Utilizing a Registry for ST Segment Elevation Myocardial Infarction from a Tertiary Care Hospital in Thailand: Opportunities to Improve the Quality of Care

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Background: *Treatment of acute coronary syndrome requires a reliable measurement of quality for ensuring evidence-based care. Clinical registries have been used to support quality improvement activities in some countries, but there are few data concerning their implementation in developing countries. In 2008, a multidisciplinary Siriraj ST segment elevation myocardial infarction (STEMI) registry team was formed with the intention to improve the process of care. This report summarizes observational data collected within the first year to characterize the clinical profile, management and in-hospital outcomes of STEMI patients at the author's institute.*
Material and Method: *The present study is a prospective, observational study. From June 2008 through June 2009, data from all consecutive patients presenting within 24 hours of STEMI at Siriraj Hospital were collected. The patient's data on demographics, procedures, medications and in-hospital outcomes were collected.*
Results: *During the 1-year period, 112 patients with STEMI were enrolled. The mean age was 59.3 years old and 81.3% were males. There was a high prevalence of diabetes, hypertension, dyslipidemia and current smoking. Median time from symptom onset to presentation was 120 minutes. 98 patients (84.8% of the patients) received reperfusion therapy in the form of thrombolytic therapy (21.4%) or primary percutaneous coronary intervention (PCI, 63.4%). For thrombolytic therapy, the median door to needle time was 68 minutes. Rescue PCI was performed in 20.8% of the thrombolytic treated patients. For primary PCI, the median door to balloon time was 118 minutes. In-hospital coronary artery bypass graft surgery was performed in 6% of the patients. In-hospital mortality rate was 9.8%. Re-infarction and stroke were rare events.*
Conclusion: *Despite a high utilization rate of reperfusion therapy the time to reperfusion therapy exceeds the length of time recommended by current guidelines. The authors' findings provide important data for future benchmarking and represent a significant opportunity for quality improvement in STEMI-related care and outcomes.*

Keywords: *Acute coronary syndrome, ST-segment elevation myocardial infarction, Thrombolytic therapy, Primary percutaneous coronary intervention, Quality of care*

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Disruption of a vulnerable plaque is the pathophysiological substrate of acute coronary syndrome (ACS). Plaque disruption leads to platelet activation, adhesion and aggregation, thrombin generation and ultimately thrombus formation[1,2]. The clinical spectrum of ACS includes ST segment elevation myocardial infarction (STEMI), non ST segment elevation myocardial infarction and unstable angina. Patients with STEMI have a high likelihood of a thrombus occluding the infarct related artery. Thus, STEMI patients are candidates for emergent reperfusion therapy (either by thrombolytic therapy or percutaneous coronary intervention, PCI) to restore

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flow in the occluded infarct related artery. The literature provides very strong evidence that prompt reperfusion therapy is associated with improved survival[3-7]. Current guidelines recommend a door-to-needle time within 30 minutes for thrombolytic therapy and a door-to-balloon time of 90 minutes or less for primary PCI[1,2]. Both time intervals are standard international quality measures of hospital performance. However, accomplishing this level of performance is an organizational challenge.

STEMI is a significant public health problem in industrialized countries and is becoming an increasingly significant problem in developing countries[8]. It is currently estimated that there are 500,000 STEMI events per year in the US[1]. Impressively, in the US, there has been a decline in the mortality rate from STEMI over the last several decades. In the authors' country, there are limited data on outcomes in STEMI patients. Srimhachota et al has reported data from the Thai ACS registry that 40% of ACS patients presented as STEMI[9]. Of these, only 52% received reperfusion therapy. The in-hospital mortality for Thai STEMI patients was alarmingly high at 17%. Data from randomized, controlled trials[10-12] and meta-analysis of the randomized studies[13] comparing primary angioplasty with thrombolytic therapy in STEMI have shown short-term mortality of 7% for primary angioplasty vs. 9% for thrombolysis ($p = 0.0002$). When compared to other reported national and international registries, in-hospital mortality for patients with STEMI who underwent primary PCI ranged from 5.5-7%[14-17].

The present study is a prospective, observational study to characterize the clinical profile, management and in-hospital outcomes of STEMI patients at our institute. In 2008, a multidisciplinary STEMI registry team was formed with the intention to improve the process of care. The present report summarizes data collected within the first year to lay the foundation for future quality improvement in the care of STEMI patients.

Material and Method

From June 2008 through June 2009, data from all patients presenting within 24 hours of acute STEMI at our 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.

The decision regarding the administration of reperfusion therapy and modality was at the attending cardiologist's discretion.

Data collection

Patient's data on clinical, demographic, treatment and in-hospital outcome were collected by cardiac nurses and/or cardiologists. Data were transcribed onto standard data forms and subsequently a web-based database. 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 either with 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 $\leq$ 50% of lung fields or presence of an S3 gallop whereas Killip class III was defined as bibasilar rales in > 50% of lung fields. Cardiogenic shock (Killip class IV) was defined as symptomatic hypoperfusion with systolic blood pressure < 90 mmHg. 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. Discharge medical management included the use of aspirin, thienopyridine, angiotensin-converting enzyme inhibitor, beta-blockers, angiotensin receptor blocker, and statins.

This protocol was approved by the hospital ethics committee and is in accordance with the Declaration of Helsinki. Informed 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 maximal) as appropriate. Differences between the two treatment groups for frequencies of categorical variables were tested by Chi-square analysis. Differences among continuous variables were tested by the t test for mean values. Multiple variable analysis was used by forward stepwise logistic regression to evaluate independent predictors of in-hospital death and expressed as odds ratio with 95% confidence intervals. 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 17.

Results

During the 1-year period, 112 patients with STEMI were enrolled. 18% of the patients were referred to the author's institute.

The baseline characteristics and risk factors are shown in Table 1. The mean age was 59.3 years old and 81.3 % were males. There was a high prevalence of diabetes, hypertension, dyslipidemia and current smoking, Median time from symptom onset to presentation was 120 minutes. Presence of high-risk features on presentation are shown in Table 2. Heart failure was frequently present on admission in one-third of the patients. Mean left-ventricular ejection fraction was 52.1 $\pm$ 13.7%. By electrocardiography, 56.3% were anterior infarcts and 44.6% were inferior infarcts. The majority of our patients received civil servant reimbursement (44%) or were under the 30-baht universal health care program (45%) (Fig. 1).

Table 3 characterizes the in-hospital management. 95 patients (84.8% of the patients) received reperfusion therapy in the form of thrombolytic therapy (21.4%) or primary PCI (63.4%) whereas 15.2% received no reperfusion therapy.

For thrombolytic therapy, streptokinase and tissue plasminogen activator were administered in 46% and 50% of the patients, respectively. The median door to needle time was 68 minutes. Rescue PCI was performed 20.8% of the thrombolytic treated patients. For primary PCI, the median door to balloon time was 118 minutes.

Among the 17 patients (15.2%) that did not receive reperfusion therapy, 5 patients had an indication for such therapy. 2 patients subsequently underwent in-hospital coronary artery bypass graft surgery (CABG, 1 emergent, another urgent), 1 patient declined, 1 patient was found to have no significant coronary stenosis and another patient had poor neurological status.

Intra-aortic balloon counterpulsation was used in 17.8% of the patients. The overall rate of in-hospital coronary angiography was 83% and 6.3% of the patients underwent elective PCI. In-hospital CABG was performed infrequently in 7 patients (6%). Three patients had emergent CABG (2 of these due to unsuccessful primary PCI), 1 urgent within 24 hours and the remaining 3 were elective cases.

Table 1. Baseline characteristics (n = 112)

Age (years), mean $\pm$ SD	59.3 $\pm$ 14
Male, n (%)	91 (81.3)
Referred, n (%)	20 (18)
Diabetes, n (%)	36 (32.1)
Hypertension, n (%)	66 (58.9)
Current smoker, n (%)	50 (44.6)
Dyslipidemia, n (%)	72 (64.3)
Previous myocardial infarction, n (%)	11 (9.8)
Previous percutaneous coronary intervention, n (%)	8 (7)
Previous coronary artery bypass surgery, n (%)	2 (1.8)
Infarct location, n (%)	
Anterior	63 (56.3)
Inferior	50 (44.6)
Right ventricular	5 (4.5)
Onset to emergency room, median (minutes, IQR)	120 (63, 235)
Left ventricular ejection fraction, mean $\pm$ SD (%)	52.1 $\pm$ 13.7

Table 2. Presenting complication (n = 112)

Heart failure, n (%)	36 (32.1)
Cardiogenic shock, n (%)	12 (10.7)
Ventricular tachycardia/ventricular fibrillation, n (%)	10 (8.9)
Cardiac arrest, n (%)	10 (8.9)
Complete heart block, n (%)	7 (6.3)

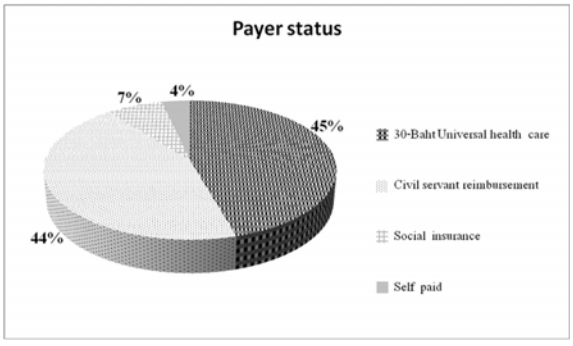

Fig. 1 Payer status (n = 112)

In-hospital outcomes are shown in Table 4. The in-hospital mortality rate was 9.8%. Re-infarction and stroke were rare events. Cardiogenic shock was a frequent in-hospital complication in 10.7% of the patients. Major bleeding occurred in 8% and was predominantly due to gastrointestinal bleeding.

Table 5 reveals crude odds ratio of predictors of in-hospital death. Multivariate logistic regression analysis, adjusted for age, to evaluate independent predictors of in-hospital mortality revealed cardiac arrest on arrival as the only significant predictor OR 155 (95% CI 18-1308, $p < 0.001$).

Discharge medications are depicted in Table 6. Secondary preventive medications were prescribed frequently, notably all patients received aspirin. Clopidogrel and statins were used in 93.1% and 97% of the patients, respectively. Beta-blockers and angiotensin converting enzyme inhibitor were prescribed less frequently. The mean length of stay was 5.7 ± 6.7 days.

Table 3. Treatment

Thrombolytic therapy, n (%)	24 (21.4)
Streptokinase	11 (46)
Tissue plasminogen activator	12 (50)
Tenecteplase	1 (4)
Onset to emergency room time in thrombolytic patients (minutes), median (P25-P75)	100 (60,180)
Door to needle time (minutes), median (P25-P75)	68 (50,93)
Rescue percutaneous coronary intervention, n (%)	5 (20.8)
Primary PCI, n (%)	71 (63.4)
Onset to emergency room time in primary PCI patients (minutes), median (P25-P75)	140 (60, 280)
Door to balloon time (minutes), median (P25-P75)	118 (92, 192)
Coronary angiography, n (%)	93 (83)
Elective PCI, n (%)	7 (6.3)
In-hospital CABG, n (%)	7 (6.3)
Use of IABP, n (%)	20 (17.8)

PCI: percutaneous coronary intervention, IABP: intra-aortic balloon pump, CABG: coronary artery bypass graft surgery

Table 4. In-hospital outcomes

Length of stay	
Median (days, P25-P75)	3.0 (3,5)
Mean (days $\pm$ SD)	5.7 ± 6.7
Cardiogenic shock, n (%)	12 (10.7)
Heart failure, n (%)	3 (2.6)
Cardiac arrest, n (%)	3 (2.6)
Sustained ventricular tachycardia, n (%)	2 (1.8)
High-grade atrioventricular block, n (%)	4 (3.6)
Stroke, n (%)	1 (0.9)
Entry site major vascular complication, n (%)	1 (0.9)
Major bleeding, n (%)	9 (8)
Re-infarction, n (%)	1 (0.9)
Unplanned PCI, n (%)	2 (1.8)
Death, n (%)	11 (9.8)
Cardiogenic death, n (%)	6 (54.5)
Non-cardiogenic death, n (%)	5 (45.5)

PCI: percutaneous coronary intervention

Discussion

In the present study, the authors used observational data on patients admitted with STEMI to report the baseline characteristics, management and in-hospital outcomes in real-world clinical practice at the author's institute. Treatment of acute coronary syndrome requires a reliable measurement of quality for ensuring evidence-based care. Clinical registries have been used to support quality improvement activities in some countries, but there are few data of their implementation in developing countries.

The presence of diabetes, hypertension and dyslipidemia was high. Importantly, almost half of the

Table 5. Crude odds ratio of predictors of in-hospital death

	Crude Odds Ratio (95% CI)	p
Cardiac arrest	132 (19 to 908)	< 0.001
VT/VF	16 (3 to 71)	< 0.001
Heart Failure	12 (3 to 61)	< 0.001
Cardiogenic shock	34 (7 to 154)	< 0.001
Reperfusion therapy not indicated	4.5 (1.1 to 20)	0.035

VT/VF: Ventricular tachycardia/fibrillation

Table 6. Discharge medications (n = 101)

Medication	n (%)
Aspirin	101 (100)
Clopidogrel	94 (93.1)
Beta-blocker	77 (76.2)
Angiotensive converting enzyme inhibitor	69 (68.3)
Angiotensive receptor blocker	4 (3.9)
Statin	98 (97)

patients were current smokers and 32% were diabetic. These findings have substantial national health implications for future preventive measures.

The median time from onset to presentation was higher in the PCI group than the thrombolytic patients. This likely represents physician bias in selecting primary PCI for patients with delayed presentation. In the present study, 84.8% of the patients received reperfusion therapy. This percentage is higher than the 62% rate of reperfusion therapy utilized in the Global Registry of Acute Coronary Events (GRACE)[17,18]. In addition, primary PCI was performed more frequently than thrombolysis. This may seem reassuring given randomized trials have documented superiority of primary PCI over thrombolysis regarding hospital mortality[13]. However, patients that underwent primary PCI had substantial time delay from admission to PCI (door to balloon time), 118 minutes. Likewise, the median delay time to initiation of thrombolytics (door to needle time) was 68 minutes. The current published guidelines recommends a door-to-needle time $\leq$ 30 minutes for thrombolytic therapy and door-to-balloon time $\leq$ 90 minutes for primary angioplasty[1,2]. Thus, the authors' time to treatment is far exceeding the length of time recommended.

In the US, substantial efforts have been made to improve door-to-balloon time[19]. In 2006, the American College of Cardiology launched the D2B Alliance[20]. The D2B Alliance sought to achieve D2B times of < 90 minutes for at least 75% of nontransfer patients nationwide. Strategies recommended by D2B Alliance include 1) activation of the catheterization laboratory by emergency physicians 2) single-call activation of the catheterization team 3) catheterization team is available within 30 minutes of being paged 4) use of data monitoring with prompt feedback to emergency department and catheterization lab staff 5) senior management commitment and 6) team-based approach.

In Singapore[21], Lee et al reported their single-center experience to shorten door-to-balloon time by 1) having the emergency services physician activate the cardiac catheterization team 2) having all team members converted from using pagers to cell phones and 3) transferring patients immediately from the emergency department to the cardiac catheterization laboratory.

Nevertheless, in real-life practice these may not be easy to implement. First, data from GRACE over a 7-year period (1999-2006) have demonstrated a relatively constant median time to primary PCI between 75 to 84 minutes[22]. This is despite a decline in median door-to-needle time from 40 minutes in 1999 to 34 minutes in 2006, Secondly, several of these tools are not applicable to all hospitals and adaptation to an individual hospital's work flow is essential.

At the author's institute, a multidisciplinary STEMI registry team was formed in 2008. The intention is to improve the process of care of STEMI patients. Team members comprise of personnel from the emergency room, cardiac catheterization laboratory, CCU, step-down unit, general medicine service including nurses, physicians and ancillary staff. Quarterly meetings are conducted to review, that is to 'audit', the process of cares, discuss obstacles and make changes in routine workflow. This approach is in line with the D2B Alliance utilizing a team-based approach with data monitoring and feedback.

In the present study, barriers to quality of care, specifically, delayed time to treatment were observed. Encountered constraints that may be unique in developing countries include lack of patient knowledge of the emergent nature of myocardial infarction. Additionally, obtaining consent for reperfusion therapy from patients and their family can be a time consuming process. In the author's society, patients generally prefer to wait for a dominant family member to consent. Thus, a simplified consenting process utilizing visual aids may assist medical professionals in the prompt delivery of care. Human resource is another major constraint in developing countries. The authors lack a case manager and quality improvement representative. Thus all data were collected by a dedicated interventional cardiologist and coronary care unit nurse. This task can be extremely tedious due to the need for time documentation in each step of the process prior to reperfusion therapy *e.g.*, ER arrival time to EKG completed; time catheterization lab was activated etc. Practical methods to improve accurate and complete data collection are imperative. Potential solutions include the implementation of radiofrequency identifications (RFID) to accurately tract patients in real-time at each time frame and location.

The in-hospital mortality rate for the patients in the present study was considerably high (9.8%) compared to GRACE (1999-2006, STEMI mortality 7%)[17] and the expanded GRACE registry (2001-2007, STEMI mortality 6.2%)[23]. This is despite an overall high utilization of invasive procedures such as coronary angiography and PCI. Compared with GRACE, the patients in the present study had a higher percentage of diabetics, higher percentage of patients who

presented with cardiogenic shock, cardiac arrest and delayed time to treatment. These have been consistently associated with poorer clinical outcomes[11,13,14,17,24-28]. As mentioned previously, prompt provision of reperfusion therapy is a crucial factor that significantly improves survival[3-7]. Patients who presented with cardiac arrest were at extremely high risk. In the multivariable model, cardiac arrest was the most powerful predictor of death, with a 155-fold increased risk for death. These findings are concordant with those from GRACE[28]. Overall, the potential remains for improved clinical outcomes with timely reperfusion and greater utilization of guideline recommended therapies. Noteworthy is the plausibility that as our hospital is a tertiary care referral center and 18% of the patients were referrals, there may have been a selection bias of transferring sicker patients to our hospital.

Limitations

This is an analysis of an observational database from a single tertiary care institute, not a population-based epidemiological study. Thus, the present findings may not be representative of all ACS patients in Thailand. Very ill patients who died during the first 24 hours after admission may have been excluded.

Conclusion

The authors' findings provide important data for future benchmarking and represent a significant opportunity for quality improvement in STEMI-related care and outcomes. The present study supports the use of a clinical registry to improve quality of care in a large tertiary care center in a developing country. Efforts to improve patient awareness and encourage early presentation are urgently needed.

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Potential conflicts of interest

None.

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การใช้ทะเบียนผู้ป่วยเพื่อพัฒนากระบวนการดูแลผู้ป่วยกล้ามเนื้อหัวใจขาดเลือดเฉียบพลันชนิด ST-segment ยก ในโรงพยาบาลระดับตติยภูมิในประเทศไทย

วิวรรณ ทังสุบุตร, ชุณหเกษม โชตินัยวัตรกุล, อดิศักดิ์ มณีไสย, เสาวนีย์ เนาวพานิช, ประดิษฐ์ ปัญจวีณิน, ดำรัส ตรีสุโกศล, เรวัตร พันธุ์กิ่งทองคำ, ณัฐวุฒิ วงษ์ประภารัตน์

ภูมิหลัง: *การรักษาผู้ป่วยกล้ามเนื้อหัวใจขาดเลือดเฉียบพลันควรมีการประเมินกระบวนการดูแลเพื่อพัฒนาคุณภาพ ในต่างประเทศมีการใช้ทะเบียนผู้ป่วยเพื่อพัฒนาคุณภาพ ข้อมูลเหล่านี้มีจำกัดในประเทศที่กำลังพัฒนา ในปี พ.ศ. 2551 โรงพยาบาลศิริราชได้จัดตั้งทีมโครงการทะเบียนผู้ป่วยกล้ามเนื้อหัวใจขาดเลือดเฉียบพลันชนิด ST-segment ยก (ST segment elevation myocardial infarction, STEMI) ขึ้นเพื่อช่วยพัฒนากระบวนการดูแลผู้ป่วย รายงานนี้สรุปข้อมูลผู้ป่วย STEMI ที่รับไว้ในโรงพยาบาลศิริราชในปีแรกของโครงการ ทั้งข้อมูลทางคลินิก การรักษา และผลการรักษาที่เกิดขึ้นในโรงพยาบาล*

วัสดุและวิธีการ: *การศึกษานี้เป็นโครงการศึกษาไปข้างหน้า โดยเก็บข้อมูลของผู้ป่วยทุกรายที่มีอาการมาภายใน 24 ชั่วโมงแรกของภาวะกล้ามเนื้อหัวใจขาดเลือดเฉียบพลันชนิด ST-segment ยก ตั้งแต่เดือนมิถุนายน พ.ศ. 2551 ถึงเดือนมิถุนายน พ.ศ. 2552 ข้อมูลที่เก็บได้แก่ ข้อมูลพื้นฐาน หัตถการ ยา และผลการรักษาที่เกิดขึ้นในโรงพยาบาล*

ผลการศึกษา: *ใน 1 ปี มีจำนวนผู้ป่วย STEMI 112 ราย ร้อยละ 18 เป็นผู้ป่วยที่รับย้ายจากโรงพยาบาลอื่น ผู้ป่วยอายุเฉลี่ย 59.3 ปี และเป็นเพศชายร้อยละ 81.3 มีผู้ป่วยที่เป็นโรคเบาหวาน ความดันโลหิตสูง ไขมันในเลือดสูง และสูบบุหรี่ เป็นจำนวนมาก ค่ามัธยฐานเวลาตั้งแต่เริ่มมีอาการจนกระทั่งผู้ป่วยมาถึงโรงพยาบาลเท่ากับ 120 นาที ผู้ป่วยจำนวน 98 ราย (ร้อยละ 84.8) ได้รับการรักษาเพื่อเปิดหลอดเลือด (reperfusion) โดยร้อยละ 21.4 ได้รับยาละลายลิ่มเลือด และร้อยละ 63.4 ได้รับการทำบอลลูนขยายหลอดเลือด (percutaneous coronary intervention, PCI) ค่ามัธยฐานเวลา door-to-needle เท่ากับ 68 นาที ร้อยละ 20.8 ของผู้ป่วยที่ได้รับยาละลายลิ่มเลือดได้รับการทำ rescue PCI ค่ามัธยฐานเวลา door-to-balloon เท่ากับ 118 นาที ขณะที่อยู่โรงพยาบาลมีผู้ป่วยได้รับการผ่าตัดบ่ายเบี่ยงหลอดเลือดหัวใจร้อยละ 6 อัตราการตายของผู้ป่วยร้อยละ 9.8 มีผู้ป่วยจำนวนน้อยที่เกิดอัมพาตหรือ reinfarction*

สรุป: *แม้ว่ามีการให้การรักษาเพื่อเปิดหลอดเลือดในเกณฑ์ที่สูง แต่ผู้ป่วยก็ยังได้รับการรักษาดังกล่าวล่าช้าเกินกว่าเกณฑ์ การศึกษานี้ให้ข้อมูลพื้นฐานที่สำคัญ เพื่อจะพัฒนากระบวนการดูแลผู้ป่วย STEMI ต่อไป*