

Predictors of In-Hospital Adverse Events after PCI for NSTEMI in the National Percutaneous Coronary Intervention (PCI) Registry

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Objective: Evaluate the in-hospital major adverse cardiovascular events (MACE) and clinical predictors of non-ST-T MI that undergoing percutaneous coronary interventions (PCI) in Thailand.

Material and Method: Thailand National PCI Registry enrolled 4,156 patients that underwent PCI in Thailand between May 1 and October 31, 2006. Four hundred eighty three patients underwent PCI with indication of non-ST-T MI. Baseline demographic and angiographic characteristic were recorded. MACE included CV death, MI, and stroke.

Results: In-hospital MACE occurred in 27 patients (5.6%), included CV death in 15 patients (3.1%), MI in 14 patients (2.9%), and stroke in 2 patients (0.4%). In-hospital MACE were higher in patients with previous history of CABG (19.2% versus 4.8%, $p = 0.01$), cardiogenic shock at presentation (29.3% versus 3.4%, $p < 0.001$), significant left main disease (19.4% versus 4.6%, $p = 0.005$), baseline ejection fraction $< 30\%$ (25% versus 4.4%, $p = 0.003$), and used of intra-aortic balloon counter pulsation (IABP) during PCI (26.3% versus 3.8%, $p < 0.001$). After multiple logistic regression analysis, prior history of CABG (OR = 6.1, 95% CI: 1.1-32.4, $p = 0.03$), baseline ejection fraction $< 30\%$ (OR = 6.5, 95% CI: 1.7-24.4, $p = 0.005$), and used of IABP during PCI (OR = 4.7, 95% CI: 1.3-16.8, $p = 0.01$) are the strongest predictors of in-hospital MACE.

Conclusion: In the National Thai PCI Registry, patients with non-ST-T MI undergoing PCI had in-hospital major adverse events rate at 5.6%. Prior CABG, low EF $< 30\%$, unstable hemodynamic required used of IABP during PCI and procedure scheduled as an urgent or emergent were predictors of in-hospital MACE.

Keywords: Non-ST elevation myocardial infarction, In-hospital MACE, Thai National PCI Registry

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Coronary artery disease (CAD) is the leading cause of death in Thailand⁽¹⁾. Treatment of CAD has been rapidly evolving. Percutaneous coronary intervention (PCI) is an attractive alternative therapy in both acute and chronic CAD. In a non-STEMI, routine coronary angiogram (CAG) within 48 hours followed by percutaneous revascularization (PCI) if coronary deemed suitable as a part of invasive strategy in a high-risk patient. The practice of PCI has been a standard treatment in Thailand for the past 20 years. However, there is no national data collection and systemic review on PCI outcome and how it affects

the public health. This PCI Registry was carried out under the auspices of the Heart Association of Thailand in collaboration with 29 cardiac catheterization laboratories in the country in 2006. The aim of the present study was to evaluate the in-hospital major adverse cardiovascular events (MACE) and the predictors of non-ST-T MI that underwent percutaneous coronary interventions (PCI) in Thailand National PCI Registry.

Material and Method

The National PCI Registry protocol enrolled patients whom underwent PCI in 29 participating institutions. Patients were invited to participate in the registry from the principal investigators and nurse coordinator at each institution. The first participating patient was in May 2006 and counted as the first patient.

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Then consecutive enrollment of participating patients until the last case on October 31, 2006. Patients were excluded if they underwent diagnostic procedure or patients refused to participate the registry. Demographic data and six months follow-up were collected by investigators or nurse coordinators. All data were keyed into online web based at each site. Case record form (CRF) was mailed to the central registry on the 15 and 30 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 defined all parameters. Myocardial infarction/myocardial necrosis was defined as clinical symptoms with either 1) Troponin T or I within 24 hours of symptoms above upper normal limit, 2) CK-MB >2 times upper normal limit and serial >2 times, or 3) Total CPK >2 times upper normal limit. STEMI was defined as myocardial necrosis plus EKG changed as follow 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. In-hospital adverse event was defined in the following five steps. 1) Cardiovascular death from arrhythmia, LV dysfunction, or cardiac arrest. 2) Non-cardiac death from other cause such as infection, neurologic, or pulmonary. 3) Cardiogenic shock, which 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, which is a clinical syndrome of new neurologic deficit, during or after PCI and persisted for more than 72 hours after onset. 5) Ventricular tachycardia/ventricular fibrillation, which is persistent and caused by arrhythmia, that required treatment of antiarrhythmic drug or DC shock. For the short-run, ventricular tachycardia or accelerated idioventricular rhythm that does not require treatment or is spontaneous resolved, is not counted as events.

Baseline demographic, inclusive of reimbursement status and angiographic characteristics were recorded. In-hospital adverse events 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 \pm SD, and comparison between groups were done using 2-sample

t tests. Categorical variables were express as frequency (percentage) and Chi-square test was used for comparison. A 2-sided value of $p < 0.05$ was considered significant. If any factors show p -value < 0.05 , multiple logistic regression was used to test between the relationship of clinical predictors and in-hospital MACE, results were demonstrated by adjusted odds ratio and 95% confidence interval. All statistics has been performed with SPSS version 19.0.

Results

Thai PCI Registry collected data on 4,156 patients that underwent PCI in 29 participating hospitals with PCI capability in Thailand between May 1 and October 31, 2006. Four hundred eighty three patients underwent PCI with the clinical presentation of non-ST-T MI and were included in this study.

Patients demographic

The mean age was 65 ± 12 years, 64% were male. There were history of prior myocardial infarction in 180 (37%), hypertension in 324 (67%), dyslipidemia in 362 (75%), and diabetes mellitus in 189 (39%). Baseline clinical characteristics were summarized in Table 1.

In-hospital MACE occurred in 27 patients (5.6%), that included CV death in 15 patients (3.1%), MI in 14 patients (2.9%), and stroke in 2 patients (0.4%).

Table 1. Baseline characteristics (n = 483)

Age (years), mean \pm SD	65 \pm 12
Male, n (%)	309 (64)
Previous myocardial infarction, n (%)	180 (37)
Previous PCI, n (%)	60 (12)
Previous CABG, n (%)	26 (5)
Previous CVA/TIA, n (%)	29 (6)
Chronic renal failure, n (%)	53 (11)
Peripheral arterial disease, n (%)	17 (4)
Family history of CAD, n (%)	41 (9)
Hypertension, n (%)	324 (67)
Dyslipidemia, n (%)	362 (75)
Smoking, n (%)	198 (41)
Diabetes, n (%)	189 (39)

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

Reimbursement status and in-hospital MACE

There were five categories of reimbursement i.e. self-paid, government civil service, social security service, national health budget, and private insurance. MACE occurred in 6.1%, 4.4%, 6.3%, 7.1%, and 7.1% respectively.

Medical history and in-hospital MACE

Patients with history of previous CABG had higher in-hospital MACE (19.2% versus 4.8%, $p = 0.01$). Other medical history such as previous PCI, previous stroke, CKD (chronic kidney disease), peripheral arterial disease, hypertension, and diabetes mellitus had no impact on in-hospital MACE.

Clinical status and in-hospital MACE

Patients with cardiogenic shock had a higher in-hospital MACE when compared to the patients without cardiogenic shock (29.3% versus 3.4%, $p < 0.001$).

The extent of coronary artery disease, defined as the number of vessel involved, has no impact on in-hospital MACE. However, the presence of significant left main (diameter stenosis $>50\%$) had an increase in-hospital MACE (19.4% versus 4.6%, $p = 0.005$).

Baseline ejection fraction and in-hospital MACE

Baseline ejection fraction (EF) had a strong impact on in-hospital MACE. The lower of baseline

Table 2. Medical history and reimbursement status of non ST-T MI (n = 483)

Medical history and reimbursement status	Patients with in-hospital MACE (n = 27)	Patients without MACE (n = 456)	p-value
Age ≥ 65 (years)	20 (74.1%)	244 (53.5%)	0.037
Previous myocardial infarction	8 (29.6%)	172 (37.7%)	0.398
Previous PCI	4 (14.8%)	56 (12.3%)	0.762
Previous CABG	5 (18.5%)	21 (4.6%)	0.011
Previous CVA/TIA	1 (3.7%)	28 (6.1%)	1.000
Chronic renal failure	6 (22.2%)	47 (10.3%)	0.102
Peripheral arterial disease	2 (7.4%)	15 (3.3%)	0.245
Family history of CAD	2 (7.4%)	39 (8.6%)	1.000
Hypertension	20 (74.1%)	304 (66.7%)	0.426
Dyslipidemia	17 (63.0%)	345 (75.7%)	0.139
Smoking	10 (37.0%)	188 (41.2%)	0.667
Diabetes	11 (42.3%)	178 (39.4%)	0.767

MACE = major adverse cardiac events; PCI = percutaneous coronary intervention; CABG = coronary artery bypass graft surgery; CVA = cerebrovascular accident; TIA = transient ischemic attack; CAD = coronary artery disease

Table 3. Clinical status of non ST-T MI (n = 483)

Clinical status	Patients with in-hospital MACE (n = 27)	Patients without MACE (n = 456)	p-value
Cardiogenic shock	12 (44.4%)	29 (6.4%)	<0.001
Coronary disease extent			0.255
1 vessel	6 (22.2%)	162 (35.5%)	
2 vessel	8 (29.6%)	146 (32.0%)	
3 vessel	3 (48.1%)	147 (32.2%)	
Only left main stenosis $>50\%$	0 (0%)	1 (0.2%)	
Left main stenosis $>50\%$	6 (22.2%)	25 (5.5%)	0.005
LVEF <50	12 (66.7%)	107 (35.7%)	0.008
LVEF <30	5 (27.8%)	15 (5.0%)	0.003

MACE = major adverse cardiac events; LVEF = left ventricular ejection fraction

Table 4. Procedure characteristic of non ST-T MI (n = 483)

Clinical status	Patients with in-hospital MACE (n = 27)	Patients without MACE (n = 456)	p-value
Circumstances of procedure			<0.001
Elective	12 (44.4%)	316 (69.3%)	
Urgent	9 (33.3%)	119 (26.1%)	
Emergent	6 (22.2%)	21 (4.6%)	
Ad hoc PCI	23 (85.2%)	393 (86.2%)	0.779
Access site			0.146
Femoral	27 (100%)	408 (89.5%)	
Radial	0 (0%)	47 (10.3%)	
Other	0 (0%)	1 (0.2%)	
Number of attempted lesions			0.635
1	19 (70.4%)	284 (62.3%)	
2	5 (18.5%)	130 (28.5%)	
3	3 (11.1%)	35 (7.7%)	
4	0 (0%)	7 (1.5%)	
IABP used	10 (37.0%)	28 (6.1%)	<0.001
Vascular closure device used	0 (0%)	15 (3.3%)	1.000

MACE = major adverse cardiac events; PCI = percutaneous coronary intervention; IABP = intra-aortic balloon pump

Table 5. Multivariate analysis of clinical predictors for in-hospital MACE

	Adjusted OR (95% CI)	p-value
Age >65	3.6 (0.9 to 14.8)	0.079
Previous CABG	6.1 (1.1 to 32.4)	0.034
LVEF <30	6.5 (1.7 to 24.4)	0.005
IABP	4.7 (1.3 to 16.8)	0.016
Circumstances of procedure		0.044
elective		
Urgent	3.6 (1.0 to 12.5)	0.043
Emergent	6.9 (1.3 to 37.4)	0.025

MACE = major adverse cardiac events; CABG = coronary artery bypass graft surgery; LVEF = left ventricular ejection fraction; IABP = intra-aortic balloon pump

LV function, the higher of in-hospital MACE. Patients with EF >50% had in-hospital MACE rate at 3% while patient with EF <50% had in-hospital MACE rate at 10% ($p = 0.008$). In-hospital MACE rate occurred at 25% in patients with LVEF <30%, in compared to 4.4% in patients with LVEF >30%, ($p = 0.003$).

Procedure characteristic and in-hospital MACE

Patients with unstable hemodynamic required intra-aortic balloon pump (IABP) during PCI had higher in-hospital MACE (26.3% versus 3.8%, $p < 0.001$).

Patients that had PCI on an emergency case had a higher in-hospital MACE when compared to patient who had elective or urgent case (six of 27 patients (22%) in emergency versus 9/128 patients (7%) in urgent versus 12/328 (3.7%) in elective case, $p < 0.001$).

Number of attempted lesion had no impact on in-hospital MACE (62.3% in one lesion, 28.5% in two lesions, 7.7% in three lesions, and 1.5% in four lesions, $p = 0.635$).

Ad hoc PCI, access site, used of bare metal stent or drug-eluting stent, and amount of contrast agents had no impact on in-hospital MACE.

Discussion

In-hospital adverse events occurred in 5.6% of non-ST-T MI undergoing PCI in the Thai National PCI Registry. In-hospital mortality rate was 3.1%, within the range reported in other studies. The major findings of the present study was that age >65 years, emergent/urgent PCI, prior CABG, baseline EF <30%, and hemodynamic instability that requires IABP were the independent predictors for major cardiac adverse events in Thai patients with non-STEMI undergoing PCI. In our study, patients' age >65 years was a predictor for MACE. Older age is a well-known predictor for adverse event. In New York State Angioplasty Registry, older age is a strong predictor for in-hospital mortality. Elective PCI in elderly has acceptable in-hospital outcome. However, emergent

PCI in elderly has a substantial higher risk of in-hospital death⁽²⁾. Non-ST-T MI patient with prior CABG had a worse prognosis when compare to non-ST-T MI patients without CABG^(3,4). In our study, 59% of patients with in-hospital MACE had history of congestive heart failure within two weeks as compare to 25% of patient without in-hospital MACE. Severe CHF was found in 62.5% in patients with MACE as compared to 31.2% in patients without MACE. Congestive heart failure is a predictor for in-hospital MACE in our univariate analysis, but not present in the multivariate analysis since many patients with CHF may have low EF. In contrast, low EF is a predictor in both univariate and multivariate analysis. Low EF has been recognized as a predictor of mortality in STEMI, chronic stable angina, and congestive heart failure. Bosch et al showed that adding EF into the TIMI risk score model improved the prediction of mortality⁽⁵⁾. In his study, mortality rate were 3.3 times higher within each TIMI risk score stratum if an EF <48% was added. Even poor LV function is one of the main predictors for poor outcome in non-ST-T MI undergoing PCI in our study. However, the patients with LV dysfunction also gain most benefit from PCI. Palua et al assessed 972 consecutive patients admitted with non-ST-T MI and found that the greatest benefit attributed to routine coronary angiogram and PCI was observed in the patient with LV dysfunction⁽⁶⁾. In hospital MACE was highest in patients with cardiogenic shock. The patients with cardiogenic shock usually required emergency PCI and needed IABP for hemodynamic support. Hemodynamic instability requiring IABP is a pre-procedural factor with poor outcome. In the present study, the interdependent predictors were the pre-procedural factor in high-risk patients and all of them were unmodified. Coronary artery bypass surgery is generally recommended for patient with left main disease. In the SYNTAX trial, patients with isolated left main may benefit from PCI. However, patients with left main stenosis or LM disease and high syntax score, CABG showed superior benefit over PCI⁽⁷⁾. In the present study, non-ST-T MI with significant left main disease had significant higher in-hospital MACE (22% versus 5.5%). Our trial started before SYNTAX result, thus we did not have details of syntax score in our patients. The CUSTOMIZE registry reported the non-ST-T elevation MI patients with left main coronary artery disease, PCI is associated with similar safety compared to CABG but higher risk of MACEs driven by increased risk of repeat revascularization⁽⁸⁾. Other procedural factor such as extent of coronary disease,

number of attempted lesion, the use of bare or drug-eluting stent, and amount of contrast used had no impact on in-hospital adverse events. Hannan et al⁽⁹⁾ suggested that benefit from DES might not be impacted an outcome for patients receiving drug-eluting stents for first six months since the benefit of DES over BMS is by reduction of restenosis rate, which usually occurred at six to nine months. We did not see the impact of the type of stent used as a predictor for in-hospital adverse events.

In summary, we defined a group of characters that associated with high in-hospital MACE in the setting of non-STEMI patients who underwent PCI.

What is already known on this topic?

In the last two decade, evolution of medication and procedure has significant reduction of mortality in the non-STEMI patients. In the high-risk non-STEMI, early invasive treatment by performing coronary angiogram with an ad hoc percutaneous coronary intervention (PCI) within 24 to 48 hours is recommended. However, 5 to 7% still suffered from major adverse events (MACE) with current treatment.

What this study adds?

Based on data from the National PCI Registry enrolled patients in 2006, in-hospital adverse events occurred in 5.6% of Thai patients with non-STEMI that underwent PCI. We identified that age >65 years, prior CABG, unstable hemodynamic required, used of IABP during PCI, low EF <30%, and urgent/emergency scheduling of the procedure were predictors of in-hospital MACE.

Potential conflicts of interest

None.

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ปัจจัยทำนายการเกิดภาวะแทรกซ้อนทางหัวใจและหลอดเลือดในขณะอยู่โรงพยาบาล (in-hospital MACE) ของผู้ป่วยที่ได้รับการรักษาด้วยภาวะหัวใจขาดเลือดแบบ non ST elevation MI

ณัฐวุฒิ วงษ์ประภารัตน์, ประดิษฐ์ ปัญญะวิณิน, คำรัส ศรีสุโกศล, ชุมพเกษม โชตินัยวัตรกุล, เรวัตร พันธุ์กิ่งทองคำ, วิวรรณ ทั้งสุขบุตร, รุ่งทิพา พงษ์อัครศิริรา, เขมจิรา การเกิดกลาง

วัตถุประสงค์: การศึกษานี้เพื่อติดตามการเกิดภาวะแทรกซ้อนทางหัวใจและหลอดเลือดในขณะอยู่โรงพยาบาล (in-hospital MACE) ของผู้ป่วยที่ได้รับการรักษาด้วยภาวะหัวใจขาดเลือดเฉียบพลันแบบ non ST elevation MI และได้รับการรักษาโดยการฉีดสตีและใส่สายสวนเพื่อทำบอลลูน (percutaneous coronary intervention, PCI) ในการศึกษา Thai national PCI registry และการติดตามการทำนายภาวะแทรกซ้อนเหล่านั้น

วัสดุและวิธีการ: Thailand PCI registry ได้ติดตามผู้ป่วยจำนวน 4,156 ราย ที่ได้รับการรักษาด้วยการฉีดสตีและใส่สายสวนและการทำบอลลูน (PCI) ในระหว่างวันที่ 1 พฤษภาคม ถึง 31 ตุลาคม พ.ศ. 2549 ในจำนวนนี้มีผู้ป่วย 483 ราย ที่ได้รับการรักษาโดยการทำ PCI ในข้อบ่งชี้ของหัวใจขาดเลือดเฉียบพลันแบบ non ST elevation MI อายุ ปัจจัยเสี่ยงพื้นฐาน ค่าผลเลือดเบื้องต้น และผลการฉีดสตี ได้รับการจัดบันทึกภาวะแทรกซ้อน (MACE) รวมถึงการเกิดภาวะหัวใจและหลอดเลือด (cardiovascular death) การเกิดภาวะหัวใจขาดเลือดเฉียบพลัน (myocardial function) การเกิดภาวะสมองขาดเลือดเฉียบพลัน (stroke)

ผลการศึกษา: การเกิดภาวะแทรกซ้อนของหัวใจและหลอดเลือดขณะอยู่โรงพยาบาล (in-hospital MACE) พบในผู้ป่วย จำนวน 27 ราย (5.6%) ในจำนวนนี้เป็น cardiovascular death จำนวน 15 ราย (3.1%) ภาวะหัวใจขาดเลือดเฉียบพลัน (MI) 14 ราย (2.9%) ภาวะสมองขาดเลือดเฉียบพลัน (stroke) 2 ราย (0.4%)

ผู้ป่วยจะมีภาวะแทรกซ้อนทางหัวใจและหลอดเลือดขณะอยู่โรงพยาบาล (in hospital MACE) มากขึ้น หากมีภาวะหัวใจขาดเลือดและได้รับการทำ CABG (19.2% เทียบกับ 4.8%, $p < 0.01$) หากมีภาวะ cardiogenic shock ตั้งแต่แรก (29.3% เทียบกับ 3.4%, $p < 0.001$) หากมีการตรวจพบการตีบบริเวณตำแหน่งส่วนซ้าย (left main disease) (19.4% เทียบกับ 4.6%, $p < 0.005$) หากมีภาวะการทำงานของหัวใจผิดปกติ โดย ejection fraction น้อยกว่า 30% (25% เทียบกับ 4.4%, $p < 0.003$) หากต้องได้รับการรักษาโดยการใส่ intra-aortic balloon pump (IABP) ระหว่างการทำ PCI (26.3% เทียบกับ 3.8%, $p < 0.0001$) หลังจากการทำ multiple logistic regression analysis เพื่อศึกษาการทำนายของการเกิดภาวะแทรกซ้อนพบว่า ผู้ป่วยที่มีอาการหัวใจขาดเลือดและได้รับการทำ coronary bypass (CABG) มาก่อนจะมี (OR = 6.1, 95% CI: 1.1-32.4, $p = 0.03$) ผู้ป่วยที่มีภาวะการบีบตัวของหัวใจที่ผิดปกติเล็กน้อยกว่า 30% (OR = 6.5, 95% CI: 1.7-24.4, $p = 0.005$) ผู้ป่วยที่มีความดันต่ำและต้องใส่ intra-aortic balloon pump ระหว่างการทำ (OR = 4.7, 95% CI: 1.3-16.8, $p = 0.01$) ซึ่งปัจจัยทั้ง 3 ข้างต้นเป็นการทำนายภาวะแทรกซ้อนทางหัวใจและหลอดเลือดขณะอยู่ในโรงพยาบาล (in-hospital MACE) อย่างมีนัยสำคัญ

สรุป: ในการศึกษา Thailand National PCI Registry ในผู้ป่วยที่ได้รับการฉีดสตีและใส่สายสวน (PCI) ในข้อบ่งชี้ของโรคหัวใจขาดเลือดเฉียบพลัน non ST elevation MI จะพบว่าการเกิดภาวะแทรกซ้อนในขณะอยู่โรงพยาบาล (in-hospital MACE) เกิดขึ้นที่ 5.6% โดยปัจจัยพื้นฐานที่ช่วยทำนายภาวะเหล่านี้คือ การที่มีภาวะหัวใจขาดเลือดและเคยทำ bypass มาก่อน ภาวะการบีบตัวของหัวใจผิดปกติโดยมี EF <30% และการที่ผู้ป่วยมาเสนอภาวะ cardiogenic shock และต้องใส่ intra-aortic balloon pump อย่างเร่งด่วน ซึ่งปัจจัยเหล่านี้สามารถทำนายการเกิด in-hospital MACE อย่างมีนัยสำคัญ
