Importance of Delayed Perfusion with Primary Angioplasty on Short-Term Mortality in Acute Myocardial Infarction Patients

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Background: *Early primary coronary interventions (PCI) in acute ST elevation myocardial infarction (STEMI) is associated with improved outcome and mortality rate but delayed reperfusion especially after 6 hours is still doubtful in terms of clinical benefits because most myocardial muscle are infarcted after 6 hours of onset of chest pain.*
Objective: *The aim of the present study was to compare the mortality rate of patients treated with PCI within 6 hours of symptom onset to those treated between 6 to 24 hours after the onset of STEMI.*
Material and Method: *The present study included consecutive patients from the data of the Fast Track Registry of King Chulalongkorn Hospital from June 1, 1999 to October 31, 2003 to compare the thirty-day mortality of patients treated with early or delayed PCI (0-6 hours vs. 6 -24 hours after symptom of chest pain) for STEMI.*
Results: *Two hundred and sixteen patients who underwent PCI were enrolled. Male gender (82% vs. 64.9%, p = 0.03) and history of smoking (72.1% vs. 50%, p = 0.04) were predominant in the early treatment group (ETG) vs. the delayed treatment group (DTG). Mean age (60.5% vs. 61.03%, p = 0.11), diabetes (31.4% vs. 29.7%, p = 0.82), hypertension (64.0% vs. 54.1%, p = 0.20), dyslipidemia (58.1% vs. 60.8%, p = 0.73), and ejection fraction < 40% (22.8% vs. 32.0%, p = 0.625) were similar in both groups. There were no differences in angiographic finding and hospital management. Door to balloon and total delay time were 124.13 $\pm$ 143.27 min and 407.94 $\pm$ 268.183 min, respectively. The thirty-day mortality (9.01% vs. 12.76%, p = 0.379) and 1 year mortality (12.4% vs. 16.9%, p = 0.532) were not significantly determined by Log rank test in both groups. As for cardiogenic shock, ETG tended to have a lower thirty-day mortality than DTG but no statistically significant difference (12.5% vs. 50.0%, p = 0.0809).*
Conclusion: *The delayed PCI up to 24 hours in STEMI does not increase short-term mortality at thirty days; therefore, it may still have benefit in STEMI patients. However, it tended to have higher short-term mortality than early PCI especially in cardiogenic shock but showed no statistical significance.*

Keywords: *Acute ST-elevation myocardial infarction (STEMI), Percutaneous coronary intervention (PCI), Delay reperfusion*

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Time to the reperfusion therapy affects myocardial salvage and improved survival in patients with acute ST-elevation myocardial infarction (STEMI). These benefits are believed to occur when coronary reperfusion can be established early enough to salvage myocardium. The experimental study in dogs of Bergmann et al demonstrated that 50% of myocardium was salvaged if streptokinase was given within 90 minutes of experimentally induced occlusion, while no significant salvage was accomplished if streptokinase was administered after 6 hours[1-5].

Consistent with this paradigm, data from randomized trials have shown that the mortality rate

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after thrombolytic therapy is strongly dependent on time to treatment. The benefit declined as the interval increased and begins to diminish after 6 hours of chest pain[6]. In contrast, studies of early primary coronary interventions (PCI) before 6 hours for treatment of acute ST-elevation myocardial infarction have not demonstrated a reduction of mortality rate of time to treatment[7-9].

The aim of the present study was to evaluate the importance of delayed perfusion with 1st PCI by comparing the mortality rate of patients treated with PCI within 6 hours of symptom onset to those treated between 6 to 24 hours after the onset of STMI.

Material and Method

Data of acute myocardial infarction patients who underwent PCI between June 1, 1999 and October 31, 2003 at King Chulalongkorn Memorial Hospital were collected from fast track registry forms, emergency department records, catheterization laboratory records, admission records and additional information by phone. The fast track registry was developed in King Chulalongkorn Memorial Hospital on June 1st 1990, to track and record the important information on every patient who underwent PCI such as; patients' demographics, risk factors, discharge status, vessels disease, lesion location and morphology, presence of bypass grafts, pre-post procedural stenosis and complications.

The authors excluded the patients who underwent PCI after unsuccessful thrombolysis (rescue angioplasty), foreigners and patients aged under 15. The time from onset of STEMI symptoms to treatment within 6 hours (early treatment group) is recorded and 6-24 hours (delayed treatment group) then compared with the thirty-day mortality of the two groups.

Definition

Total delayed time was the time from the onset of symptoms until initial balloon inflation. Door to balloon time was the time from arrival in the emergency department until initial balloon inflation. Early PCI was the time from the onset of symptoms until initial balloon inflation within 6 hours. Delayed PCI was the time from the onset of symptoms until initial balloon inflation between 6-24 hours.

Statistical analysis

Categorical variables were compared by Chi-squared analysis. Continuous variables were compared using student's t-tests. All probability values are 2-tailed. A difference in survival was evaluated with the Kaplan-Meier method. Comparisons were made with the log-rank test. Characteristics of patients in the early and delayed groups that differed on univariate analysis with a p-value of < 0.1 were entered into a multivariable logistic regression model to identify independent predictors of 30-days mortality.

Results

Two hundred and forty patients from the Fast Track Registry of King Chulalongkorn Memorial Hospital who underwent PCI between June 1, 1999 and October 31, 2003 were enrolled. Twenty-four patients were excluded due to unsuccessful thrombolysis (rescue angioplasty) (11), foreigners (6), and total delay time > 24 hours (7). From 216 patients, early PCI (within 6 hours of chest pain onset) was attempted in 122 patients (56.5%) while 94 patients (43.5%) had delayed PTCA (between 6 and 24 hours after chest pain onset) (Fig. 1).

Overall mean door to balloon time and mean total delay time of the whole group were 124.13 ± 143.27 min and 407.94 ± 268.18 min, respectively. In the ETG, door to balloon time (95.73 ± 65.67 min versus 161.38 ± 199.01 min, $p = 0.01$) and total delay time (235.54 ± 81.39 min versus 631.68 ± 260.89 min, $p < 0.01$) were significant less than the DTG (Fig. 2).

Baseline characteristics of the ETG and DTG are presented in Table 1. Male gender (82% vs. 64.9%, $p = 0.004$) and history of smoking (72.1% vs. 50.0%, $p = 0.004$) were predominant in the ETG vs. the DTG. There were no significant differences in the prevalence of hypertension, diabetes and dyslipidemia between both groups. Mean age, mean blood pressure and mean heart

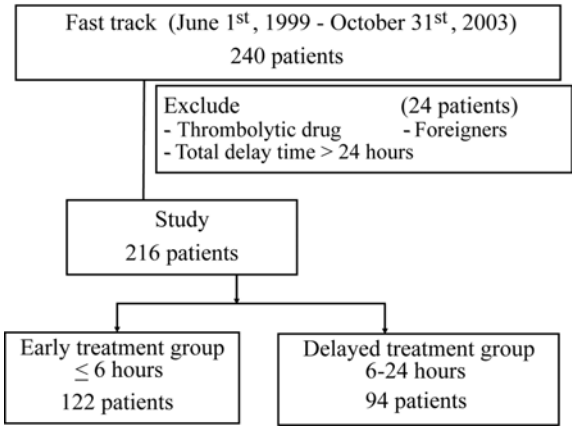

Fig. 1 Flow chart of patients in the study

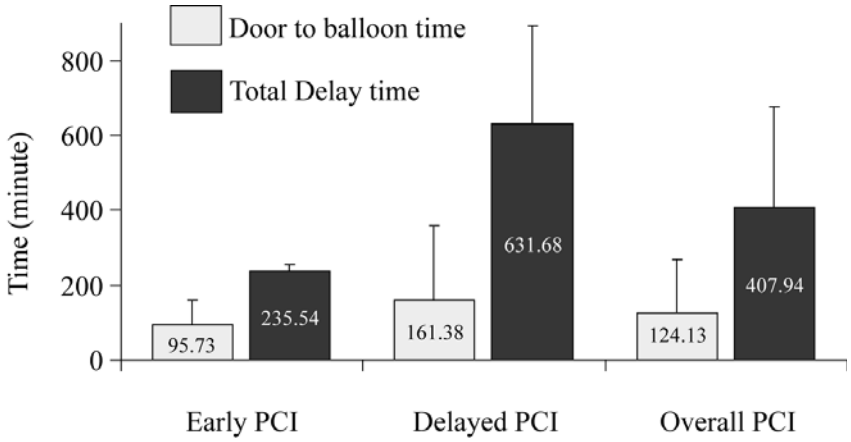

Fig. 2 Mean door to balloon time and mean total delay time of both groups

rate were not different. Killip class, resuscitation prior to PCI, shock prior to PCI and left ventricular ejection fraction (LVEF < 40%) were similar in both groups. A comparison of management during hospitalization (Table 2) and angiographic variables (Table 3) revealed no significant differences.

Overall, the thirty-day mortality and 1-year mortality were 10.6% and 14.4%, respectively. The thirty-day mortality (9.01% vs. 12.76%, p = 0.379), 1-year mortality (12.4% vs. 16.9%, p = 0.532) (Fig. 3), reinfarction (1.2% vs. 0%, p = 0.613) and emergency CABG (1.1% vs. 0%, p = 0.368) were not statistically significantly different determined by Log rank test in both groups (ETG vs. DTG) (Table 4). Fig. 4 shows the Kaplan-Meire cumulative survival curve for the thirty-day mortality. The thirty-day mortality in Killip class 4 patients, ETG trend to be lower than DTG but showed no statistically significant difference (12.5% vs. 50.0%, p = 0.0809).

The univariate analyses for the factors that affect the thirty-day mortality are shown in Table 5. Failed PCI, shock prior to PCI, CPR prior to PCI, LVEF < 40%, tripple vessel disease, age ≥ 65 years, female gender, diabetes, history of smoking and Killip class 4

Table 1. Patient baseline characteristics

Variable	Early Rx group (122 patients)	Delayed Rx group (94 patients)	p-value
Age - yr	60.5 ± 12.67	61.0 ± 13.21	0.768
Heart rate - beats/min	78.7 ± 21.32	83.7 ± 23.62	0.174
Systolic BP - mmHg	133.96 ± 35.14	124.60 ± 32.83	0.095
Diastolic BP - mmHg	80.96 ± 23.54	74.0 ± 23.10	0.070
Male sex - %	82.0	64.9	0.004
Hypertension - %	64.0	54.1	0.204
Diabetes - %	31.4	29.7	0.820
Dyslipidemia - %	58.1	60.8	0.732
History of smoking - %	72.1	50.0	0.004
Killip class 4 - %	10.6	12.4	0.228
Shock prior to PCI - %	38.0	28.6	0.108
CPR prior to PCI - %	17.2	13.2	0.625
LVEF < 40% - %	22.8	32.0	0.625

BP - blood pressure; PCI - percutaneous coronary intervention; CPR - cardiopulmonary resuscitation; LVEF - left ventricular ejection fraction

Table 2. Management during hospitalization

Variable	Early Rx group (122 patients)	Delayed Rx group (94 patients)	p-value
Aspirin - %	100	100	1.000
Clopidogrel - %	63.6	66.7	0.777
Ticlopidine - %	10.0	8.0	0.863
Heparin - %	100	100	1.000
Nitrate - %	57.8	53.3	0.678
ACEI - %	67.8	52.0	0.057
ARB - %	1.1	2.7	0.873
Statin - %	66.7	60.0	0.469
G2b3a inhibitors - %	31.1	40.0	0.122
IABP insertion - %	5.6	9.6	0.338
Temporary pacemaker insertion - %	3.4	2.7	0.946

ACEI - angiotensin converter enzyme inhibitor; ARB - angiotensin receptor blocker; GP2b3a - glycoprotein 2b3a; IABP - intra-aortic balloon pump

Table 3. Angiographic variables

Variable	Early Rx group (122 patients)	Delayed Rx group (94 patients)	p-value
Culprit lesion at LAD - %	54.3	57.1	0.210
Tripple vessel disease - %	28.3	37.7	0.397
Initial TIMI flow 3 - %	8.3	8.4	0.168
Final TIMI flow 3 - %	89.0	88.0	0.987
Successful PCI - %	96.7	96.8	0.971
Thrombolectomy - %	16.3	16.9	0.917

LAD - left anterior descending artery; PCI - percutaneous coronary intervention

Table 4. Clinical outcome

Variable	Early Rx group (122 patients)	Delayed Rx group (94 patients)	p-value
30-days mortality - %	9.01	12.76	0.379
: Killip 1-3	8.3	9.1	0.883
: Killip 4	12.5	50.0	0.080
1 year mortality - %	12.4	16.9	0.532
Reinfarction - %	1.2	0	0.613
Emergency CABG - %	1.1	0	0.368

CABG - coronary artery bypass graft

were the risk predictors on thirty-day mortality. When using multivariate models by using Cox proportional hazard enter method, Killip class 4, female gender and failed PCI were independent factors to predict the thirty-day mortality (Table 6). Delayed PCI for STEMI was not an independent predictor of thirty-day mortality.

Discussion

The present article is the first study in

Table 5. Univariate analysis of factors that effect survival time

Variable	p-value	Variable	p-value
Failed PCI - %	<0.0001	Age ≥ 65 years - %	0.1935
Shock prior to PCI - %	0.0497	Female sex - %	0.0308
CPR prior to PCI - %	0.0065	Hypertension - %	0.4965
LVEF < 40 % - %	0.0003	Diabetes - %	0.0131
Culprit lesion at LAD - %	0.6148	Dyslipidemia - %	0.4986
Delayed PCI - %	0.3794	History of smoking - %	0.0325
Thrombectomy - %	0.9009	Killip class 4 - %	0.0027
Tipple vessel disease - %	0.0029		

PCI - percuteneous coronary intervention; CPR - cardiopulmonary resuscitation; LVEF - left ventricular ejection fraction; LAD - left anterior descending artery

Table 6. Multivariate analysis of factors that effect survival time

Variable	p-value	Hazard ratio	95% CI	
			Lower	Upper
Female gender	0.004	4.402	1.620	11.960
Age	0.662	0.988	0.938	1.041
Killip class 3	0.111	3.863	0.732	20.392
Killip class 4	<0.001	7.678	2.571	22.936
Diabetes	0.260	2.023	0.594	6.886
Hypertension	0.428	0.564	0.137	2.321
Hx of smoking	0.325	0.428	0.079	2.318
Dyslipidemia	0.383	0.464	0.083	2.604
LAD lesion	0.068	0.075	0.005	1.206
RCA lesion	0.267	0.495	0.143	1.712
DVD	0.137	6.239	0.557	69.864
TVD	0.60	9.007	0.908	89.333
Stenting	0.001	0.201	0.075	0.537
Delayed PCI	0.870	1.117	0.298	4.189

LAD - left anterior descending artery; RCA - right coronary artery; DVD - double vessel disease; TVD - triple vessel disease; PCI - percutaneous coronary intervention

Thailand to compare the short-term mortality of acute ST-elevation myocardial infarction that underwent PCI. The overall mean door to balloon time was 124.13 ± 143.27, which was over the time recommended by the ACC/AHA guidelines (90 ± 30 min)[10]. In the authors' experience, the causes of delay in door to balloon time were 1) delayed diagnosis of acute myocardial infarction 2) prolonged catheterization laboratory team assembled time especially in nonofficial hours 3) prolonged process time in emergency room 4) stabilization of hemodynamically unstable cases[11-14].

Frequency of the patients who had PCI performed by time to reperfusion was 16.20% (< 3 hours), 40.28% (3 to < 6 hours), 29.63% (6 to < 12 hours) and 13.89% (12-24 hours). In comparison to an other study, the over all mean total delay time (407.94 ± 268 min) was longer, so that patients should be educated to show up at the emergency department as soon as possible when they have acute chest pain suspected of STEMI[15].

The benefit of thrombolytic therapy depends on time to reperfusion and begins to diminish after 6 hours of chest pain. However, recent studies have suggested that time to reperfusion may be less important with PCI. The large Second National Registry of Myocardial Infarction (NRMI-2) Registry[16,17], the

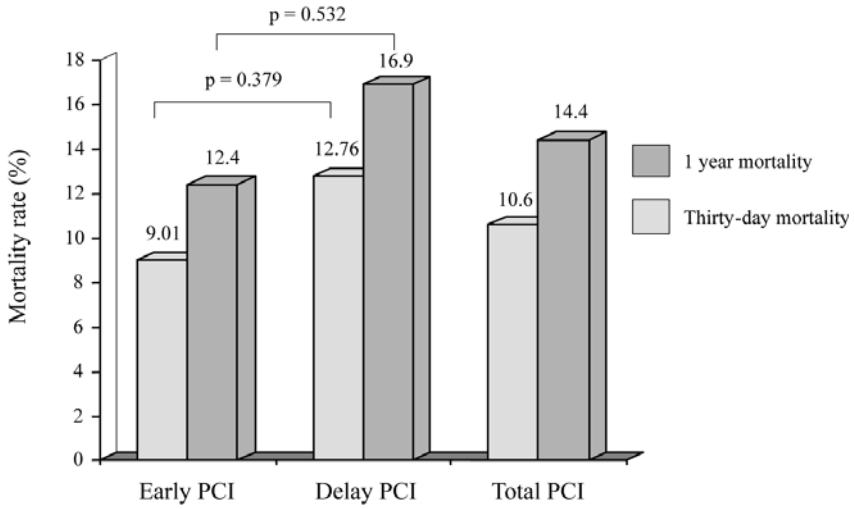

Fig. 3 Results of thirty-day mortality and 1 year mortally in both groups

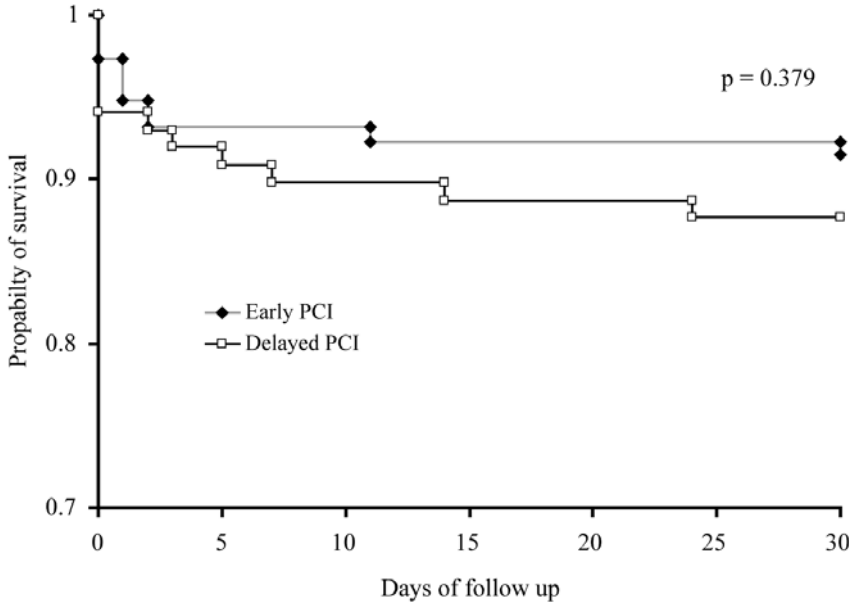

Fig. 4 Kaplan-Meier Survival analysis for thirty-day mortality in early PCI versus delayed PCI

Global Use of Strategies to Open Occluded Arteries in Acute Coronary Syndromes (GUSTO) IIb trial[18,19] and the Stent Primary Angioplasty in Myocardial Infarction Trial (STENT PAMI)[9] found no significant relation between total time to reperfusion and short-term mortality. The Moses Cone Hospital Registry[8,9,13] found that mortality with primary PTCA was lower when patients were reperfused within 2 hours, but after 2 hours, mortality was nearly constant with increasing time to reperfusion. In the present study, early and delayed PCI did not result in greater thirty-day mortality even though the thirty-day mortality tended to be lower in early PCI. The in-hospital of the 30-day mortality of reperfusion with thrombolytic therapy in King Chulalongkorn Memorial Hospital[20] was 11.2%, which was nearly the same as 30-day mortality of delayed PCI

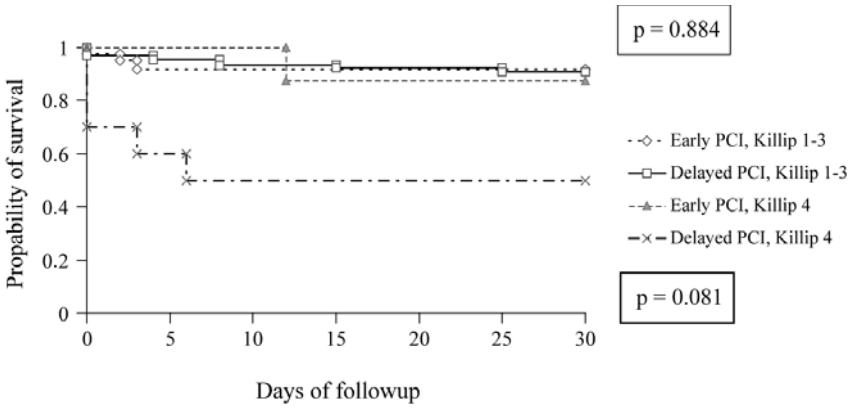

Fig. 5 Kaplan-Meier Survival analysis for thirty-day mortality in early PCI versus delayed PCI classified by Killip

(12.76%). From multivariate analysis, time to reperfusion appeared to have little effect on short-term mortality.

Since the results of the present study showed no significance difference for the thirty-day mortality rate of the treatment for early and late PCI, which does not mean late PCI is a treatment for AMI. As for Killip class 4 criteria, we will see that "the sooner the better. Besides that this study did not have any comparison with those AMI, which did not get any treatment at all."

The outcome of the present studies should stimulate re-evaluation the mechanism of benefit of reperfusion with PCI especially delayed PCI. Several studies demonstrated that time to treatment may be less important with PCI than with thrombolytic therapy[12, 21-23]. Conclusions from these studies were first, TIMI 2 to 3 flows is achieved less often with increasing time to treatment with thrombolytic therapy. On the other hand, in the present study and others with PCI, TIMI 3 flow was achieved in a high percentage of patients regardless of time to treatment. Second, in patients treated with thrombolytic therapy, mortality rates from myocardial rupture increased progressively with increasing time to treatment. In contrast, mortality rates due to myocardial rupture after PCI are very low. Third, for reasons that are not clear, the GUSTO-1 trial found that the incidence of intracranial hemorrhage after thrombolytic therapy increased with increasing time to treatment. The occurrence of intracranial hemorrhage with PCI is very rare. Killip class 4, female gender and failed PCI were independent factors to predict the thirty-day mortality. Most of the patients in Killip 4 died in the hospital. Female patients had worse prognostic factors than males owing to higher pain threshold, atypical chest pain, higher incidence of diabetes, delayed treatment and lack of aggressive investigation than males. Usually when they were first seen by doctors, their atherosclerosis had already advanced.

Study limitation

The present study was not a randomized controlled trial, retrospective nature, and differences characteristic of some baselines between two groups. Nevertheless, the authors tried to adjust the different variables by using multivariate analysis model.

Conclusion

The delayed primary coronary intervention up to 24 hours for acute ST elevation myocardial infarction does not increase short term mortality at thirty-days. Therefore, it may still have benefit in acute myocardial infarction patients.

In the present study, Killip class 4, female gender, and failure to open the occluded vessel are independent predictors of short-term mortality for AMI. The delayed primary coronary intervention up to 24 hours for acute ST elevation myocardial infarction does not increase short-term mortality at thirty-days. Since the results of the present study showed no significant difference, it may still have benefit for the patients. In the present study, Killip class 4, female gender and failure to open the occluded vessel are independent predictor of short-term mortality for STEMI.

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ความสำคัญของความล่าช้าในการทำบอลลูนขยายหลอดเลือดต่ออัตราตายระยะสั้นในผู้ป่วยกล้ามเนื้อหัวใจตายเฉียบพลัน

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ภูมิหลัง: *การทำบอลลูนขยายหลอดเลือดหัวใจในผู้ป่วยกล้ามเนื้อหัวใจตายเฉียบพลันชนิด ST elevation ในเวลาอันรวดเร็วมีผลให้ผลการรักษาดีและอัตราตายลดลง แต่ถ้าการรักษาล่าช้าโดยเฉพาะถ้าเกิน 6 ชั่วโมงหลังจากอาการเจ็บหน้าอก ยังเป็นที่ถกเถียงว่าจะได้ประโยชน์มากน้อยเพียงใด ทั้งนี้เชื่อว่ากล้ามเนื้อหัวใจสามารถทนต่อการขาดเลือดได้ไม่เกิน 6 ชั่วโมง การศึกษานี้ต้องการเปรียบเทียบอัตราตายของผู้ป่วยที่ได้รับการรักษาด้วยการทำบอลลูนขยายหลอดเลือดภายใน 6 ชั่วโมง เทียบกับ 6-24 ชั่วโมงหลังอาการเจ็บหน้าอก*

วัสดุและวิธีการ: *การศึกษานี้ได้รวบรวมข้อมูลผู้ป่วย fast tract registry ทุกรายติดต่อกันของรพ.จุฬาลงกรณ์ ตั้งแต่ 1 มิย. 2542 ถึง 31 ตค. 2547 และเปรียบเทียบอัตราตายที่ 30 วันในกลุ่มที่ได้รับการทำบอลลูนภายใน 6 ชั่วโมงเทียบกับ 6-24 ชั่วโมง หลังงอาการเจ็บหน้าอก*

ผลการศึกษา: *ผู้ป่วยจำนวน 216 คนที่ได้รับการทำบอลลูนขยายหลอดเลือดหัวใจ ร้อยละของเพศชาย (82.0% เทียบกับ 64.9%, p = 0.003) และประวัติการสูบบุหรี่ (72.1% เทียบกับ 50.0%, p = 0.04) มีมากกว่าในกลุ่มที่ได้รับการรักษาเร็ว ไม่พบความแตกต่างของอายุเฉลี่ย (60.5 ปี เทียบกับ 61.0 ปี, p = 0.11) ร้อยละของการเป็นเบาหวาน (31.4% เทียบกับ 29.7%, p = 0.82) ความดันโลหิตสูง (60.0% เทียบกับ 54.1%, p = 0.20) ไขมันในเลือดสูง (58.1% เทียบกับ 60.8%, p = 0.73) ร้อยละการบีบตัวของหัวใจน้อยกว่า 40% (22.8% เทียบกับ 32.0%, p = 0.63) รวมทั้งผลการฉีดสีและวิธีการรักษาระหว่างอยู่ในโรงพยาบาล ระยะเวลาเฉลี่ยของ door to balloon และ ระยะเวลาเฉลี่ยตั้งแต่ อาการเจ็บหน้าอกจนได้ทำบอลลูนเท่ากับ 124.1 $\pm$ 143.3 นาทีและ 407.8 $\pm$ 268.2 นาที ตามลำดับ ไม่พบความแตกต่าง ระหว่างผู้ป่วยทั้ง 2 กลุ่มใน อัตราตายที่ 30 วัน (9.01% เทียบกับ 12.76%, p = 0.379) และ 1 ปี (12.4% เทียบกับ 16.9%, p = 0.532) สำหรับกลุ่มที่มีภาวะช็อก พบว่า กลุ่มที่ได้รับการรักษาที่รวดเร็วมีแนวโน้มของอัตราตายที่ 30 วันต่ำกว่ากลุ่มที่รักษาช้า (12.5% เทียบกับ 50.0%, p = 0.081)*

สรุป: *ความล่าช้าในการรักษาผู้ป่วย STEMI โดยการทำบอลลูนขยายหลอดเลือดเพิ่มอัตราตายที่ 30 วันและ 1 ปี แต่อย่างไรก็ตาม อัตราตายมีแนวโน้มจะสูงกว่าในกลุ่มที่รักษาล่าช้าโดยเฉพาะผู้ป่วยที่มีภาวะช็อก*