Primary Percutaneous Transluminal Coronary Intervention Compared with Intravenous Thrombolysis in Patients with ST Segment Elevation Myocardial Infarction

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Background: *Primary percutaneous transluminal coronary intervention (PCI) and thrombolytic therapy (TT) are alternative means of achieving reperfusion in patients with acute ST segment elevation myocardial infarction (STEMI).*
Objective: *To compare the outcomes between both reperfusion strategies. The authors sought to compare in-hospital outcomes after PCI or TT for patients with acute STEMI.*
Material and Method: *From August 2002 through June 2004, data from all patients who received reperfusion therapy for acute STEMI were collected prospectively. The decision regarding type of reperfusion strategy was at the attending cardiologist's discretion. The patient's data on demographics, procedures, medications, and in-hospital outcomes were analyzed.*
Results: *From August 2002 through June 2004, 234 patients were admitted to the authors' institute with the diagnosis of acute STEMI. Of the 146 patients who received reperfusion therapy, 91 were treated with primary PCI and 55 received intravenous TT as the reperfusion modality. In the TT group, 51 (93%) patients received streptokinase and 11 (21.6%) underwent rescue angioplasty. The two groups had similar baseline characteristics. Both patient groups had frequent presence of diabetes (PCI 44.2% vs. TT 39.6%, p = 0.6). Cardiogenic shock on admission was present in 11% of the PCI patients and 7.3% of the TT patients (p = ns). In-hospital mortality was not significantly different in the two groups (PCI 14.3% vs. TT 10.9%, p = 0.56). In the TT group, there was a trend toward a higher rate of major bleeding (PCI 6.6% vs. TT 16.4%, p = 0.06) and stroke (PCI 2.2% vs. TT 7.3%, p = 0.13) complications without statistical significance.*
Conclusion: *The present findings suggest that both PCI and TT are comparable alternative methods of reperfusion among STEMI patients in terms of in-hospital mortality. In certain subgroups that are at increased risk of bleeding or stroke, primary PCI may be the preferred treatment strategy.*

Keywords: *Acute coronary syndrome, Acute myocardial infarction, Primary angioplasty, Thrombolysis*

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Primary percutaneous coronary intervention (PCI) was introduced for the treatment of patients with acute myocardial infarction (AMI) in 1982[1]. Since then, several prospective randomized trials comparing primary PCI with intravenous thrombolysis have been published[2-4]. A meta-analysis of these randomized trials showed superiority of primary PCI over thrombolysis regarding short-term mortality (7% mortality for primary angioplasty vs. 9% for thrombolysis, p = 0.0002)[5].

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Differences in hospital and operator expertise with performing primary angioplasty and time to treatment are important factors that contribute to the outcomes of patients treated with primary PCI. Thus, there was concern whether the survival advantage for primary PCI, from highly specialized cardiac centers, could be replicated in real world clinical practice. These valid concerns were demonstrated in three large AMI registries[6-8] all of which consistently failed to show an advantage of primary angioplasty over thrombolysis in real world practice.

For these reasons, primary PCI is considered an alternative to thrombolytic therapy in achieving reperfusion in patients with acute ST segment elevation myocardial infarction (STEMI). In Thailand, there are limited data comparing the outcomes between both reperfusion strategies[9]. The present study is a prospective, observational study to compare in-hospital outcome of STEMI patients who received reperfusion therapy by either primary PCI or intravenous thrombolysis.

Material and Method

From August 2002 through June 2004, data from all patients who received reperfusion therapy for acute STEMI at the institute were collected prospectively and consecutively. STEMI was diagnosed by having elevated biochemical markers of myocardial necrosis and ECG changes demonstrating either 1) ST-segment elevation $\geq$ 1 mm in two consecutive leads or 2) new or presumed new left bundle branch block.

In the current study, the authors divided patients into two reperfusion categories, those that received primary percutaneous coronary intervention (PCI) and those that received intravenous thrombolysis (TT). The decision regarding type of reperfusion strategy was at the attending cardiologist's discretion.

Data collection

Patient's data on clinical, demographic, treatment and in-hospital outcome were collected by trained cardiac nurses and transcribed onto standard data forms. Demographic variables included gender and age. Dyslipidemia, diabetes, hypertension, history of tobacco use, and family history were used to characterize risk factors. Diabetes was diagnosed when the patient's fasting plasma glucose was 126 mg/dl or higher on at least two occasions or the presence of a history of diabetes treated with either dietary control or antidiabetic medication. Hypertension was defined as systolic blood pressure > 140 mmHg or diastolic blood pressure > 90 mmHg or a previous diagnosis of hypertension. Dyslipidemia was diagnosed when total cholesterol was > 200 mg/dl, LDL cholesterol > 130 mg/dl, HDL cholesterol < 40 mg/dl or a previous diagnosis of dyslipidemia and/or currently being treated with a lipid-lowering agent. Tobacco use was defined by the habitual use of tobacco within 2 years of index hospital admission. Congestive heart failure included patients with Killip Class II or III. Killip class II was defined as bibasilar rales in < 50% of lung fields or presence of an S3 gallop whereas Killip class III was defined as bibasilar rales in $\geq$ 50% of lung fields. Cardiogenic shock (Killip class IV) was defined as symptomatic hypoperfusion with systolic blood pressure < 90 mm Hg. Medical management included the use of aspirin, thienopyridine, heparin, low-molecular weight heparin, GP IIb/IIIa antagonist, angiotensin-converting enzyme inhibitor, beta-blockers, calcium channel blocker, angiotensin receptor blocker, nitrates and statins. In-hospital complications included major bleeding, congestive heart failure, cardiogenic shock, stroke, arrhythmias, and death. In-hospital mortality was categorized as cardiac or non-cardiac death. Major bleeding was defined as bleeding other than intracranial hemorrhage that resulted in hemodynamic compromise.

This protocol was approved by the hospital ethics committee and is in accordance with the Declaration of Helsinki. Verbal consent was obtained from every patient.

Statistical analysis

Categorical variables are described as frequency and percentages. Continuous variables are presented as mean $\pm$ standard deviation or median (minimum and maximum) as appropriate. Differences between the two treatment groups for frequencies of categorical variables were tested by Chi-square test or Fisher's exact test were appropriated. Differences among continuous variables were tested by unpaired t test for mean values and by the nonparametric sign test for median values. All statistical tests are 2-tailed with p-value < 0.05 considered statistically significant. Statistical analysis was performed using the Statistical Package for Social Sciences (SPSS) Windows version 11.5.

Results

From August 2002 through June 2004, 234 patients were admitted to the institute with the diagnosis of acute STEMI. Of these, 146 patients received reperfusion therapy, 91 were treated with PCI, and 55

received TT as the reperfusion modality. In the TT group, 51 (93%) patients received streptokinase and the remainder received recombinant tissue-type plasminogen activator. Eleven (21.6%) patients in the TT group underwent rescue angioplasty.

Baseline characteristics of the 91 patients who were treated with primary PCI and 55 patients who received intravenous TT are shown in Table 1. The two groups had similar baseline characteristics. The primary PCI patients were slightly but significantly older than the TT patients. Both patient groups had a high prevalence of diabetes (PCI 44.2% vs. TT 39.6%, p = 0.6). Cardiogenic shock on admission was present in similar frequency in the two groups although overall numbers were small (PCI 11% vs. TT 7.3%, p = 0.46).

Treatment intervals (Table 2)

The median time to initiation of TT (door to needle time) was 135 minutes. The median time to balloon inflation (door to balloon time) in the PCI group was 120 minutes. The median time from onset to treatment was significantly higher in the PCI group than the TT group.

In-hospital medical treatment (Table 3)

Nitrates and statins were prescribed more often in patients who received TT. The patients in the PCI group had a higher use of thienopyridines (PCI 94.5% vs. TT 50.9%, p < 0.001). Other medications reported were similar in the two groups.

In-hospital outcomes (Table 4)

In-hospital mortality was 14.3% in the PCI group and 10.9% in the TT group (p = 0.56). In the TT group, there was a trend toward a higher rate of major bleeding (PCI 6.6% vs. TT 16.4%, p = 0.06) and stroke (PCI 2.2% vs. TT 7.3%, p = 0.13) without statistical significance.

Discussion

In the present study, the authors used observational data on patients with acute STEMI to evaluate whether the results of randomized trials could be replicated in real-world clinical practice at the institute. There were no substantial differences in baseline demographic or clinical characteristics between patients treated in the PCI group and those in the TT group.

Table 1. Baseline characteristics of patients treated with primary angioplasty compared with thrombolysis

Variable	Primary angioplasty n = 91, N (%)	Thrombolysis n = 55, N (%)	p-value
Age, years	64.3 ± 10.4	59.6 ± 11.6	0.013
Male gender	65 (71.4)	36 (65.5)	0.45
Risk factors			
Diabetes mellitus	38 (44.2)	21 (39.6)	0.6
Hypertension	50 (56.8)	30 (54.5)	0.7
Tobacco use	32 (42.7)	23 (41.8)	0.92
Dyslipidemia	63 (75.9)	39 (75)	0.91
Family history of premature CAD*	17 (21.3)	8 (15.1)	0.37
Congestive heart failure on presentation	28 (34.1)	15 (27.3)	0.15
Cardiogenic shock on presentation	10 (11)	4 (7.3)	0.46

* CAD = Coronary artery disease

Table 2. Time to treatment intervals

Variable	Primary angioplasty n = 91	Thrombolysis n = 55	p-value
Onset to treatment, mins	405 (260, 655)	287 (165, 345)	<0.001
Presentation to treatment, mins	120 (70, 218)	135 (105, 181)	0.63

Data presented are median (25^{th}, 75^{th} percentiles)

Table 3. In-hospital medical treatment

Medication	Primary angioplasty n = 91, N (%)	Thrombolysis n = 55, N (%)	p-value
Aspirin	88 (96.7)	55 (100)	0.29
Nitrates	53 (58.2)	41 (74.5)	0.052
Beta-blocker	61 (67)	38 (69.1)	0.86
Calcium channel blocker	1 (1.1)	1 (1.8)	1.0
Heparin	27 (29.7)	11 (20)	0.24
GP II b/ IIIA inhibitor	13 (14.3)	4 (7.3)	0.29
LMWH	9 (9.9)	9 (16.4)	0.3
Thienopyridine	86 (94.5)	28 (50.9)	<0.001
Statin	70 (76.9)	50 (90.9)	0.044
ACE inhibitor	63 (69.2)	41 (74.5)	0.57
ARB	4 (4.4)	1 (1.8)	0.65

LMWH = low-molecular weight heparin, ACE = angiotensin converting enzyme, ARB = angiotensin receptor blocker

Table 4. In-hospital outcome

Event	Primary angioplasty n = 91, N (%)	Thrombolysis n = 55, N (%)	p-value
Death	13 (14.3)	6 (10.9)	0.56
Major bleeding	6 (6.6)	9 (16.4)	0.06
Stroke	2 (2.2)	4 (7.3)	0.13
Congestive heart failure	4 (12.5)	0	0.29
Ventricular arrhythmia	18 (19.8)	11 (20)	0.65

There was no difference in the mortality rate during hospitalization between the two treatment groups. There was a trend toward higher in-hospital complications of stroke and major bleeding rates in the TT group.

Randomized, controlled trials[2-4] and meta-analysis of the randomized studies[5] comparing primary angioplasty with thrombolytic therapy have shown improved short-term mortality in patients treated with primary angioplasty (7% mortality for primary angioplasty vs. 9% for thrombolysis, p = 0.0002). The lack of a survival advantage for primary PCI in the present study is, however, concordant with those of other international registries[6-8] comparing primary angioplasty and intravenous thrombolysis in acute STEMI. All fail to document a mortality benefit associated with the use of the former mode of reperfusion. The reasons for the discrepancies between the findings from registries and randomized studies are likely multifactorial; randomized trials tend to select lower-risk patients than real-world patients, possible differences in hospital and operator expertise with performing primary angioplasty, later time to treatment in real-world practice, and the limited number of patients in the present study. Other differences between the present study and reported randomized trials could not be addressed and are limitations of the analysis.

Although the present study is subject to the same limitations as any registry, both treatment groups are similar in nearly all clinical characteristics. The only difference was the slighter older age and higher percentage of patients receiving thienopyridines in the primary angioplasty treated patients. The latter likely reflects the use of dual antiplatelet therapy in patients that received stent implantation. Despite this, it is conceivable that patients who underwent primary angioplasty had more clinical signs of severity that were not captured in the present study. For instance, there was a small, not significant, excess of patients with cardiogenic shock (11% vs. 7.3%) and congestive heart failure (34.1% vs. 27.3%) among patients who underwent primary angioplasty. Furthermore, from the

presented data, the authors could not determine how many patients treated with primary angioplasty had contraindications to thrombolysis. All together, these may explain, in part, why the present findings failed to show a survival advantage for primary PCI.

In-hospital mortality in the presented patients was similar to those reported by Srimahachota[9] in 2002. In their prospective registry of acute myocardial infarction patients from King Chulalongkorn Memorial Hospital, in-hospital mortality was 13.2% in the angioplasty group and 11.1% in the thrombolysis group. Nevertheless, the overall in-hospital mortality rate for the presented patients was considerably high, 14.3% in the PCI group, and 10.9% in the TT group, compared to reported international registries. In the Myocardial Infarction Triage and Intervention (MITI) Registry[7], in-hospital mortality for patients who underwent primary PCI was 5.5%, identical to those in the Second National Registry of Myocardial Infarction (NRMI-2)[8] and was 7% in the French Registry[6]. Compared with the patients in these aforementioned registries, the presented patient population had a higher percentage of diabetics and had substantially longer time from presentation until they received reperfusion treatment. Diabetes has been consistently shown to have an adverse effect on survival in acute myocardial infarction patients[10-13].

Shorter time from presentation to treatment with either reperfusion modality has been consistently associated with improved clinical outcome[14-16]. In the present study, the median time to initiation of TT (door to needle time) was 135 minutes and the median time to balloon inflation (door to balloon time) in the PCI group was 120 minutes. This is in contrast with others that in-hospital time to treatment is 28 to 69 minutes longer in patients treated with primary angioplasty than in those treated with thrombolysis[2,3,6-8,17]. The current published guidelines recommends a door-to-needle time < 30 minutes for thrombolytic therapy and door-to-balloon time < 90 minutes for primary angioplasty[18]. Thus, these findings provide an important opportunity for improving outcome by establishing a critical pathway in our health care system to minimize time-to-treatment in patients with STEMI.

Limitations

This is an analysis of an observational database from a single institute, not a randomized controlled trial. Differences or similarities in outcomes may be related to differences in patient selection and baseline characteristics rather than treatment effects.

The limited number of patients in the present study results in insufficient power to detect a small difference in in-hospital mortality. Reinfarction and intracranial hemorrhage were not captured as in-hospital outcomes. Both of which have been consistently shown to be the advantage of primary PCI over thrombolytic therapy[5].

Conclusion

In the present study of STEMI patients treated with primary angioplasty or thrombolytic therapy at the institute over a 2-year period, there was no difference in short-term mortality. There was a trend towards lower morbidity in those treated with primary angioplasty. These results suggest that PCI and thrombolytic therapy are alternatives means of reperfusion in terms of in-hospital mortality. In certain subgroups that are at increased risk of bleeding or stroke, primary PCI may be the preferred treatment strategy.

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การรักษาภาวะกล้ามเนื้อหัวใจตายเฉียบพลันด้วยการทำบอลลูนขยายหลอดเลือดเปรียบเทียบกับการให้ยาละลายลิ่มเลือด

วิวรรณ ทังสุบุตร, ดำรัส ตรีสุโกศล, รุ่งโรจน์ กฤตยพงษ์, ประดิษฐ์ ปัญจวีณิน, เรวัตร พันธุ์กิ่งทองคำ, ชุณหเกษม โชตินัยวัตรกุล

ภูมิหลัง: *การรักษาภาวะกล้ามเนื้อหัวใจตายเฉียบพลันด้วยการเปิดหลอดเลือด สามารถทำได้ด้วยการทำบอลลูนขยายหลอดเลือด หรือ ด้วยการใช้ยาละลายลิ่มเลือด*

วัตถุประสงค์: *เพื่อเปรียบเทียบข้อมูลการรักษาทั้งสองวิธี*

วัสดุและวิธีการ: *เป็นการเก็บรวบรวมทะเบียนผู้ป่วยแบบไปข้างหน้าของผู้ป่วยกล้ามเนื้อหัวใจตายเฉียบพลันชนิด ST segment ยกในโรงพยาบาลศิริราช ตั้งแต่เดือน สิงหาคม พ.ศ. 2545 ถึง มิถุนายน พ.ศ. 2547 เพื่อเปรียบเทียบผลของการรักษาขณะผู้ป่วยอยู่ในโรงพยาบาล*

ผลการศึกษา: *ในผู้ป่วยจำนวน 234 รายที่เป็นกล้ามเนื้อหัวใจตายเฉียบพลันชนิด ST segment ยกนั้น มี 146 รายที่ได้รับการรักษาด้วยการเปิดหลอดเลือด 91 รายได้รับการทำบอลลูนขยายหลอดเลือด ส่วนอีก 55 ราย ได้รับยาละลายลิ่มเลือด ในผู้ป่วยกลุ่มที่ได้รับยาละลายลิ่มเลือด 93% ได้รับยา streptokinase และ 21.6% ได้รับการทำบอลลูนขยายแบบ rescue angioplasty ผู้ป่วยทั้งสองวิธีการรักษามีลักษณะทางคลินิกคล้าย ๆ กัน ทั้งสองกลุ่มเป็นเบาหวานบ่อย (บอลลูน 44.2% เทียบกับยาละลาย 39.6%, p = 0.6) ภาวะช็อกจากหัวใจไม่แตกต่างกันในทั้งสองกลุ่ม อัตราการเสียชีวิตในทั้งสองวิธีการรักษาไม่แตกต่างกัน (บอลลูน 14.3% เทียบกับยาละลาย 10.9%, p = 0.56) ในกลุ่มผู้ป่วยที่ได้ยาละลายลิ่มเลือดพบแนวโน้มการเกิดผลแทรกซ้อนมากกว่า ได้แก่ ภาวะเลือดออกที่อันตราย (บอลลูน 6.6% เทียบกับยาละลาย 16.4%, p = 0.06) และโรคหลอดเลือดสมอง (บอลลูน 2.2% เทียบกับ ยาละลาย 7.3%, p = 0.13)*

สรุป: *การรักษาภาวะกล้ามเนื้อหัวใจตายเฉียบพลันสามารถทำได้ด้วยการทำบอลลูนขยายหลอดเลือด หรือด้วยยาละลายลิ่มเลือดโดยอัตราการเสียชีวิตในโรงพยาบาลไม่แตกต่างกัน อย่างไรก็ตามการรักษาด้วยการทำบอลลูนอาจปลอดภัยกว่าในผู้ป่วยที่มีความเสี่ยงต่อการเกิดเลือดออก หรือเกิดโรคหลอดเลือดสมอง*