ORIGINAL ARTICLE

Factors Associated with Groin Hematoma after Trans-femoral Percutaneous Coronary Intervention: A Study from Thai PCI Registry

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Background: Groin hematoma is a well-recognized and common complication after percutaneous coronary intervention (PCI) with trans-femoral approach (TFA). However, understanding of groin hematoma is lacked in Thailand.

Objective: To study the incidence and factors associated with groin hematoma after PCI with TFA in recent practices among Thai PCI centers.

Materials and Methods: Patients who were consecutively recruited into Thai PCI registry and had undergone PCI with TFA were included in the analysis. Various clinical and procedural variables were collected. Groin hematoma was defined as hematoma >5 cm. Univariate and multivariate logistic regression were performed.

Results: Of 11,253 overall patients, 161 patients (1.43%) developed groin hematoma. Incidence of groin hematoma was slightly higher in patients with acute coronary syndrome (1.62%) compared with patients with stable coronary artery disease (1.21%). From statistical and clinical model multivariate analysis, older age (Odds ratio (OR) 1.02, 95% confidence interval (CI) 1.01 to 1.04, p=0.001, and OR 1.03, 95% CI 1.01 to 1.04, p=0.001), prolonged fluoroscopic time (OR 1.006, 95% CI 1.001 to 1.010; p=0.014, and OR 1.006, 95% CI 1.001 to 1.010, p=0.013), emergency or urgent PCI (OR 1.56, 95% CI 1.14 to 2.13, p=0.006, and OR 1.53, 95% CI 1.11 to 2.12, p=0.010), and more than one puncture (OR 2.89, 95% CI 1.90 to 4.39, p<0.001, and OR 2.84, 95% CI 1.87 to 4.31, p<0.001) were found to be significantly associated with groin hematoma, respectively. Closure device use was also significantly associated with groin hematoma from statistical model multivariate analysis (OR 1.66, 95% CI 1.03 to 2.66, p=0.038).

Conclusion: In a large contemporary patient registry, incidence of groin hematoma after PCI with TFA was low. Most of predisposing factors for groin hematoma remained the same as traditional knowledges, except prolonged fluoroscopic time which was newly identified.

Keywords: Groin hematoma; Percutaneous coronary intervention; Incidence; Risk factors; Trans-femoral approach

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Percutaneous coronary intervention (PCI) is a well-established and standard method of coronary revascularization in both patients with stable coronary artery disease (CAD) and acute coronary syndrome (ACS)[1,2]. In order to perform PCI, vascular access is simply the first crucial step of procedure which interventionist needed to consider, where the site of approach has a critical effect on procedural techniques and also individual patient's outcomes[3,4].

Trans-femoral approach (TFA) and trans-radial approach (TRA) are current two major vascular approaches used for PCI worldwide. TFA, even being introduced earlier and considered as a fundamental approach, has been gradually replaced by TRA in nowadays practice, as it associated with bleeding risk and hematoma, delayed ambulation and longer hospital stay, less patient's preference, higher cost, and importantly increased risk of morbidity and mortality[5-9]. Large randomized clinical trials have demonstrated significantly increased rates of access site-related bleeding and blood transfusion with TFA compared to TRA[10,11]. As increased bleeding events in TFA could translated into its clinical disadvantages, current

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major clinical practice guidelines have solid agreement with recommendation for TRA as a standard or preferred route over TFA in PCI, especially in patients with ACS, unless overriding procedural conditions existed[1,2,12,13].

Although TRA is currently being on its rise, however, there are some limitations for TRA such as small radial artery size, radial artery spasm, occlusion, or anatomical variations, whereas TFA was indeed still a traditional technique for interventionist training, was mandatory for particular procedures, and was still widely used worldwide[14,15]. Therefore, dealing with vascular complications after TFA was inescapable for all practitioners, especially groin hematoma which is a major vascular complication after TFA in PCI[16].

In Thailand, PCI has rapidly grown up in number like many other regions, which over 22,000 patients underwent PCI in recent years, and femoral artery was still the mostly used access site[17,18]. However, the nature of groin hematoma has never been studied before. We therefore aimed to elucidate the incidence and factors associated with groin hematoma after TFA PCI in Thais.

Materials and Methods

Study design and settings

Groin hematomas among 11,253 patients undergoing PCI with TFA were identified from a Thai PCI Registry. Briefly, a Thai PCI Registry was a prospective, multi-center, nationwide study of 19,701 consecutive patients aged 18 years or over who underwent PCI for any indication in 39 hospitals across all regions in country from May 2018 through July 2019, which details of study design and main outcomes were previously published[18,19]. The present study was approved by the Khon Kaen University Ethics Committee for Human Research (HE641244) and was authorized by the Thai PCI Registry Research Committee to use data from the research project. Flow of patient was showed in Figure 1.

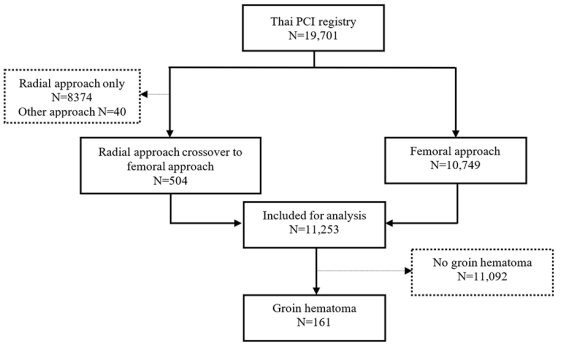

Figure 1. Flow of patient.

Operational definitions

Known CAD was defined as patients who have had invasive coronary angiography (CAG) or computed tomography of coronary arteries and found coronary artery stenosis >50%. Chronic kidney disease (CKD) was defined as serum creatinine >1.5 mg/dL or estimated glomerular filtration rate (eGFR) <60 mL/min/1.73 m^2. Peripheral arterial disease (PAD) was defined as patients with ankle-brachial index <0.9 or had history of interventional or surgical therapy for peripheral artery. PCI status was defined as follows, 1) elective; non-urgent procedure, 2) urgency; semi-urgent procedure which warranted quick action, which waiting time should not exceeds 72 hours, however, depended on patient's conditions and availability of the facilities, and 3) emergency; prompt action, which procedure must be performed as soon as possible. Groin hematoma was defined as swelling mass size >5 cm surrounding the puncture site with hard, palpable, and tender character occurred within 72 hours after PCI[20].

Measurement of variables and data collection

The study variables were developed and assessed by researchers and expert cardiologists and were divided into three parts including; 1) baseline characteristics and comorbidities (age, gender, body mass index (BMI), smoking status, diabetes mellitus (DM), hypertension, dyslipidemia, cerebrovascular disease, chronic kidney disease, chronic lung disease, PAD, anemia, prior PCI, prior coronary artery bypass graft (CABG), and prior valve surgery), 2) presentation and procedural details (vital signs, CAD presentation, cardiogenic shock, status of PCI, thrombolytics use, intra-aortic balloon pump (IABP) use, number of punctures, and closure method), and 3) periprocedural (24 hours before or during procedure) use of antithrombotic drugs (antiplatelet and anticoagulant therapy). Data were collected by researchers of each site and were audited by auditors from other sites. All data were stored at a central data management unit (DMU), Faculty of Medicine, Ramathibodi Hospital, Mahidol University. The DMU had continuously conducted data monitoring to assure data accuracy and quality, and a regular meeting (at least once a month) was set between DMU team and PCI registry consortium to solve issues of invalid data.

Statistical analysis

Data including characteristics of patients were described using mean or median for continuous variables, and frequency and percentage for categorical variables. These data were then compared across clinical outcomes using Chi-square or Fisher's exact test where appropriated. Clinical and treatment factors which are important or interested were put into a univariate analysis. A

multiple multinomial logistic regression was applied to simultaneously multinomial logistic regress clinical outcomes on variables whose p-value in a univariate analysis were less than 0.1. Likelihood ratio test was applied to select and keep only significant variables in the final equation. A multivariate analysis was done for both statistical and clinical model. Adjusted odds ratio (OR) along with 95% confidence interval (CI) were then estimated. All analyses were performed using STATA 17.0. The p-value of less than 0.05 was considered as statistical significance.

Results

Among overall 11,253 patients who underwent PCI with TFA across Thailand, groin hematoma occurred in 161 patients (1.43%). In subgroup of patients with ACS and stable CAD, incidences of groin hematoma were 1.62% and 1.21%, respectively (Table 1). Among patients who developed groin hematoma, mean age ± standard deviation (SD) was 68.8±11.5 years, 64 patients were female (39.8%), and DM, hypertension, and chronic kidney disease were presented in 67 (41.6%), 109 (67.7%), and 66 (41.0%) patients, respectively (Table 2). From a univariate analysis (Table 2), significant risk factors predisposing to groin hematoma were older age (OR 1.03, 95% CI 1.01 to 1.04), chronic lung disease (OR 2.31, 95% CI 1.27 to 4.19), thrombolytics use (OR 3.72, 95% CI 2.08 to 6.63), prolonged fluoroscopy time (FT) (OR 1.005, 95% CI 1.001 to 1.010), emergency or urgent PCI (OR 1.59, 95% CI 1.16 to 2.17), closure device use (OR 1.67, 95% CI 1.04 to 2.68), and more than one puncture (OR 3.01, 95% CI 1.99 to 4.65). There was also a trend of increasing groin hematoma risk in female (OR 1.35, 95% CI 0.98 to 1.85), whereas a significant protective factor for groin hematoma was BMI 23.0 to 29.9 kg/m^2 (OR 0.46, 95% CI 0.28 to 0.76), and a trend of reducing groin hematoma risk was found in manual compression (OR 0.61, 95% CI 0.36 to 1.03).

From a statistical model multivariate analysis (Table 3.1), significant risk factors predisposing to groin hematoma were older age (OR 1.02, 95% CI 1.01 to 1.04), chronic lung disease (OR 1.86, 95% CI 1.01 to 3.41), prolonged FT (OR 1.006, 95% CI 1.001 to 1.010), emergency and urgent PCI (OR 1.56, 95% CI 1.14 to 2.13), closure device use (OR 1.66, 95% CI 1.03 to 2.66), and more than one puncture (OR 2.89, 95% CI 1.90 to 4.39), whereas a trend of reducing groin hematoma risk was found in BMI 23.0 to 29.9 kg/m^2 (OR 0.61, 95% CI 0.36 to 1.02).

From a clinical model multivariate analysis (Table 3.2), significant risk factors predisposing to groin hematoma were older age (OR 1.03, 95% CI 1.01 to 1.04), prolonged FT (OR 1.006, 95% CI 1.001 to 1.010), emergency or urgent PCI (OR 1.53, 95% CI 1.11 to 2.12), and more than one puncture (OR 2.84, 95% CI 1.87 to 4.31), whereas a trend of reducing groin hematoma risk was found in BMI 23.0 to

Table 1. Baseline characteristics of participants

Factors	All patients n=11,253
Age (years), mean (SD)	65.0 (11.9)
Female, n (%)	3,710 (33.0)
BMI group, n (%)	
≥30.0 kg/m^2	986 (8.8)
23.0 to 29.9 kg/m^2	5,712 (50.8)
18.5 to 22.9 kg/m^2	3,765 (33.5)
<18.5 kg/m^2	788 (7.0)
Smoking status, n (%)	
Current smoker	2,319 (20.6)
Ex-smoker	3,630 (32.3)
Never	5,304 (47.1)
Admission SBP, mean (SD)	137.8 (28.0)
Admission HR, mean (SD)	75.9 (17.0)
Diabetes mellitus, n (%)	5,161 (45.9)
Hypertension, n (%)	7,920 (70.4)
Chronic kidney disease, n (%)	4,213 (37.4)
Dialysis, n (%)	604 (5.4)
Cerebrovascular disease, n (%)	716 (6.4)
Chronic lung disease, n (%)	386 (3.4)
Peripheral arterial disease, n (%)	246 (2.2)
Prior PCI, n (%)	7,537 (67.0)
CAD presentation, n (%)	
STEMI	2,856 (25.4)
NSTEMI/unstable angina	3,258 (29.0)
Stable CAD	5,139 (45.7)
Cardiogenic shock, n (%)	1,103 (9.8)
Thrombolytics, n (%)	634 (22.4)
PCI status, n (%)	
Emergency or urgent	3,944 (35.0)
Elective	7,309 (65.0)
Fluoroscopy time (min), median (IQR)	13.4 (8.0, 23.5)
More than one puncture, n (%)	752 (6.7)
IABP, n (%)	603 (5.4)
Manual compression, n (%)	10,536 (93.6)
C-arm, n (%)	37 (0.3)
Closure device, n (%)	889 (7.9)
P2Y12 inhibitors, n (%)	
Clopidogrel	9,937 (88.3)
Prasugrel	174 (1.5)
Ticagrelor	1,069 (9.5)
No	73 (0.6)
Parenteral anticoagulant, n (%)	
Unfractionated heparin	9,523 (84.6)
Low molecular weight heparin	610 (5.4)
Fondaparinux	11 (0.1)
Combine parenteral anticoagulant	746 (6.6)
No	363 (3.2)

Table 1. Cont.

Factors	All patients n=11,253
Aspiration catheter, n (%)	1,011 (9.0)
Number of PCI procedure/doctor/year, n (%)	
≥75 cases	10,507 (93.4)
<75 cases	746 (6.6)
Number of PCI procedure/center/year, n (%)	
≥500 cases	8,396 (74.6)
200 to 499 cases	2,402 (21.3)
<200 cases	455 (4.0)

BMI=body mass index; CAD=coronary artery disease; HR=heart rate; IABP=intra-aortic balloon pump; IQR=interquartile range; NSTEMI=non-ST-segment elevation myocardial infarction; PCI=percutaneous coronary intervention; SBP=systolic blood pressure; SD=standard deviation; STEMI=ST-segment elevation myocardial infarction.

29.9 kg/m^2 (OR 0.62, 95% CI 0.37 to 1.06).

Comorbidities (DM, hypertension, chronic kidney disease, and peripheral arterial disease), female, and manual compression were also included in a clinical model multivariable analysis, however, significant association between those factors and groin hematoma were not demonstrated.

Discussion

From a contemporary large PCI registry, we have found that the incidence of groin hematoma was 1.43% among overall patients who underwent PCI with TFA, which incidence was slightly higher in patients with ACS than patients with stable CAD (1.62% vs. 1.21%). We found that older age, prolonged FT, emergency or urgent PCI, and more than one puncture were significant predictors for groin hematoma from both statistical and clinical model analysis, while there was no significant protective factor identified in our study.

Our reported general incidence of groin hematoma after PCI (1.43%) was low as compared with many other reports, which previous remote studies which used varying criteria of groin hematoma, i.e., >2 cm, >4 cm, >5 cm, and >10 cm had found wide ranges of observed incidence of hematoma from 1.0% to 12.1%[21-26], while a recent prospective observational study in broad range CAD patients reported groin hematoma frequency, using criteria of >5 cm, of 9.3% after PCI[27]. Considering the incidence among studies in patients underwent PCI using the same criteria of hematoma >5 cm (Berry et al.; 11%[24], Andersen et al.; 12.1%[26], Al-Momani et al.; 9.3%[27]), our study had shown the lowest incidence of groin hematoma. In addition, a recent meta-analysis of randomized controlled trials between TRA and TFA in patients with ACS undergoing PCI using various procedural method and peri-procedural medications and various definition of hematoma showed incidence of groin hematoma of 4.3%,(28) which was higher as compared with our incidence of 1.62% in patients with the same setting.

Many factors related with groin complications after PCI, which is simply divided into patient-related (advanced age, female, increased BMI, lower BMI, hypertension, heart failure, CKD, chronic lung disease, and PAD[24,26,29-31], procedure-related (larger vascular sheath and catheter, interventional procedures, emergent procedures, >1 arterial puncture, and use of anti-thrombotic drugs[24,26,29,32,33], and operator/institution-related (low operator volume and low institutional volume[34]), have been reported. Considering those aforementioned risk factors, the low incidence of groin hematoma found in our study could possibly be explained by a low-risk patients' characteristics, i.e., low proportion of elderly patients (mean age ± SD of 65.0±11.9 years), low proportion of female (33.0%), low proportion of patients with obesity and underweight (BMI ≥30 kg/m^2 of 8.8%, and BMI <18.5 kg/m^2 of 7.0%), low proportion of patients presenting with severe hypertension (mean admission systolic blood pressure <140 mmHg), and low proportion of patients with heart failure, chronic lung disease, and PAD (15.7%, 3.4%, and 2.2%, respectively). In addition, most of the procedures were performed at high-volume PCI centers (≥500 PCI/center/year of 74.6%) and with high-experience operators (≥75 PCI/operator/year of 93.4%), which then possibly resulting to a low proportion of >1 puncture (6.7%). Although some proportions of patients had CKD (37.4%) and underwent emergency or urgent PCI (35.0%) which could increase risk of groin hematoma, however, the high risk-containing characteristics was considerably low in overall population, and this could reasonably result to such a low incidence of groin hematoma.

From our findings about predisposing factors of groin hematoma, older age, emergency or urgent PCI status, and more than one puncture are among factors that were previously well identified[24,26,29-31]. Although Nikolsky et al. had found relationship between prolonged FT and retroperitoneal hematoma[35]; however, to our knowledge, prolonged FT as a risk factor for groin hematoma after PCI has never been reported. There was a relevant report about prolonged sheath time (sheath time >16 min) as a risk for groin hematoma after PCI[26]; however, prolonged sheath time from such report was partly somewhat a result of delay sheath removal due to unachieved activated clotting time (ACT) level, hence it was not the same as FT which specifically reflected only to procedural activity, and ideally, a FT should never exceed a sheath time. Since FT has no major relationship with groin procedure, though some operators may perform groin puncture under fluoroscopic guidance which this could led to some degrees of association between FT and groin procedure, however, the association between prolonged FT and groin hematoma is hard to

Table 2. Factors associated with groin hematoma at access site: a univariate analysis

Factors	Status of hematoma		OR (95% CI)	p-value
	Yes, n=161	No, n=11,092		
Age (years), mean (SD)	68.8 (11.5)	64.9 (11.9)	1.03 (1.01, 1.04)	<0.001
Female, n (%)	64 (1.7)	3,646 (98.3)	1.35 (0.98, 1.85)	0.066
BMI group, n (%)				
≥30.0 kg/m^2	14 (1.4)	972 (98.6)	0.55 (0.28, 1.10)	0.092
23.0 to 29.9 kg/m^2	67 (1.2)	5,645 (98.8)	0.46 (0.28, 0.76)	0.002
18.5 to 22.9 kg/m^2	60 (1.6)	3,705 (98.4)	0.62 (0.37, 1.04)	0.069
<18.5 kg/m^2	20 (2.5)	768 (97.5)	1	
Smoking status, n (%)				
Current smoker	34 (1.5)	2,285 (98.5)	0.92 (0.62, 1.38)	0.702
Ex-smoker	43 (1.2)	3,587 (98.8)	0.74 (0.51, 1.08)	0.119
Never	84 (1.6)	5,220 (98.4)	1	
Admission SBP, mean (SD)	137.0 (28.9)	137.8 (28.0)	1.01 (0.99, 1.00)	0.737
Admission HR, mean (SD)	76.1 (16.4)	75.9 (17.0)	1.00 (0.99, 1.01)	0.879
Diabetes mellitus, n (%)	67 (1.3)	5,094 (98.7)	0.84 (0.61, 1.15)	0.276
Hypertension, n (%)	109 (1.4)	7,811 (98.6)	0.88 (0.63, 1.23)	0.454
Chronic kidney disease, n (%)	66 (1.6)	4,147 (98.4)	1.16 (0.85, 1.60)	0.348
Dialysis, n (%)	12 (2.0)	592 (98.0)	1.43 (0.79, 2.59)	0.239
Cerebrovascular disease, n (%)	14 (2.0)	702 (98.0)	1.41 (0.81, 2.45)	0.224
Chronic lung disease, n (%)	12 (3.1)	374 (96.9)	2.31 (1.27, 4.19)	0.006
Peripheral arterial disease, n (%)	5 (2.0)	241 (98.0)	1.44 (0.59, 3.55)	0.424
Prior PCI, n (%)	49 (1.3)	3,667 (98.7)	0.89 (0.63, 1.24)	0.482
CAD presentation, n (%)				
STEMI	47 (1.6)	2,809 (98.4)	1.37 (0.94, 2.01)	0.106
NSTEMI / Unstable angina	52 (1.6)	3,206 (98.4)	1.33 (0.92, 1.93)	0.134
Stable CAD	62 (1.2)	5,077 (98.8)	1	
Cardiogenic shock, n (%)	18 (1.6)	1,085 (98.4)	1.16 (0.71, 1.90)	0.554
Thrombolytics, n (%)	24 (3.8)	610 (96.2)	3.72 (2.08, 6.63)	<0.001
PCI status, n (%)				
Emergency or urgent	74 (1.9)	3,870 (98.1)	1.59 (1.16, 2.17)	0.004
Elective	87 (1.2)	7,222 (98.8)	1	
Fluoroscopy time (min), median (IQR)	16.1 (9.2, 29.3)	13.4 (8.0, 23.4)	1.005 (1.001, 1.010)	0.013
More than one puncture, n (%)	28 (3.7)	724 (96.3)	3.01 (1.99, 4.56)	<0.001
IABP, n (%)	6 (1.0)	597 (99.0)	0.68 (0.30, 1.54)	0.357
Manual compression, n (%)	145 (1.4)	10,391 (98.6)	0.61 (0.36, 1.03)	0.065
C-arm, n (%)	0 (0.0)	37 (100.0)	-	-
Closure device, n (%)	20 (2.2)	869 (97.8)	1.67 (1.04, 2.68)	0.034
P2Y12 inhibitors, n (%)				
Clopidogrel	130 (1.3)	9,807 (98.7)	0.95 (0.13, 6.92)	0.963
Prasugrel	2 (1.1)	172 (98.9)	0.84 (0.07, 9.38)	0.885
Ticagrelor	28 (2.6)	1,041 (97.4)	1.94 (0.26, 14.44)	0.519
No	1 (1.4)	72 (98.6)	1	
Parenteral anticoagulant, n (%)				
Unfractionated heparin	128 (1.3)	9,395 (98.7)	0.98 (0.40, 2.40)	0.957
Low molecular weight heparin	10 (1.6)	600 (98.4)	1.19 (0.40, 3.52)	0.749
Fondaparinux	0 (0.0)	11 (100.0)	-	-
Combine parenteral anticoagulant	18 (2.4)	728 (97.6)	1.77 (0.65, 4.81)	0.262
No	5 (1.4)	358 (98.6)	1	
Aspiration catheter, n (%)	13 (1.3)	998 (98.7)	0.89 (0.50, 1.57)	0.684

Table 2. Cont.

Factors	Status of hematoma		OR (95% CI)	p-value
	Yes, n=161	No, n=11,092		
Number of PCI procedure/doctor/year, n (%)				
≥75 cases	150 (1.4)	10,357 (98.6)	0.97 (0.52, 1.79)	0.917
<75 cases	11 (1.5)	735 (98.5)	1	
Number of PCI procedure/center/year, n (%)				
≥ 500 cases	135 (1.6)	8,261 (98.4)	1.05 (0.49, 2.25)	0.909
200 – 499 cases	19 (0.8)	2,383 (99.2)	0.51 (0.21, 1.22)	0.131
< 200 cases	7 (1.5)	448 (98.5)	1	

BMI=body mass index; CAD=coronary artery disease; HR=heart rate; IABP=intra-aortic balloon pump; IQR=interquartile range; NSTEMI=non-ST-segment elevation myocardial infarction; OR=odds ratio; PCI=percutaneous coronary intervention; SBP=systolic blood pressure; SD=standard deviation; STEMI=ST-segment elevation myocardial infarction.

Table 3.1. Factors associated with groin hematoma: a multivariate analysis (statistical model)

Factors	OR (95% CI)	p-value
Age, years	1.02 (1.01, 1.04)	0.001
BMI group		
≥30.0 kg/m^2	0.80 (0.39, 1.63)	0.534
23.0 to 29.9 kg/m^2	0.61 (0.36, 1.02)	0.061
18.5 to 22.9 kg/m^2	0.74 (0.44, 1.24)	0.254
<18.5 kg/m^2	1	
Chronic lung disease	1.86 (1.01, 3.41)	0.045
Fluoroscopy time (min)	1.006 (1.001, 1.010)	0.014
Emergency and urgent PCI	1.56 (1.14, 2.13)	0.006
Closure device use	1.66 (1.03, 2.66)	0.038
More than one puncture	2.89 (1.90, 4.39)	<0.001

BMI=body mass index; PCI=percutaneous coronary intervention

Table 3.2. Factors associated with groin hematoma: a multivariate analysis (clinical model)

Factors	OR (95% CI)	p-value
Age, years	1.03 (1.01, 1.04)	0.001
Female	1.18 (0.85, 1.64)	0.328
BMI group		
≥30.0 kg/m^2	0.83 (0.40, 1.70)	0.604
23.0 to 29.9 kg/m^2	0.62 (0.37, 1.06)	0.081
18.5 to 22.9 kg/m^2	0.74 (0.44, 1.25)	0.266
<18.5 kg/m^2	1	
Diabetes mellitus	0.85 (0.60, 1.19)	0.334
Hypertension	0.87 (0.60, 1.25)	0.449
CKD	0.95 (0.67, 1.34)	0.755
Peripheral arterial disease	1.23 (0.49, 3.07)	0.655
Fluoroscopy time (min)	1.006 (1.001, 1.010)	0.013
Emergency or urgent PCI	1.53 (1.11, 2.12)	0.010
Manual compression	0.67 (0.40, 1.14)	0.140
More than one puncture	2.84 (1.87, 4.31)	<0.001

BMI=body mass index; CKD=chronic kidney disease; PCI=percutaneous coronary intervention

directly explain. Asada et al. found that prolonged FT was an indicator of complex PCI, in which larger vascular sheath/catheter was used and more vessel manipulation was administered[36], and also maybe more anti-thrombotic medications were required for such complex and prolonged procedures, which those factors are directly contributed to groin hematoma and this could explain how prolonged FT showed an association with this complication. Unfortunately, data regarding procedure complexity and size of vascular sheath/catheter were not collected in our study, hence we could not further inspect this postulation.

It was interesting that closure device use was found to be associated with increasing risk of groin hematoma from univariate and multivariate (statistical model) analysis, whereas a trend of reducing risk of groin hematoma was found in manual compression from univariate analysis. Although a remote meta-analysis of randomized trials implied that closure device use had a higher rate of vascular complication including groin hematoma compared with manual compression after cardiac catheterization[37], however, our findings were contrary from recent studies, in which a large registry showed that use of femoral artery closure devices was associated with reduction of groin hematoma compared with manual compression in patient underwent PCI[38], and meta-analyses of randomized clinical trials in patients after TFA PCI revealed similar rate of groin hematoma between use of closure devices and manual compression[39,40], albeit patients with high risk of puncture site complications were excluded from most of studies. Manual compression is still considered a "default" hemostatic method among interventionists in Thailand, as 93.6% of patients underwent manual compression in this study. This practice has been long well established which most practitioners are expertise in safely managing manual compression, so this could probably result to a low rate of groin complication with this method, whereas closure device is considered a non-traditional practice, which

its use accompanied with less experiences and probably was applied in patients with not at-low-risk of groin complication, then the rate of groin hematoma was high after closure device use in our practice atmosphere.

Strong points of our study include large all-comer population and capturing all spectrum of CAD presentations in contemporary practices. However, some limitations are contained including 1) only visible hematoma was studied, whereas invisible hematoma, i.e., retroperitoneal hematoma, which is more clinically important, was not evaluated, then all burden and risk of bleeding could not be completely elucidated. The incidence of retroperitoneal hematoma, however, was generally low compared with groin hematoma and its predisposing risk was mainly related with site of puncture (high puncture) rather than patient- or procedure-related, so lack of data of retroperitoneal hematoma seems to have less impact on studying of groin bleeding in overall. 2) since evaluation of hematoma was totally relied on researchers of each site, hence interobserver variation in interpretation of hematoma could not be excluded. And 3) most of the participating study sites are referral center, where PCI volume is high and operators hold lot of experiences, so the results of study should certainly contain biases and may not be generally inferred to all PCI center settings. Findings from this study assured safety of TFA PCI regarding groin hematoma in present-day practices among all spectrums of CAD patients, however, as TFA is generally not a preferred approach, especially in patients with ACS, then groin hematoma should still be aware in high-risk conditions, i.e., old age, emergency or urgent PCI, more than one puncture, and prolonged FT or procedural time. This study also raised concerns about association between use of vascular closure device and groin hematoma in our country, especially in particular setting where closure device is not a conventional hemostatic method.

Conclusion

From this large and contemporary registry of PCI, we found that incidence of groin hematoma after TFA PCI was low across spectrums of CAD presentations. The identified predisposing factors for developing groin hematoma were old age, prolonged FT, emergency or urgent PCI, and more than one puncture, which almost all of those factors were in line with old knowledge, except prolonged FT which was novel. Our findings reflected the nature of groin hematoma after PCI with TFA in current practices, where TRA is gaining more popularity and TFA is less performed. TFA, however, is obligatory and unavoidable in particular procedure, hence being aware of at-risk patients and keeping adjustment of modifiable risk factors should always be emphasized in aiming to curb the arising of this preventable complication.

What is already known on this topic?

Definition and incidence of groin hematoma after percutaneous coronary intervention (PCI) with trans-femoral approach (TFA) was markedly varied across studies.

Traditional risk factors for groin hematoma after PCI with TFA are advanced age, female, increase body mass index (BMI), lower BMI, hypertension, heart failure, chronic kidney disease, chronic lung disease, peripheral arterial disease, emergency or urgent PCI, and multiple punctures.

What this study adds?

Incidence of groin hematoma after PCI with TFA among Thai PCI centers was very low (1.43%).

Older age, emergency or urgent PCI, and more than one puncture were consistently associated with development of groin hematoma after PCI with TFA even during modern PCI era.

Prolonged fluoroscopic time was newly found to be associated with development of groin hematoma.

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Conflicts of interest

The authors declare no conflict of interest.

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