First Medical Contact to Device Time in the Thailand Percutaneous Coronary Intervention (PCI) Registry

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Objective: *The aim of this study is to evaluate the first medical contact (FMC) to device time in the Thai national PCI registry 2006, and its effect on the clinical outcome.*
Material and Method: *Thailand national PCI registry enrolled 4,156 patients who underwent PCI from the all catheterization laboratories in Thailand between May 1st and October 31st, 2006.*
Results: *581 patients with acute myocardial infarction (AMI), 352 patients underwent primary angioplasty, 229 patients underwent rescue angioplasty/facilitated PCI or after successful thrombolytic. Median FMC to device time in primary angioplasty group was 115 minutes (range 24-1335 minutes); only 29.8% of patients who able to achieve FMC to device time ≤90 minutes. Cardiogenic shock was significant lower if FMC to device time ≤90 minutes (2.1% (1/48) versus 12.4% (14/113) if FMC to device time >90, p = 0.040). In-hospital mortality occurred for 4.8% (2/48) if FMC to device time ≤90 minutes and was 8.8% (10/113) if FMC to device time >90 minutes, p = 0.510). Death occurred in 4.2% (2/48) if FMC to device time ≤90 minutes, 6.3% (5/79) if FMC to device time between 91-180 minutes, 6.7% (1/15) if FMC to device time between 181-270 minutes, 42.9% (3/7) if FMC to device time between 271-360 minutes and 8.3% (1/12) if FMC to device time >360 minutes, (p = 0.040).*
Conclusion: *FMC to device time is strongly associated with the risk of cardiogenic shock and mortality. In Thailand national PCI registry in 2006, the majority of the patients did not receive primary PCI in timely fashion.*

Keywords: *First medical contact to device time, Door to balloon time, ST elevation myocardial infarction (STEMI), Mortality*

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Coronary artery disease (CAD) is the leading cause of death in Thai patients[1]. Treatment of CAD has been rapidly evolving. Percutaneous coronary intervention (PCI) is a main therapy in both acute and chronic CAD. In STEMI, primary PCI has been shown to provide superior outcome compared with thrombolytic therapy[2-4]. Rapid reperfusion by primary PCI measured by FMC to device time is a key concept for myocardial salvage and mortality reduction[5-9]. FMC to device time should be less than 90 minutes according to the guideline[10,11]. PCI has been performed in Thailand over last 10 years. The Heart Association of Thailand under Royal Patronage started the National PCI registry in 2006 with collaboration from the all catheterization laboratories in the country. The aim of this study was to evaluate the FMC to device time in Thai PCI registry and see its impact on outcomes.

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Material and Method

National PCI registry protocol: The protocol enrolled patients who underwent PCI in 29 participating institutions. Patient invited to participate the registry from principal investigators, nurse coordinator at each institution. The first participating patient of May 2006 count as the first patient and then consecutive enrollment of participating patients until the last case at October 31st 2006. Patient were excluded if underwent diagnostic procedure or patients refused to participated the registry. Demographic data and 6 month follow-up were collected by investigators or nurse coordinators of each institution. Then all data were keyed into online web based at each site. Case record form (CRF) was mailed to the central registry

at date 15th and 30th of each month. Coordinator at the central registry then examined the accuracy of the data comparing data from the web based and data from CRF of each site. The CRF has defined the definition of each parameter. For definition of myocardial infarction/myocardial necrosis defined as clinical symptoms with either 1) Troponin T or I within 24 hours of symptoms above upper limit normal, 2) CK-MB >2 times upper limit normal when serial >2 times, or 3) Total CPK >2 times upper limit normal. For the definition of STEMI, defined as the definition of myocardial necrosis plus EKG changes as the followings 1) ST segment elevation >2 mm in two consecutive leads, 2) New left bundle branch block, or 3) New Q wave formation in two consecutive leads that depth >1 mm. For the definition of in-hospital adverse events as followings: 1) Cardiovascular death is death from arrhythmia, LV dysfunction or cardiac arrest. 2) Non cardiac death is death from other cause such as infection, neurologic or pulmonary. 3) Cardiogenic shock is new clinical state of hypoperfusion during or after percutaneous coronary intervention (PCI) as index by systolic blood pressure <80 mmHg or cardiac index <1.8 liter/min and/or required IV inotropes or intraaortic balloon pump. 4) Stroke is clinical syndrome of new neurologic deficit during or after PCI, which persisted more than 72 hours after onset. 5) Ventricular tachycardia/ventricular fibrillation is an persistent of arrhythmia that required treatment of antiarrhythmic drug or DC shock. For the short run ventricular tachycardia or accelerated idioventricular rhythm that not required treatment or spontaneous resolved is not counting as events.

Baseline demographic, inclusive of reimbursement status and angiographic characteristics were recorded. FMC to device time was the time from arrival to ER to the initiation of first coronary balloon dilatation. In-hospital adverse events defined as death, cardiovascular death (CV death), myocardial infarction (MI), stroke, cardiogenic shock, ventricular tachycardia (VT)/ventricular fibrillation (VF) required treatment, congestive heart failure (CHF) were searched and recorded. MACE included CV death, MI and stroke. Six and 12 months data were also followed and recorded. The institutional review board approved the study, Protocol number is 009/2006.

Statistical analysis

Continuous variables were expressed as median with interquartile range or mean ± SD, and compared between groups using 2-sample t-tests. Categorical variables were express as frequency (percentage) and compared using Chi-square test. A 2-sided value of $p<0.05$ was considered significant. All statistics were performed with SPSS version 19.0.

Results

Patients demographic

The mean age ± SD of subjects was 61±13 years, majority of them were male (75%). There was history of prior myocardial infarction in 28 of 352 (8%), hypertension in 179 of 352 (51%), dyslipidemia in 174 of 352 (49%), and diabetes mellitus in 109 of 352 (31%). There are 6 types of reimbursement status, including universal national health care plan, government civil servant, social security health plan, private third party insurance, company paid and self-paid. Baseline clinical characteristics are summarized in Table 1.

From 352 patients who underwent primary PCI, patients with complete data to calculate FMC to

Table 1. Baseline characteristics of ST-T MI undergoing primary PCI (n = 352)

	Number (%)
Age (years), mean ± SD	61±13
Male	266 (75.6)
Previous myocardial infarction	28 (8.0)
Previous PCI	30 (8.5)
Previous CABG	2 (0.6)
Previous CVA/TIA	20 (5.7)
Chronic renal failure	24 (6.8)
Peripheral arterial disease	4 (1.1)
Family history of CAD	35 (10.0)
Hypertension	179 (51.0)
Dyslipidemia	174 (50.0)
Smoking	187 (53.1)
Diabetes	109 (31.0)
Reimbursement status	
Government civil servant	125 (35.5)
Self paid	98 (27.8)
Universal national health care plan	92 (26.1)
Private third party insurance	17 (4.8)
Social security health plan	12 (3.4)
Company paid	8 (2.3)

MI = myocardial infarction; PCI = percutaneous coronary intervention; CABG = coronary artery bypass graft; CVA = cerebrovascular accident; TIA = transient ischemic attack; CAD = coronary artery disease

device time were available for only 161 patients (46%) (Fig. 1). The details of FMC to device time and time of symptoms onset showed in Table 2.

FMC to device time and type of intervention

Median FMC to device time were 115 minutes in primary PCI (range 24-1,335 minutes), 446 minutes in rescue angioplasty (range 117-1,431) and 2,721 minutes in late/delayed presentation (range 55-33,214 minutes). Impact of reimbursement status on FMC to device time and mortality demonstrated in Table 2.

Achievement of door to balloon ≤90 minutes in real life practice

Only 29.8% of patients able to achieve FMC to device time ≤90 minutes but for the 70.2% in which primary PCI was intended, it was not done in a timely fashion according to guidelines, with FMC to device time ≤90 minutes.

There was a lower number of patients with cardiogenic shock (2.1% vs. 12.4%) in the group whose FMC to device time was ≤90 minutes compared to those with time >90 minutes, $p = 0.040$). Mortality, however, was not significant lower in the ≤90 minute group (4.2% (2/48) versus 8.8% (10/113), $p = 0.510$). Indeed, there was a trend toward more death in FMC to device time >90 minutes group. Major adverse events (MACE) was slightly lower if FMC to device time ≤90 (10.4% (5/48) versus 15.9% (18/113) in FMC to device time >90, $p = 0.360$) (Fig. 2).

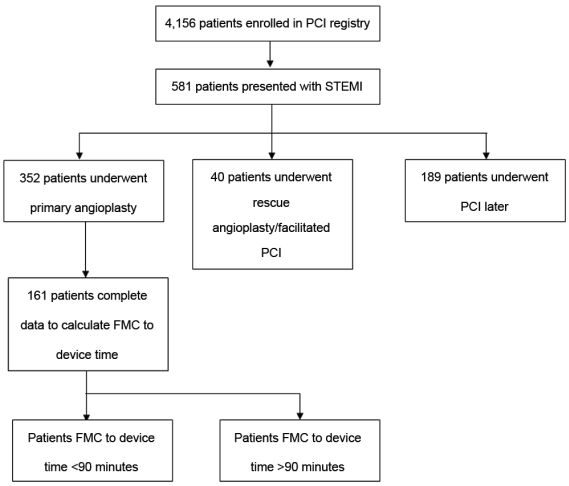

Fig. 1 Figure demonstrated patient population enrolled in the study.

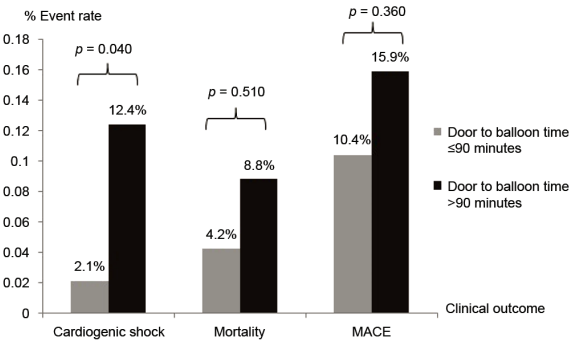

Fig. 2 FMC to device time and clinical outcome.

Table 2. Impact of reimbursement status on FMC to device time and mortality

	Number (%)						
	Civil service	Self paid	National health	Private insurance	Social security	Company paid	*p*-value
No. with PCI	125	98	92	17	12	8	
No. with complete data	63 (50.4)	50 (51.0)	27 (29.0)	8 (47.0)	5 (41.6)	8 (100)	
FMC to device time (minute)							
Median	122	115	85	226	107	116	0.060
Min, max	30, 677	27, 803	24, 1,150	93, 1,335	86, 151	44, 305	
≤90	15 (23.8)	12 (24.0)	16 (59.3)	0 (0.0)	1 (20.0)	4 (50.0)	0.003
>90	48 (76.2)	38 (76.0)	11 (40.7)	8 (100)	4 (80.0)	4 (50.0)	
Time of symptoms (minute)							
Median	120	102	225	83	95	75	0.040
Min, max	10, 870	15, 942	55, 1,159	60, 570	20, 569	36, 293	
Mortality outcome, n (%)							
Total death	11 (8.8)	14 (14.3)	22 (23.9)	0 (0.0)	3 (25.0)	1 (12.5)	0.017
CV death	8 (6.4)	11 (11.2)	20 (21.7)	0 (0.0)	3 (25.0)	1 (12.5)	0.070

FMC = first medical contact; CV = cardiovascular

In-hospital mortality was significant higher in the patients whom FMC to device time was delayed. Death occurred in 4.2% (2/48) if FMC to device time ≤90 minutes, 6.3% (5/79) if FMC to device time 91-180 minutes, 6.7% (1/15) if FMC to device time 181-270 minutes, 42.9% (3/7) if FMC to device time 271-360 minutes and 8.3% (1/12) if FMC to device time >360 minutes, (p = 0.040) (Table 3).

Cardiogenic shock was significantly higher in the patients whom FMC to device time was delayed. Two percent (1/48) of patients had cardiogenic shock if FMC to device time was ≤90 minutes, 13.9% (11/79) if FMC to device time was 91-180 minutes, 0% (0/15) if FMC to device time was 181-270 minutes, 28.6% (2/7) if FMC to device time was 271-360 minutes and 8.3% (1/12) if FMC to device time was >360 minutes, (p = 0.030) (Table 3).

MACE was significant higher in the patients whom FMC to device time was delayed. MACE occurred in 10.4% (5/48) if FMC to device time ≤90 minutes, in 13.9% (11/79) if FMC to device time 91-180 minutes, in 6.7% (1/15) if FMC to device time 181-270 minutes, in 57.1% (4/7) if FMC to device time 271-360 minutes and 16.7% (2/12) if FMC to device time >360 minutes, p = 0.040) (Table 3).

Discussion

Our findings are consistent with prior studies by others[5-9]. FMC to device time is a strong impact on the adverse outcome when performed the primary PCI[5-7]. Cardiogenic shock occurred in 2.1% if FMC to device time ≤90 minutes, but in 12.4% if FMC to device time >90 minutes. In-hospital mortality occurred at 4.8% if FMC to device time ≤90 minutes while it occurred at 8.8% if FMC to device time >90 minutes. STEMI patients who received primary PCI within 90 minutes of ER arrival would have more myocardium salvaged, which resulted in fewer incidences of cardiogenic shock and mortality.

However, in this registry of primary PCI in Thailand in 2006, only one-third of patients (29.8%) had achieved that goal. Primary PCI was not performed in timely fashion in the majority of patients.

After plaque rupture, platelets were activated leading to platelet aggregation and thrombus formation. Epicardial vessel then occluded causing myocardial infarction. When an epicardial vessel was completely occluded, it is critical to revascularize it in the timely fashion. The myocardial salvage slope significantly dropped during the first 3 hours after symptom onset[12]. The longer time before revascularization will result in less myocardial salvage and a larger myocardial infarct size. Miller et al, demonstrated the significant higher mortality if post infarction measure myocardial infarction size >12%[13]. De Luga et al, demonstrated the longer ischemic time and higher 1 year mortality[14]. From previous databases of thrombolysis, the benefit of thrombolytic treatment decreases rapidly as the time of clot formation increases, Boersman et al demonstrated 65 lives per 1,000 patients treated could be saved if thrombolysis were administered in the first hour. Thirty-seven lives are saved for every 1,000 patients in the 1-2 hour interval after symptom onset while 26 lives are saved for every 1,000 patients in the 2-3 hour interval after symptom[15]. From the primary PCI database, the benefits of primary PCI decrease rapidly as the time of clot formation increases. McNamara et al, showed a well correlation of higher mortality and longer FMC to device time. Mortality occurred in 3% if FMC to device time ≤90 minutes, in 4.2% if FMC to device time in the 90-120 minutes interval, in 5.7% if FMC to device time

Table 3. FMC to device time on Mortality cardiogenic shock and MACE

FMC to device time (minute)	n	Number (%)		
		Death	Cardiogenic shock	Major adverse events
≤90	48	2 (4.2)	1 (2.1)	5 (10.4)
>90	113	10 (8.8)	14 (12.4)	18 (15.9)
p-value		0.510	0.040	0.360
≤90	48 (29.8)	2 (4.2)	1 (2.1)	5 (10.4)
91-180	79 (49.1)	5 (6.3)	11 (13.9)	11 (13.9)
181-270	15 (9.3)	1 (6.7)	0 (0.0)	1 (6.7)
271-360	7 (4.3)	3 (42.9)	2 (28.6)	4 (57.1)
>360	12 (7.5)	1 (8.3)	1 (8.3)	2 (16.7)
p-value		0.040	0.030	0.040

MACE = major adverse cardiac events

in the 121-150 minutes interval and in 7.4% if the FMC to device time was more than 150 minutes[5].

The findings is similar to the present study. In the present study, mortality was significant rise when FMC to device time 271-360. This could be by chance since the number of patient that falls into this period is very small (7 patients). These findings affirmed the importance of time in revascularization the patients with STEMI.

Many obstacles may effect in the time delay in revascularization such as public education, ambulance network, fast track STEMI pathway development, 24-hour primary PCI on call service availability at a nearby hospital and the referral network. Public awareness in the presenting symptoms of STEMI will bring the patients in early after onset symptoms. A well-trained ambulance service network that can activate the STEMI pathway, will shorten the time for primary PCI team arriving the hospital. Hospitals should have a fast track pathway for STEMI to shorten the diagnosis and treatment time. In the hospital providing the primary PCI service, there should be a 24 hour on call team available. In hospitals that do not have primary PCI service, they should have a referral network to shorten the transfer time if there is a plan for primary PCI otherwise thrombolytic should be given if no contraindication.

The authors also found the reimbursement status also impact on the FMC to device time. However, due to incomplete data, data interpretation must be cautious. From 92 patients of total patients with national health care with AMI, only 27 patients (29%) had complete data which enabled calculation of FMC to device time. For the other 65 patients (71%), data to calculate FMC to device time is missing. From the available data that we had, universal national health care plan service had lowest median FMC to device time at 85 minutes, while private insurance had longest median FMC to device time at 226 minutes. Part of the procedural approval protocol, the referring hospital network, could play some role in these findings. In acute MI settings, decision making to go for primary PCI must be immediate. Any time delay in getting procedure approval will prolong the FMC to device time and increase in hospital mortality. The data is somewhat contradicts to the outcome. The authors expect the lowest mortality in the patients who had shortest FMC to device time. However, the mortality is lowest in private insurance group (0%) followed by civil service (8.8%). The highest mortality is in the Social security (25.0%) followed by national healthcare (23.9%). Correlation of FMC to device time and mortality that impact by reimbursement status must carefully interpreted. Minority of the patients in each reimbursement status had complete data to calculate FMC to device time. Incomplete data gathering may play role in the opposite direction of FMC to device time and mortality rate in each reimbursement status. Other confounding factor such as limitation of drug and device that can be used during treatment may also play some role.

Twenty-four percent of government civil service achieved FMC to device time ≤90 minutes. Some of these patients went to the hospital without a primary PCI facility, and were subsequently transferred to the hospital with PCI facility for primary PCI. Time for transfer could be responsible for treatment delayed. Pinto et al, reported that the mortality benefit of primary PCI over thrombolytic treatments declines if PCI related delay (FMC to device time minus door to needle) is over 114 minutes[11]. In high-risk patients with STEMI, for whom immediate transfer for primary PCI in timely fashion is not available, Thrombolysis should be given, then a transfer to the hospital with PCI facility for pharmaco-invasive strategy within 6-24 hours after thrombolysis may be recommended[16,17].

In summary, FMC to device time is strongly associated with the risk of cardiogenic shock and mortality. In Thailand national PCI registry, if median FMC to device time were 115 minutes (range 24-1,335 minutes), only 29.8% of patients would be able to achieve FMC to device time ≤90 minutes.

What is already known on this topic?

In the patients who presented with acute ST elevation myocardial infarction, rapid reperfusion is a key concept for myocardial salvage and mortality reduction. FMC to device time should be less than 90 minutes, if planned for primary PCI is based on the ACC/AHA guidelines.

What this study adds?

Based on data from National PCI registry enrolled patients in 2006, FMC to device time is a major dictation for clinical outcome. Patients were less likely to suffer from cardiogenic shock or death if Primary PCI performed within 90 minutes. However, majority of the patients with STEMI whom underwent primary PCI in 2006 had a FMC to device time of more than 90 minutes. It is crucial to shorten the FMC to device time to improve the patients' outcome.

Potential conflicts of interest

None.

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การศึกษาผลกระทบของระยะการทำ primary PCI (first medical contact to device time) ต่ออัตราการเสียชีวิตและภาวะแทรกซ้อนใน Thai National PCI registry

ณัฐวุฒิ วงษ์ประภารัตน์, ชุณหเกษม โชตินัยวัตรกุล, ประดิษฐ์ ปัญจวีณิน, ดำรัส ตรีสุโกศล, เรวัตร พันธุ์กิ่งทองคำ, วิวรรณ ทังสุบุตร, รุ่งทิวา พงษ์อัคคศิรา, เขมจิรา การเกตุกลาง

วัตถุประสงค์: เพื่อติดตามดูค่าเฉลี่ยของระยะเวลาในการทำ primary PCI (first medical contact to device time) ในชีวิตจริงของประชากรชาวไทยที่ทำการศึกษาใน พ.ศ. 2549

วัสดุและวิธีการ: การศึกษา Thailand National registry ได้ติดตามผู้ป่วยจำนวน 4,156 ราย ที่เข้ามาทำหัตถการฉีดสีและใส่สายสวน และทำ balloon ในสถาบัน 29 แห่ง ทั่วประเทศไทย ตั้งแต่วันที่ 1 พฤษภาคม ถึง 31 ตุลาคม พ.ศ. 2549

ผลการศึกษา: มีผู้ป่วย 581 ราย ได้รับการวินิจฉัยว่ามีภาวะหัวใจขาดเลือดเฉียบพลัน (acute myocardial infarction) จากผู้ป่วยจำนวนนี้มี 352 ราย ได้รับการทำหัตถการ primary PCI ภายใน 12 ชั่วโมง และอีก 229 ราย ได้รับการรักษาโดยการให้ thrombolytic ในเบื้องต้น และทำการฉีดสีในภายหลังทั้งฉีดสีแบบ rescue angioplasty/facilitated PCI และ successful thrombolytic เมื่อติดตามดูค่ากึ่งกลางเฉลี่ยของการทำ first medical contact to device time (FMC to device time) อยู่ที่ 115 นาที (24-1,335) มีผู้ป่วยเพียง 29.8% เท่านั้นที่ได้รับการทำ primary PCI ในระยะเวลาน้อยกว่า 90 นาที เมื่อเปรียบเทียบอัตราการเสียชีวิตและภาวะแทรกซ้อนในผู่ป่วยที่ได้รับการทำหัตถการทำ primary PCI ภายในระยะเวลา 90 นาที เทียบกับกลุ่มที่ทำในระยะเวลามากกว่า 90 นาที พบว่าอัตราการเกิดภาวะ cardiogenic shock ลดลงที่ 2.1% เทียบกับ 12.4%, p = 0.040 อัตราการเสียชีวิตลดลงที่ 4.8% เทียบกับ 8.8%, p = 0.510 เมื่อติดตามอัตราการเสียชีวิตโดยแบ่งตามระยะเวลาและค่าเฉลี่ยที่ผู้ป่วยได้รับการ primary PCI พบว่าหากผู้ป่วยได้ทำการรักษา primary PCI ภายในเวลา 90 นาที ติดตามเปรียบเทียบดูอัตราการเสียชีวิตพบ 4.2% หากผู้ป่วยได้รับการรักษาสามารถทำ FMC to device time น้อยกว่า 90 นาที และที่ 6.3% หากทำ FMC to device time ระหว่าง 91-180 นาที และที่ 6.7% เมื่อ FMC to device time ระหว่าง 181-270 นาที และที่ 42.9% เมื่อ FMC to device time ระหว่าง 271-360 นาที และ 8.3% เมื่อ FMC to device time มากกว่า 360 นาที (p = 0.040)

สรุป: การรักษาโดย primary PCI ระยะของเวลา FMC to device time มีความสำคัญในการลด cardiogenic shock จาก Thailand National PCI registry พ.ศ. 2549 ในประชากรชาวไทยยังพบว่าการทำ primary PCI ในระยะเวลาของ FMC to device time ที่น้อยกว่า 90 นาที มีส่วนน้อย