better than primary angioplasty group. Both groups were similar regarding reinfarction, stroke or revascularization ($P > 0.05$), but the incidence of 3-year cumulative death is higher in the primary angioplasty group ($P < 0.01$). Conclusion: Ultra early routine post-fibrinolysis angioplasty can significantly improve effective time window within effective reperfusion treatment percentage, results in better myocardial perfusion, lower no-reflow and preserving left ventricular function and the prognosis of patients with STEMI than primary angioplasty.

Keywords

Acute Myocardial Infarction, Fibrinolysis, Primary Angioplasty

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Subject Areas: **Cardiology, Clinical Trials**

1. Introduction

Early and complete reperfusion in dealing with acute ST-elevation myocardial infarction (STEMI) is effective in limiting left ventricular damage and improving clinical outcomes. Although direct PCI treatment in reperfusion therapy of acute myocardial infarction increased rapidly in recent years, a large proportion of patients did not receive effective reperfusion therapy in the time window of effective internal [1] [2] due to various reasons, reducing the direct advantage of PCI. There is still a lot of improving space in reperfusion treatment. Ultra early administration of fibrin-specific thrombolytics is at least as effective as primary angioplasty, and can abort infarction and dramatically reduce mortality when given during the first 1 - 3 h of onset. Thrombolysis therapy has the characteristics of rapid, simple and is easy to operate. In the modern era of percutaneous coronary intervention, early routine post-fibrinolytic angiography and stenting may improve outcomes [3] [4]. This approach combines the advantages of rapid and simple use of fibrinolysis for myocardial salvage with the advantages of stenting in achieving a normal stable flow, and is a reasonable alternative to primary angioplasty. However, the safety and efficacy of early post-fibrinolysis coronary intervention compared with primary angioplasty is still unknown [5] [6]. Thus, we carried out an retrospective investigation in patients with STEMI to assess whether immediate fibrinolysis with Urokinase followed by early cardiac catheterization and coronary stenting if indicated led to a greater degree of myocardial salvage and clinical outcomes than primary angioplasty; and therefore provided a wide time window for percutaneous intervention when the application of primary angioplasty within the optimal time limit was not possible [7] [8].

2. Methods

2.1. Patient Population

Patients were enrolled from four hospitals with interventional facilities. Patients were enrolled if they had chest pain lasting more than 15 minutes, ST-segment elevation of more than 0.1 mV in at least two limb leads, ST-segment elevation of more than 0.2 mV in two or more contiguous precordial leads, or left bundle-branch block or paced rhythm [9].

Exclusion criteria included contraindication to fibrinolysis; evidence of cardiac rupture; non-cardiac condition with a life expectancy of less than 12 months; contraindication to aspirin or clopidogrel; renal failure (indicated by a serum creatinine concentration above 221 umol/L); history of neutropenia, thrombocytopenia, or hepatic dysfunction; previously known multivessel coronary artery disease which is not suitable for revascularization; major surgery pending in the following year; and peripheral vascular disease prohibiting catheterization [10].

Approval was obtained from Ethical Committees at institutional level. An informational brochure was provided to each patient who met inclusion criteria and informed written Consent was obtained from all patients. All patients were divided into early routine post-fibrinolysis angioplasty or primary angioplasty [11].

2.2. Study Protocol and Interventions

After providing informed consent, patients who satisfied the inclusion criteria were divided into two groups: 1) early routine post-fibrinolysis angioplasty: providing immediate fibrinolysis with Urokinase within 3 h followed by cardiac catheterization and coronary intervention within 3 - 12 h or 2) primary angioplasty: providing primary angioplasty of the culprit artery within 12 h (from onset to angiography). All patients received 300 mg aspirin and 300 mg or 600 mg clopidogrel after diagnose. Patients in early routine post-fibrinolysis angioplasty group received 1.5 million u Urokinase dissolved in 100 ml saline through intravenous drip in 30 minutes, For patients suffering from high blood pressure, blood pressure was controlled under 160/90 mmHg. The infarct-related artery was dilated if there was a severe stenosis (greater than 70%), or if the TIMI flow grade (TFG) was less than three. Stenting of the culprit lesions were performed when they were morphologically suitable for stenting and when the procedure was expected to achieve an adequate result. low-molecular weight heparin was given whenever revascularization was successful. In the early routine post-fibrinolysis angioplasty group, immediate rescue angioplasty was undertaken when both chest pain and ST-segment elevation lasted 90 minutes following Uroki-

nase administration. Patients in primary angioplasty group received unfractionated heparin (based on body-weight, given at a bolus of 100 u/kg). Abciximab was given at a bolus of 0.25 mg/kg, followed by a continuous infusion at a rate of 0.125 ug/kg/min (maximum of 10 ug/min) if there was no-reflow or slow-reflow. Abciximab was administered in the catheterization laboratory. Betablockers, angiotensin-converting-enzyme inhibitors, statins, and post-interventional anti-thrombotic therapy were administered to all patients, as outlined in the international guidelines.

2.3. Study Endpoints and Definitions

The efficacy (primary) endpoint included the reperfusion time within 3 h and incidence of no-reflow or slow-reflow after percutaneous coronary intervention. The secondary endpoints were the acute incidence of bleeding, the extent of myocardial damage, determined by 6-month left ventricular function and the 3 year-composite incidence of death, reinfarction, stroke, or revascularization.

2.4. Evaluation of the Left Ventricular Function

Left ventriculograms were performed after percutaneous coronary intervention and at 6-month to assess the changes in left ventricular function. Color doppler flow imaging was used to measure left ventricular volumes, ventricular ejection fraction and to analysis the regional wall motion.

2.5. Statistical Analysis

Data were entered using double data entry and the accuracy of the collected data was validated against medical records by an independent clinical research organization. Clinical and safety endpoints were reviewed and adjudicated by an independent event committee who were unaware of treatment assignment. The data are presented as mean and standard deviation, medians and their interquartile range (25th and 75th percentiles), or proportions. The non-inferiority between the two groups was assessed by means of 95% confidence intervals derived from a x^2 test or Fisher's exact test for categorical data, and the non-parametric Wilcoxon rank-sum test for continuous data. The survival was analyzed according to the Kaplan-Meier method. The relative risks of adverse events during the first 3 years after randomization were derived from proportional-hazards regression analysis. Differences in event-free survival were also assessed for significance by means of the log-rank test. All clinical events were reviewed and adjudicated by an independent event committee who were blinded to treatment assignment. A two-tailed P-value of less than 0.05 indicated statistical significance.

3. Results

3.1. Characteristics of the Patients

A total of 936 patients were enrolled, 472 in early routine post-fibrinolysis angioplasty group and 464 in primary angioplasty group. The frequency of missing data was similar between the two groups. There were no differences in baseline characteristics between the two groups. The-3-year-follow-up was available for all patients, and the analysis of clinical and safety endpoints was performed in all patients randomized. There were no differences in concomitant medications given during hospitalization, at discharge, or at the 3-year-follow-up in either group. A high proportion of patients received b-blockers, angiotensin-converting-enzyme inhibitors, statins, aspirin, and clopidogrel (**Table 1**).

3.2. Treatment Interventions

Patients of early routine post-fibrinolysis angioplasty were all acceptted the immediate fibrinolysis treatment with Urokinase within 3 h. The recanalization rate within 3 h was 84.32%. While only 33.41% patients in the primary angioplasty group received angioplasty within 3 h. The recanalization rate within 3 h was significantly less than the early routine post-fibrinolysis angioplasty group ($P < 0.001$). There were no differences in infarct related artery location and the number of vessels disease in two groups ($P > 0.05$) (**Table 2**).

3.3. Myocardial Perfusion and No-Reflow

59.75% of patients treated with early routine post-fibrinolysis angioplasty had TIMI3 flow in the infarct-related

Table 1. Baseline characteristics of both group.

Baseline characteristic	Post-fibrinolysis angioplasty (n = 472)	Primary angioplasty (n = 464)	P-value
Age (year)	62.4 ± 12.6	63.3 ± 12.8	0.281
Interquartile range	52 - 72.75	54.25 - 75	
Male sex, n (%)	356 (75.42)	352 (75.86)	0.629
Current smoking, n (%)	212 (44.92)	208 (44.83)	0.562
Family history, n (%)	72 (15.25)	68 (14.66)	0.809
Hypertension, n (%)	176 (37.29)	172 (37.07)	0.820
Diabetes, n (%)	104 (22.03)	108 (23.28)	0.432
Cholesterol (>5.5 mmol/l), n (%)	156 (33.05)	164 (35.34)	0.428
Heart rates (beats/minutes)	77.3 ± 18.5	75.6 ± 18.1	0.105
Systolic blood pressure (mmHg)	136.2 ± 20.6	135.3 ± 21.2	0.730
Aspirin, n (%)	356 (75.42)	360 (77.59)	0.927
Beta-blockers, n (%)	44 (9.32)	48 (10.34)	0.442
ACE-inhibitors, n (%)	56 (11.86)	52 (11.21)	0.324
Calcium antagonists, n (%)	32 (6.78)	28 (6.03)	0.923

Table 2. Treatment interventions of both group.

Treatment interventions	Post-fibrinolysis angioplasty (n = 472, %)	Primary angioplasty (n = 464, %)	P-value
Perfusion treatment within 3 hours	472/472 (100%)	155/464 (33.41%)	<0.001
the recanalization rate within 3 hours	398/472 (84.32%)	155/464 (33.41%)	<0.001
the recanalization rate within 12 hours	472/472 (100%)	453/464 (97.63)	0.082
Infarct related artery location			
Left anterior descending, n (%)	216 (45.76)	212 (45.69)	
Left circumflex, n (%)	72 (15.25)	64 (13.79)	0.174
RCA, n (%)	184 (38.98)	188 (40.52)	
Number of vessels disease			
Non-stenotic vessels, n (%)	11 (2.33)	12 (2.59)	0.251
Single-vessel disease, n (%)	256 (54.24)	248 (53.45)	
Double-vessel disease, n (%)	152 (32.20)	156 (33.62)	
Triple-vessel disease, n (%)	53 (11.23)	48 (10.34)	

artery at initial angiography compared with 2.59% in the primary angioplasty group ($P < 0.01$). Despite these differences, the rate of post-procedural TIMI3 flow was higher in early routine post-fibrinolysis angioplasty group compared with primary angioplasty group (98.52% vs 89.66%). Full reperfusion following angioplasty was more common in the post-fibrinolysis angioplasty group than in the primary angioplasty group. No-reflow was quite often in primary angioplasty beyond 3 h group. The no-reflow rate was higher in primary angioplasty group than in early routine post-fibrinolysis angioplasty group ($P < 0.01$) **Table 3**.

3.4. Left Ventricular Function

All patients got color doppler flow imaging evaluation at baseline and the 6-month follow-up, indexes of ventricular function were better in early routine post-fibrinolysis angioplasty group than in primary angioplasty group. At 6-month, a significant increase in the left ventricular ejection fraction was observed in early routine post-fibrinolysis angioplasty group compared with baseline (**Table 4**).

3.5. Safety and Efficacy

3 patients in the early routine post-fibrinolysis angioplasty group and 6 patients in the primary group died during the 3 year follow-up. There was 1 case of non-fatal reinfarction among patients in the early routine post-fibrinolysis angioplasty group and 1 case among patients in the primary angioplasty group. 8 patients in the post-fibrinolysis angioplasty group and 7 patients in the primary angioplasty group required coronary revascularization. The composite endpoint of death, reinfarction, disabling stroke, or revascularization at 3 year was reached in 13 patients in the early routine post-fibrinolysis angioplasty group and in 15 patients in the primary angioplasty group. There was no significant difference in major bleeding rate between the two groups. There was 11 case of heart failure at 3-year follow-up among patients in the early routine post-fibrinolysis angioplasty group and 82 cases among patients in the primary angioplasty group. The rate of heart failure was significantly higher in the primary angioplasty group than the early routine post-fibrinolysis angioplasty group. The clinical and safety endpoints and individual components are shown in **Table 5**.

Table 3. Myocardial perfusion and no-reflow of both group.

Variable	Early routine post-fibrinolysis angioplasty, n (%)	Primary angioplasty, n (%)	95% confiden-ceinterval
At baseline of infarct related artery TIMI grade			
0	74 (15.68)	398 (85.78)	
1	28 (5.93)	33 (7.11)	
2	88 (18.64)	21 (4.53)	
3	282 (59.75)	12 (2.59)	(29.6 - 55.1)
After the angioplasty of infarct related artery TIMI grade			
0	0 (0.00)	11 (2.37)	
1	1 (0.21)	16 (3.45)	
2	6 (1.27)	62 (13.36)	
3	465 (98.52)	416 (89.66)	(9.2 - 23.4)
No-reflow	0 (0.00)	11 (2.37)	

Table 4. Left ventricular function evolution of both group.

Varible	Early routine post-fibrinolysis angioplasty(n = 472)	Primary angioplasty (n = 464)	95% confidence interval
Ejection fraction			
Following the angioplasty	53.4 ± 11.2	50.6 ± 12.8	(−3.35, 3.64)
At 6-month follow-up	59.2 ± 11.7	52.1 ± 13.1	(−0.68, 6.32)
Increment	5.6 ± 10.2	2.2 ± 7.8	(−0.32, 5.43)

Table 5. Cardiovascular events and bleeding complications of both group.

Outcome, n (%)	Early routine post-fibrinolysis angioplasty (n = 472)	Primary angioplasty (n = 464)	95% confidence interval
Cardiovascular event			
Death	3 (0.64)	6 (1.29)	(−0.08, 0.03)
Non-fatal reinfarction	1 (0.21)	1 (0.22)	(−0.02, 0.03)
Disabling stroke	1 (0.21)	1 (0.22)	(−0.02, 0.03)
Ischaemia-driven revascularization	8 (1.69)	7 (1.51)	(−0.06, 0.07)
Any of the previous cardiovascular events	11 (2.33)	13 (2.8)	(−0.11, 0.06)
Bleeding complication	12 (2.54)	9 (1.94)	(−0.04, 0.13)
Heart failure at 3-year	11 (2.33)	82 (17.67)	(−0.84, 7.62)

4. Discussion

The most important finding of our trial is that the strategy of performing routine stent-angioplasty within 3 - 12 h of fibrinolysis in patients with STEMI is safe and superior to primary stenting in increasing myocardial perfusion, preventing no-reflow and preserving myocardial function. Of note, this strategy seems to bring better and earlier myocardial perfusion than primary angioplasty, as demonstrated by the presence of better angiographic reperfusion parameters in this group. To the best of our knowledge, the application of a combined lytic-based pharmacological and mechanical reperfusion in acute myocardial infarction is feasible and could safely allow a wide time window for the definitive repair of the infarct-related artery so that we can calmly deal with these patients and patients can get better prognosis. These findings showed that the combination of immediate thrombolysis and routine early coronary stenting could extend the benefits of early coronary intervention to the entire population with acute myocardial infarction, irrespective of geographical and logistical barriers.

We assumed that early routine post-fibrinolysis angioplasty was superior to primary angioplasty in patients with STEMI. In our trial, although the participating hospitals were able to provide primary angioplasty within the recommended time, it was still hard to make reperfusion therapy within 3 hours. Thrombolysis therapy has the characteristics of rapid, simple and is easy to operate. Once a patient is diagnosed, thrombolysis treatment can begin immediately. In the modern era of percutaneous coronary intervention, routine early post-fibrinolytic angiography and stenting can improve outcomes. This approach combines the advantages of rapid and simple use of fibrinolysis with the advantages of stenting in achieving a normal stable flow, and could represent a reasonable alternative to primary angioplasty. In addition, in order to prevent reocclusion associated with the early mechanical manipulation of the culprit artery, all patients received clopidogrel and aspirin. As a result, primary and post-fibrinolysis stenting had a low and identical incidence of ischaemic events. It is also important that inspite of longer intervention delay, post-fibrinolysis intervention resulted in less infarct size and better ventricular outcome when compared with primary stent-angioplasty [12]. Finally, there was no significant difference in major bleeding rate between the two groups. We have consistently found that post-fibrinolysis stenting is superior to primary patients in infarct size, left ventricular volumes and ejection fraction, which have been shown to be the most powerful predictors of survival after acute myocardial infarction. The changes in these measurements reflect changes in mortality and survival [13]. Furthermore, the post-fibrinolysis stenting group shows a better left ventricular outcome, particularly in terms of the left ventricular ejection fraction which is the most powerful independent predictor of long-term mortality after infarction. Secondly, we have compared the impact of the two strategies on myocardial perfusion, which have also been identified as strong predictors of post-infarction left ventricular evolution and clinical outcome, leading to the modern paradigm (time is muscle) should be expanded to myocyte and microvascular reperfusion [14]. In our study, post-fibrinolysis angioplasty patients underwent coronary angiography much later than primary patients and therefore some of them could have achieved spontaneous recovery of culprit artery flow. However, this mechanism does not justify the magnitude of the observed differences, which demonstrates that previous fibrinolysis produces better pre-intervention myocardial perfusion than primary angioplasty performed under IIb/IIIa inhibitors [15]. Concordantly, in our study, patients allocated to post-fibrinolysis intervention showed a lower thrombotic burden than primary patients. Altogether, these data are in accordance with the better left ventricular parameters observed in the post-fibrinolysis angioplasty group and suggest that fibrinolysis “stops the clock”, allowing patients to be tranferred for definitive mechanical repair [16].

Our findings seem to be relevant, the strategy of performing stenting hours after intravenous fibrinolysis is applicable to the entire population with acute myocardial infarction, and could represent a good alternative for the high proportion of victims of whom primary angioplasty is not available or delay.

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