EuroIntervention

Percutaneous coronary intervention in the elderly: results from the Thai National Percutaneous Coronary Intervention Registry (TPCIR)

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KEYWORDS

Coronary artery disease, angioplasty, coronary artery disease

Abstract

Aims: The objective of this study was to evaluate the outcomes and identify the risk factors of in-hospital mortality among elderly patients undergoing PCI in Thailand.

Methods and results: Included in this study were 4,156 consecutive patients (comprising 639 elderly [age ≥75 years] and 3,517 non-elderly [age <75 years]) undergoing PCI between May 2006 and October 2007. The success rate of PCI was less favourable among elderly compared to the non-elderly patients (91.2% vs. 87.5%; p=0.003). Elderly patients had higher rate of post PCI renal failure (3.9% vs. 1.8%; p=0.001), Q-wave myocardial infarction (3.0 vs. 1.4%, p=0.003), and unadjusted in-hospital mortality (5.3% vs. 2.4%, p≤0.001), compared with non-elderly patients. After adjustment for baseline variables, acute coronary syndrome and heart failure were the two variables most associated with increased mortality (OR=5.95, 95% CI=3.22-11.01), p<0.001 and OR=5.73,95% CI=3.80-8.63), p<0.001, respectively). According to the multivariate analysis, age was not significantly related with increased mortality (OR=1.37, 95% CI=0.87-2.16, p=0.174).

Conclusions: Our study highlights the safety and effectiveness of PCI in elderly patients since advanced age is not a predictor of in-hospital mortality.

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Introduction

Coronary artery disease is the leading cause of morbidity and mortality in elderly patients and represents a high cost to the healthcare system.[1] The emergence of percutaneous coronary intervention (PCI) for the treatment of coronary artery disease makes it the dominant revascularisation procedure in today's cardiology practice. The data regarding the beneficial effect of PCI among the elderly, however, is limited because elderly patients are usually excluded from clinical trials.[2,3] Previous studies showed that PCI among elderly patients was associated with more frequent procedural complications and less successful outcomes.[4] Recently, however, PCI in the elderly has had more acceptable short-term outcomes.[5] In order to guide today's practice, evidence on the current effectiveness and safety of PCI among elderly patients is needed.

The Committee of the Thai Heart Association developed a percutaneous coronary intervention registry that includes all patients undergoing PCI in Thailand. This prospective registry provides an opportunity to evaluate the outcomes of PCI among unselected elderly patients. The objective of this study was to evaluate the safety and hospital outcomes of PCI among patients over 75 years of age and to compare the outcomes among younger patients.

Material and methods

The Thai Percutaneous Coronary Intervention Registry (TPCIR) is a clinical database, which includes all of the patients undergoing PCI between May 2006 and October 2007 at 27 cardiac centres in Thailand. Data collection was conducted by trained nurses and re-checked by the principle investigators at each site. Web-based, double data entry was used to prevent data entry error. Data were then sent to the data management centre at the Thai Heart Association Research Centre. Each electronic submission was re-examined by the researchers to ascertain completeness and accuracy.

The TPCIR includes information on: age, sex, clinical indications for PCI, the presence or absence of heart failure, coronary risk factors, kidney disease, cerebrovascular disease, coronary artery bypass surgery, coronary anatomy, type of stent, and in-hospital outcomes. Written informed consent was obtained from each patient before performing the PCI procedure, and the research protocol was approved by each local institutional ethics committee.

Definitions

Death was defined as all causes of mortality during hospitalisation. Procedural success was defined as <50% residual stenosis with normal coronary flow. In-hospital adverse events included stroke (new neurological deficit occurring after the procedure and lasting >24 hours), renal failure (an increase in creatinine >2 mg/dL), myocardial infarction (CK-MB >2× upper normal limit), or access site complications e.g., haematoma, pseudoaneurysm.

Any bleeding complications were carefully assessed according to the standard of care. Major bleeding was defined as any bleeding associated with the need for blood transfusion, a drop in haemoglobin >3.0 g/dL, haematoma >10 cm for femoral access or >2 cm for radial access. Lesion characteristics were recorded by each operator according to the ACC/AHA classification.[6] The patients were subdivided into elderly (>75 years of age) and non-elderly (<75 years of age).

Statistical analysis

The frequencies and percentages of the categorical data are presented. The continuous variables are reported as a mean ±standard deviation or median and 25th and 75th percentiles. Differences between the patient groups were examined using the chi-square or Fisher's exact test or the Z-test for categorical variables. Differences in continuous variables between groups were assessed using the Student's *t*-test or the Mann-Whitney U-test. Univariate analyses were used to examine the relationship between each variable and in-hospital death. Multivariate analyses was used to assess whether prognostic variables were statistically significant when adjusted for other variables significantly associated with in-hospital death in the univariate analysis. A p value of <0.05 was required for statistical significance. All of the analyses were done using STATA/SE 8 software package (StataCorp LP, College Station, TX, USA).

Results

Patients and procedural characteristics

A total of 4,156 patients undergoing PCI were enrolled in the Thai Percutaneous Coronary Intervention Registry between May 2006 and October 2007. Of these patients, 3,517 were <75 years of age and 639 were ≥75 year of age. The baseline characteristics of both groups are shown in Table 1. The mean age was 79 in elderly group and 60 in the younger group. Elderly patients were more likely to have hypertension, heart failure, chronic renal failure, cerebrovascular disease and cardiogenic shock. Smoking and family history of coronary artery disease were more common in the non-elderly patients. Multivessel coronary artery disease and cardiogenic shock before PCI procedure were more common in the elderly group.

Indications for PCI and clinical presentation differed between the two groups (Table 2). The elderly patients were more likely to present with non ST elevation acute coronary syndrome (16.3% vs. 10.8%, p<0.001) but the proportion of ST elevation acute coronary syndrome within both groups was similar (13.8 % vs. 14.9%, p=0.482).

Table 3 shows the procedural characteristics of the patients. Overall, there were no significant differences between the elderly and non-elderly patients regarding the location and type of lesion. Drug eluting stents were used in about 50% of both groups and there was no difference in the type of stent used between the elderly and non-elderly groups.

In-hospital mortality and adverse effects

Overall in-hospital mortality rate was higher among elderly patients than non-elderly (2.4% vs. 5.3%; p<0.001) (Table 4); however, the subgroup analysis with respect to clinical presentation revealed a significantly increased mortality in only the elderly patients

Table 1. Baseline characteristic of both age groups.

Characteristics	<75 years of age n/total (%)	≥75 years of age n/total (%)	p-value
Sex (male)	2521/3517 (71.7)	356/639 (55.7)	<0.001
Diabetes	1313/3483 (37.7)	245/637 (38.5)	0.715
Hypertension	2387/3484 (68.5)	483/634 (76.2)	<0.001
Dyslipidaemia	2643/3390 (78.0)	460/613 (75.0)	0.111
Currently smoking	543/2424 (22.4)	40/462 (8.7)	<0.001
Heart failure within 2 weeks	411/3517 (11.7)	145/639 (22.7)	<0.001
Chronic renal failure	207/3502 (5.9)	69/634 (10.9)	<0.001
Previous myocardial infarction	1047/3390 (30.9)	161/613 (26.3)	0.022
Previous PCI	866/3517 (24.6)	162/639 (25.4)	0.694
Previous CABG	130/3517 (3.7)	31/639 (4.9)	0.164
Previous stroke	155/3477 (4.5)	65/618 (10.5)	<0.001
Family history of CAD	407/3085 (13.2)	29/524 (5.5)	<0.001
Number of vessel			
1 vessel	1249/3517 (35.5)	195/639 (30.5)	0.015
2 vessel	1200/3517 (34.1)	199/639 (31.1)	0.143
3 vessel	1058/3517 (30.1)	243/639 (38.0)	<0.001
left main disease	10/3517 (0.3)	2/639 (0.3)	0.901
Cardiogenic shock	205/3517 (5.8)	52/639 (8.1)	0.026

Patients with only left main disease were counted as "left main disease" and those with an left main plus another vessel disease were counted in the group with "2 vessel" or "3 vessel" disease, respectively.

Table 2. Indications for PCI and clinical presentation.

Characteristics	<75 years of age (n=3517) n (%)	≥75 years of age (n=639) n (%)	p-value
ST elevation MI	486 (13.8)	95 (14.9)	0.482
Primary PCI	293 (60.3)	60 (63.2)	0.600
Facilitated PCI	1 (0.2)	0 (0.0)	0.658
Rescue PCI	37 (7.6)	2 (2.1)	0.050
Others PCI	155 (31.9)	33 (34.7)	0.588
Non-ST elevation MI	379 (10.8)	104 (16.3)	<0.001
Unstable angina	907 (25.8)	161 (25.2)	0.752
Stable angina	1043 (29.7)	134 (21.0)	<0.001
Asymptomatic CAD	194 (5.5)	32 (5.0)	0.602
PCI prior to non-cardiac surgery	18 (0.5)	10 (1.6)	0.003
PCI as a staged procedure	215 (6.1)	41 (6.4)	0.769
Other	275 (7.8)	62 (9.7)	0.109

presenting with acute coronary syndrome compared to younger patients (8.3% vs. 4.3% ; p=0.002) (Figure 1). In patients with non acute coronary syndrome, in-hospital mortality was not significantly different between the elderly and non-elderly groups (1.4 % vs. 0.5%; p=0.071).

The success rate of PCI procedure was high in both groups, although the success rate of PCI was less favourable in the elderly patients (91.2% vs. 87.5 %; p=0.003). There was no significant difference between the elderly and non-elderly patients in their rate of stroke (0.5% vs. 0.2%; p=0.232) and urgent coronary artery bypass graft (0.8% vs. 0.5%; p=0.464).

Table 3. Procedural characteristics.

Lesion characteristic	<75 years of age (n=5149) n (%)	≥75 years of age age (n=973) n (%)	p-value
Location of target lesions			
LM	71 (1.4)	19 (2.0)	0.173
LAD	2339 (45.4)	445 (45.7)	0.859
LCX	1062 (20.6)	196 (20.1)	0.733
RCA	1677 (32.6)	313 (32.2)	0.807
Segment in bypass graft	47 (0.9)	13 (1.3)	0.219
Previously treated lesions	358 (7.0)	64 (6.6)	0.697
ACC/AHA classification			
A	194 (3.8)	29 (3.0)	0.308
B1	1336 (25.9)	246 (25.3)	
B2	1503 (29.2)	309 (31.8)	
C	2116 (41.1)	389 (40.0)	
Bifurcation	990 (19.2)	165 (17.0)	0.097
Evidence of thrombus	577 (11.2)	105 (10.8)	0.706
CTO >3 month	419 (8.1)	63 (6.5)	0.077
Balloon angioplasty	584 (11.3)	119 (12.2)	0.426
Stent			
DES	2662 (51.7)	519 (53.3)	0.348
BMS	1639 (31.8)	289 (29.7)	0.190
DES & BMS	54 (1.0)	11 (1.1)	0.820
Other	210 (4.1)	35 (3.6)	0.482

CTO: chronic total occlusion; DES: drug-eluting stent; BMS: bare metal stent

Table 4. In-hospital outcomes.

Lesion characteristic	<75 years of age (n=3517) n (%)	≥75 years of age age (n=639) n (%)	p-value
Procedural success	3207 (91.2)	559 (87.5)	0.003
Q wave MI	48 (1.4)	19 (3.0)	0.003
Urgent CABG	29 (0.8)	3 (0.5)	0.464
Stroke	8 (0.2)	3 (0.5)	0.232
Increased in CK-MB >2x UNL	1090 (31.0)	236 (36.9)	0.003
Access site complication			
Major bleeding/haematoma	51 (1.5)	15 (2.3)	0.095
Pseudo-aneurysm	3 (0.1)	3 (0.5)	0.050
Thrombotic occlusion	5 (0.1)	3 (0.5)	0.111
Vascular surgery repair	3 (0.1)	1 (0.2)	0.487
Other	2 (0.1)	0 (0.0)	1.000
Renal failure	63 (1.8)	25 (3.9)	0.001
Death			
Over all	85 (2.4)	34 (5.3)	<0.001
Non acute coronary syndrome	8 (0.5)	4 (1.4)	0.071
Acute coronary syndrome	77 (4.3)	30 (8.3)	0.002

UNL: upper normal limit

The incidence of raising of the creatinine kinase MB level >2× upper normal limit after PCI was significantly higher in the elderly patients than the non-elderly patients (36.9% vs. 31.0; p=0.003). The elderly patients also had a greater incidence of post-PCI renal failure (3.9% vs. 1.8%; p=0.001). Access site complications – including bleeding, haematoma and thrombotic occlusion – were not significantly different between the two groups.

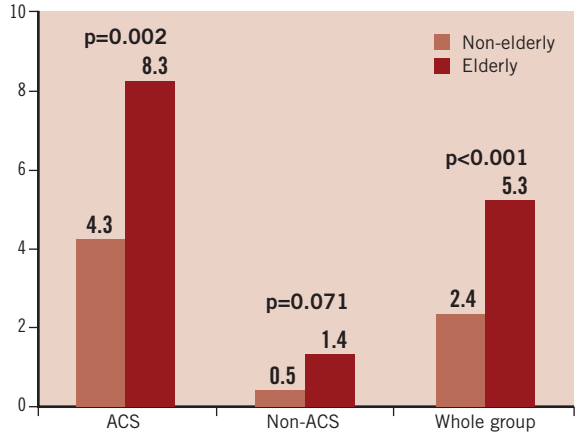

Figure 1. Comparison of in-hospital mortality rate between elderly and non-elderly patients. ACS: acute coronary syndrome

Univariate and multivariate analysis

In the univariate analysis age ≥75 years, diabetes, previous history of cerebrovascular disease, congestive heart failure within two weeks prior to PCI, chronic kidney disease, CK-MB >2× upper normal limit after PCI and PCI in acute coronary syndrome were independently related with in-hospital mortality (Table 5). After adjustment for variables from Table 5, acute coronary syndrome and heart failure were the two variables most often associated with increased mortality (OR= 5.95, 95% CI=3.22-11.01, p<0.001 and OR=5.73, 95% CI=3.80-8.63, p<0.001, respectively). Age, however, was not significantly related to increased mortality (OR= 1.37, 95% CI=0.87-2.16, p=0.174) in the multivariate analysis (Table 6).

Table 5. Univariate regression analysis.

Risk factors	Mortality rate n/total (%)	Odd ratio (95% CI)	p-value
Age ≥75 of age	34/639 (5.3)	2.27 (1.51-3.41)	<0.001
Sex (male)	62/2877 (2.2)	0.47 (0.33-0.68)	<0.001
Diabetes	57/1558 (3.7)	1.73 (1.19-2.52)	0.004
Previous stroke	12/220 (5.5)	2.48 (1.34-4.61)	0.004
Heart failure within 2 weeks	67/556 (12.1)	9.35 (6.43-13.59)	<0.001
Acute coronary syndrome	107/2132 (5.0)	8.86(4.86-16.14)	<0.001
Chronic renal failure	18/276 (6.5)	2.71 (1.61-4.55)	<0.001
CK-MB >2x UNL	48/1326 (3.6)	1.46 (1.01-2.12)	0.046

Table 6. Multivariate logistic regression analysis.

Risk factors	Mortality rate n/total (%)	Odd ratio (95% CI)	p-value
Age ≥75	34/639 (5.3)	1.37 (0.87-2.16)	0.174
Gender (male)	62/2877 (2.2)	0.62 (0.41-0.92)	0.018
Diabetes	57/1558 (3.7)	1.12 (0.73-1.70)	0.607
Previous stroke	12/220 (5.5)	1.93 (0.99-3.77)	0.053
Heart failure within 2 weeks	67/556 (12.1)	5.73 (3.80-8.63)	<0.001
Acute coronary syndrome	107/2132 (5.0)	5.95 (3.22-11.01)	<0.001
Chronic renal failure	18/276 (6.5)	1.26 (0.70-2.28)	0.443
CK-MB >2x UNL	48/1326 (3.6)	1.36 (0.91-2.04)	0.131

Discussion

We have demonstrated that acute coronary syndrome and heart failure are the two most important predictors of in-hospital mortality in patients undergoing PCI. Age itself was not a predictor of in-hospital mortality in this large PCI registry in Thailand.

Our study arose from daily routine practice providing evidence for the effectiveness of PCI in elderly patients. We clinically and angiographically characterised elderly patients with a relative large sample of subjects undergoing PCI. Elderly patients in our registry had more comorbidities, presented more often with heart failure, renal failure, and were more likely to present with more extensive coronary disease. Age-associated structural and functional changes of the coronary artery – including arterial wall thickening, increased vascular stiffness and endothelium dysfunction – might contribute to the lower success rate of the PCI procedure in elderly patients. Post PCI complications – such as renal failure and an increased CK-MB level – were more common in the elderly patients undergoing PCI. We did not observe a higher incidence of vascular access site complications in elderly patients compared to non-elderly patients.

Earlier studies thoroughly documented that age was a strong predictor of adverse outcomes after PCI;[2,7-10] however, only small samples of elderly patients were included so the safety and efficacy regarding PCI in the elderly patients was limited. In one large, multicentre angioplasty registry[5], age was a strong predictor of in-hospital mortality for emergency and elective PCI in elderly patients. By contrast, a recent study by Bagur et al[11] showed that age was not a predictor of major cardiovascular outcome after PCI. Evidently, the continuous improvement of PCI techniques in the last decade – including the introduction of drug-eluting stents and highly efficacious pharmacological therapy – has made PCI a safe and effective coronary revascularisation procedure.

Predictive variations identified from multivariate analysis in our study are different from those of previous studies.[12-16] In the Thai registry, congestive heart failure and acute coronary syndrome are strongly associated with in-hospital mortality (odds ratio=5.95 and 5.73, respectively). Feldman et al[5], using the 2000/2001 New York State Angioplasty Registry, reported that age, congestive heart failure, renal failure, and peripheral vascular disease were predictive factors of in-hospital mortality in patients undergoing both elective and emergency PCI. In a systemic review and meta-analysis of 66 studies of coronary revascularisation in patients >80 years of age performed by Mc Kellar et al [17] the short- and long-term outcomes were acceptable. The pooled estimate for 30-day mortality in that review was 6.3%.

Our study demonstrates that PCI in elderly patients can be performed with a high rate of success (87%) and acceptable in-hospital outcomes. The procedural success rate continues to rise in other contemporary studies over against studies pre-dating the coronary stenting era[18]. Between 1990 and 2000, the success rate of PCI among elderly patients increased from 85% to 93%.[4,13,19-21] Although a bleeding complication is one of the major concerns in elderly patients undergoing PCI, the risk of bleeding in the Thai PCI registry was not significantly different between the elderly and non-elderly patients.

In conclusion, the Thai PCI Registry which included more than 4,000 patients, provides strong evidence that PCI can be performed safely

with acceptable outcomes in elderly patients, despite their having more frequent comorbidities and the risk of in-hospital mortality remaining high in patients with ACS and heart failure.

The limitation of this multicentre study registry is that post-interventional complications may be under reported. In addition, since the results of the procedure were reported by each investigator, without agreement from another investigator, there may be inconsistencies between investigators.

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