

Vascular Complications from Coronary Angiography/Percutaneous Coronary Intervention: Comparing Day Case Patients and Inpatients in a Tertiary Hospital in Thailand: A Retrospective Cohort Study

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Abstract:

Objective: To compare the incidence along with risk factors of vascular complications between patients having undergone Coronary angiography/Percutaneous Coronary Interventions (CAG/PCIs); as day cases and those as inpatients.

Material and Methods: Our study is a retrospective cohort study. We performed a retrospective chart review of the patients, visiting a heart center of the hospital from October, 2014 to September, 2018. We included patients of a minimum 18 years of age, who had undergone CAG/PCIs. Excluded patients were those who had been referred from other hospitals. The main outcomes were vascular complications defined as: (1) bleeding with significant blood loss during the procedure. (2) Hematoma within 1 month after the procedure. Wilcoxon's rank sum and chi-squared test were used to assess the risk factors.

Results: Of all 784 patients having undergone CAG/PCI, 387 were day cases and 397 were inpatients. Only 12 cases developed vascular complications. The incidence of vascular complications was not significantly different between either day case; whose incidence was 1.3% (95% confidence interval (CI), 0.72–1.87), and inpatients; whose incidence was 1.8% (95% CI, 1.10–2.42). We found that the risk factors of vascular complications were percutaneous coronary intervention, and using a vascular closure device to remove the introducer sheath.

Conclusion: Performing CAG/PCI as day cases did not increase the risks of complications post-procedure, as compare to the inpatients. However, due to the small numbers of patients with complications future studies with more patients are needed to ensure the safety of day case CAG/PCI. Patients undergoing PCI, or patients with vascular closure devices used should be closely observed before discharge.

Keywords: cardiac catheterization, day case, percutaneous coronary intervention, vascular complications

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Introduction

Cardiovascular catheterization is a standard procedure for diagnosis and treatment of coronary artery disease (CAD).¹ Coronary angiography (CAG) is a procedure in which the cardiac catheterization is performed with angiography, so as to obtain images of coronary arteries to confirm the diagnosis of CAD. Percutaneous coronary intervention (PCI) is an angioplasty performed with stent implantation as a treatment for CAD. During the procedure, the introducer sheaths are placed into the femoral or radial artery as a guide for catheter insertion. Placement of the introducer sheath may cause vascular complications, including bleeding, hematoma and retro-peritoneal bleeding.²⁻⁴ Most major, adverse events often occur within the first 6 hours after PCI.⁵

In 2009, the Society for Cardiovascular Angiography and Interventions, endorsed by the American College of Cardiology Foundation, stated on their consensus documents that: after PCI, patients could be discharged within the same calendar day after the intervention.⁶ After that, various studies also supported that same day discharge PCIs or day case PCIs are both feasible and safe.⁷⁻⁹ Day case PCIs can alleviate the financial burden for patients, increase the turnover rate of hospital beds and reduce healthcare expenditures; especially in countries whose universal healthcare covers a majority of their population.

Currently, 57.0% of the British cardiologists along with 32.0% of Canadian cardiologists perform same day discharge CAG/PCIs as routine practice.¹⁰ In Thailand, the proportion of cardiologists performing day case practice has not been clearly reported. In Songklanagarind Hospital the numbers of same-day cases were 28 cases in 2009 and 177 cases in 2016.

From systematic review, a randomized control trial by Brayton et al.⁵, reported factors related to vascular

complications were patients with hypertension, receiving dual antiplatelet, coronary intervention, receiving heparin, introducer sheath size, and use of glycoprotein IIb/IIIa inhibitors during the procedure.⁵

Although, the incidence of vascular complications after cardiac catheterization were reported by studies in Thailand¹¹ and other countries¹²⁻¹⁵, the risk factors and criteria for selecting patients as a day case CAG/PCI has not been studied in the Thai population, and this in effect may be different from other countries. In so saying, we hypothesized vascular complications would not differ between the day case and inpatient CAG/PCI groups. Therefore, we conducted a cross sectional to objectively compare the incidence along with risk factors of vascular complications between patients having undergone CAG/PCIs, as day cases and those as inpatients.

Material and Methods

This research project has been approved by the Human Ethics Research Committee of Faculty of Medicine, Prince of Songkla University (REC. 61-021-24-7).

The study design was a retrospective cohort study. The study setting was at Naradhiwas Rajangarindra Heart Center, Songklanagarind Hospital, a tertiary hospital in southern Thailand. CAG/PCIs were performed by 3 interventionists in 2 catheterization laboratory rooms at the center. A retrospective electronic chart review by purposively sampling was performed to collect demographic factors, laboratory data and clinical outcome. These were vascular complications of patients having undergone CAG/PCI, from October, 2014 to September, 2018. We included patients with a minimum of 18 years of age whom had undergone CAG/PCI. Patients, referred to and from the other hospitals were excluded. Day case patients were observed for 4 hours after sheath removal to ensure good mobility

before discharge from the heart center. Inpatients were observed overnight before discharge from the ward. The outcomes were vascular complications defined as: (1) bleeding with significant blood loss; determined by a Hematocrit drop $>3.0\%$ ¹⁶ and required a blood transfusion during the procedure. (2) Hematoma diameter of more than 5 cm.¹⁷ Vascular complications were retrieved from the electronic medical records of Songklanagarind Hospital. The complications observed by nurses, or doctors at the inpatient department (IPD), outpatient department (OPD) or emergency room (ER) within 1 month after the procedure were noted in the case record forms.

The sample size was calculated based on the differences of two sample proportions of patients with vascular complications, between the day case and the inpatient group, assuming z-distribution according to Wang and Chow.¹⁸ From a meta-analysis by Brayton et al.⁵, the incidences of vascular complications in the day case group was 7.4%; whereas, the occurrence of vascular complications in the inpatient group was 5.3%.⁵ Assuming alpha error of 0.05 and power of 80.0%, the required sample size was 288 cases per group.

All analysis was performed in R version 3.5.2 (R Core Team, Austria). Double entry was performed by two researchers who entered and examined the integrity of the data of each patient independently, if the data showed inconsistencies, corrections were made for the patient records. For descriptive statistics, numbers and percentages were used to describe the categorical data. The mean, with standard deviation or median with Interquartile range (IQR), were used to describe the continuous variables, according to the distribution. To compare the characteristics as well as outcomes between the day case and inpatient groups, either Wilcoxon's test or chi-squared was used; where applicable. For subgroup analysis, we stratified and compared the patients by procedures: CAG and PCI,

as shown in Table 3. The p-value of chi-squared was based on Yates' continuity correction to prevent over-estimation of statistical significance for small incidence of complications.¹⁹ A p-value of equal to or less than 0.05 was considered statistically significant.

Results

In total 784 patients underwent CAG/PCIs, from October, 2014 to September, 2018 and were included in this study. Of the 784 patients, 387 were day cases and 397 were inpatients. Patients were predominantly male (69.8%), and the median (IQR) age was 61 (54–70) years of age. The most common underlying diseases were hypertension (13.3%) and dyslipidemia (12.6%). The inpatients were older than the day case patients (62 (56–71) vs 60 (52–69) years old). Most of the inpatients (81.6%) were taking dual anti-platelet drugs (Table 1).

In comparison to the inpatients, day case patients had a higher proportion of patients undergoing CAG (86.0% vs 31.0%, respectively, p -value <0.001). None of the inpatients had their radial artery as the vascular access site. The proportion of 7 French. (Fr.) sheath used was slightly higher in inpatients (3.5% vs 0.5%, respectively, p -value=0.004). Inpatients received higher doses of heparin than the day case patients 6,000 (5,000–6,000) units vs 5,000 (2,500–6,000) units, respectively, p -value <0.001 (Table 2)

Of the 784 patients, 456 (58.2%) patients having undergone CAG, a whole 328 (41.8%) had undergone PCI. The common vascular access site was mainly the femoral artery (95.7%). Introducer sheath size 6 Fr. was used in about half of the procedures. The median heparin usage were about 5,000 units. The common method for hemostasis was manual compression (88.4%). Hemostasis methods used were not different between day cases or inpatients (Table 2).

Table 1 Baseline characteristics

Characteristics	Total	Inpatients	Day case	p-value
Continuous variables				
Age (yrs) [median (Q1-Q3)]	61 (54-70)	62 (56-71)	60 (52-69)	0.001**
BMI (kg/m ²) [median (Q1-Q3)]	23.8 (21.3-26.7)	24.1 (21.8-27.0)	23.6 (21.0-26.5)	0.106**
Total [n (%)]	784 (100.0)	397 (50.6)	387 (49.4)	
Sex				0.243*
Male	547 (69.8)	285 (71.8)	262 (67.7)	
Underlying disease				0.995*
No known underlying disease	321 (40.9)	162 (40.8)	159 (41.1)	
Only one disease				
DM	28 (3.6)	17 (7.2)	11 (4.8)	0.372*
HT	104 (13.3)	51 (12.8)	53 (13.7)	0.806*
DLP	99 (12.6)	36 (9.1)	63 (16.3)	0.003*
Two or more diseases				
DM+HT	54 (6.9)	27 (6.8)	27 (7.0)	1.000*
HT+DLP	103 (13.1)	65 (16.4)	38 (9.8)	0.009*
DM+DLP	12 (1.5)	2 (0.5)	10 (2.6)	0.037*
DM+HT+DLP	63 (8.0)	37 (9.3)	26 (6.7)	0.230*
History of anticoagulant uses				
No anticoagulant	69 (8.8)	18 (4.5)	51 (13.2)	<0.001*
ASA	88 (11.2)	34 (8.6)	54 (14.0)	0.023*
P2Y12	8 (1.0)	4 (0.1)	4 (0.1)	1.000*
DAPT (ASA+P2Y12)	522 (66.6)	324 (81.6)	198 (51.2)	<0.001*
Warfarin	74 (9.4)	14 (3.5)	60 (15.5)	<0.001*
ASA+warfarin	13 (1.7)	2 (0.2)	11 (2.8)	0.022*
P2Y12+warfarin	1 (0.1)	1 (0.3)	0 (0.0)	1.000*
DAPT+warfarin	9 (1.1)	0 (0.0)	9 (2.3)	0.006*

BMI=body mass index, Q1=1st quartile, Q3=3rd quartile, kg/m²=kilogram per square meter, DM=diabetes mellitus, HT=essential hypertension, DLP=dyslipidemia, ASA=aspirin; P2Y12=P2Y12 receptor antagonist, DAPT=dual antiplatelet therapy

*X² test **Wilcoxon's rank sum test

Table 2 Distribution of patients by procedural characteristics

Procedural factors	Total Number (%)	Inpatients Number (%)	Day case Number (%)	p-value
Total	784 (100.0)	397 (50.6)	387 (49.4)	
Procedure				<0.001*
CAG	456 (58.2)	123 (31.0)	333 (86.0)	
PCI	328 (41.8)	274 (69.0)	54 (14.0)	
Vascular access site				<0.001*
Femoral artery	750 (95.7)	397 (100.0)	353 (91.2)	
Radial artery	34 (4.3)	0 (0.0)	34 (8.8)	
Sheath size				
Sheath 5 Fr.	331 (42.2)	150 (37.8)	181 (46.8)	0.013*
Sheath 6 Fr.	436 (55.6)	232 (58.4)	204 (52.7)	0.123*
Sheath 7 Fr.	17 (2.2)	15 (3.5)	2 (0.5)	0.004*

Table 2 (continued)

Procedural factors	Total	Inpatients	Day case	p-value
	Number (%)	Number (%)	Number (%)	
Heparin (units) [median (Q1–Q3)]	5,000 (5,000–6,000)	6,000 (5,000–6,000)	5,000 (2,500–6,000)	<0.001**
Blood pressure during procedure				
SBP (mmHg) [median (Q1–Q3)]	141 (126–161)	144 (129–165)	138 (123–155)	<0.001**
DBP (mmHg) [median (Q1–Q3)]	82 (73.0–90.5)	82.5 (74.0–91.0)	80 (72.0–90.0)	0.036**
Hemostasis method after sheath removal				0.928*
Manual compression	693 (88.4)	366 (92.2)	327 (92.6)	
Vascular closure device (proglide®)	57 (7.3)	31 (7.8)	26 (7.4)	
Vascular compression device (TR band® in transradial accessed sited)	34 (4.3)	0 (0.0)	34 (100.0)	
Vascular complications	12 (1.5)	7 (1.8)	5 (1.3)	
Bleeding	6 (0.8)	5 (1.3)	1 (0.3)	0.231*
Hematoma	6 (0.8)	2 (0.5)	4 (1.0)	0.659*

CAG=percutaneous transluminal coronary angiography, PCI=percutaneous coronary intervention; Fr.=french; Q1=1st quartile, Q3=3rd quartile, SBP=systolic blood pressure; DBP=diastolic blood pressure; mmHg.= millimeters of mercury; p-value= probability value

*X² test **Wilcoxon's rank sum tes

For either day case patients or inpatients, patients who underwent PCI used a sheath size of 7 French, while none undergoing CAG used. Patients who underwent PCI, in both groups, received median (Q1–Q3) amounts of heparin at 6,000 (5,000–6,000) units; while for patients undergoing CAG received the median (Q1–Q3) amounts of heparin, at 0 units in the inpatient group, and 2,000 (2,000–3,000) units. For the inpatient subgroup, patients undergoing CAG had slightly higher systolic blood pressure (SBP) and diastolic blood pressure (DBP) than patients undergoing PCI (p-value=0.003). Despite not being statistically significant, the patients who underwent PCI showed slightly higher incidence of vascular complications; including bleeding and hematoma, than patients having undergone CAG (Table 3).

Only 12 patients had vascular complications, 6 patients had access site bleeding; while another 6 patients

had access site hematoma within a month. The incidence of vascular complications did not differ between the day case group (1.30%, 95% confidence interval (CI): 0.72–1.87) or inpatients (1.80%, 95% CI: 1.10–2.42). Vascular complications were related to PCI, and the hemostasis method after sheath removal. Vascular complications occurred more frequently in patients who underwent PCI than those who underwent CAG (2.7% vs 0.7%, p-value =0.040). Using Proglide® [Abbott, The United State of America (USA)], a vascular closure device, as a hemostasis method after sheath removal, had a higher chance of vascular complication occurrence, than those performed via manual compression (10.5% vs 0.9%, p-value<0.001) (Table 4). However, there were no serious vascular complications. Underlying diseases, SBP, DBP, vascular access site, history of anticoagulant uses were not related to vascular complications (Table 4).

Table 3 Distribution of Patients by procedures, stratified by CAG and PCI

Procedural factors	Total n (%)		Inpatients n (%)		Day case n (%)		p-value
	CAG	PCI	CAG	PCI	CAG	PCI	
Total	784 (100.0)	274 (69.0)	123 (31.0)	274 (69.0)	333 (86.0)	54 (14.0)	
Vascular access site							
Femoral artery	750 (95.7)	274 (69.0)	123 (31.0)	274 (69.0)	301 (90.4)	52 (96.3)	0.912*
Radial artery	34 (4.3)	0 (0.0)	0 (0.0)	0 (0.0)	32 (9.6)	2 (3.7)	0.088*
Sheath size							
Sheath 5 Fr.	331 (42.2)	55 (36.7)	95 (63.3)	55 (36.7)	178 (53.5)	3 (5.6)	0.468*
Sheath 6 Fr.	436 (55.6)	204 (87.9)	28 (12.1)	204 (87.9)	155 (46.5)	49 (90.7)	0.527*
Sheath 7 Fr.	17 (2.2)	15 (1.0)	0 (0.0)	15 (1.0)	0 (0.0)	2 (3.7)	0.005*
Heparin (units)	5,000	6,000	0 (0-0)	6,000	2,000	6,000	<0.001**
[median (Q1-Q3)]	(5,000-6,000)	(5,000-6,000)		(5,000-6,000)	(2,000-3,000)	(5,000-6,000)	
Blood pressure during procedure							
SBP (mmHg) [median (Q1-Q3)]	141 (126-161)	143 (127-163)	153 (133-172)	143 (127-163)	139 (123-155)	137 (121-152)	0.575**
DBP (mmHg) [median (Q1-Q3)]	82 (73.0-90.5)	81 (73.0-90.0)	85 (78.0-86.0)	81 (73.0-90.0)	81 (73.0-90.0)	75 (70.0-89.0)	0.126**
Hemostasis method after sheath removal							
Manual compression	693 (88.4)	243 (66.4)	123 (33.6)	243 (66.4)	301 (92.0)	26 (8.0)	0.926*
Vascular closure device (proglide®)	57 (7.3)	31 (12.7)	0 (0.0)	31 (12.7)	0 (0.0)	26 (50.0)	0.074*
Vascular compression device	34 (4.3)	0 (0.0)	0 (0.0)	0 (0.0)	32 (94.1)	2 (5.9)	
(TR band® in transradial accessed sited)							
Vascular Complications	12 (1.5)	5 (1.3)	7 (1.8)	5 (1.3)	0 (0.0)	1 (1.9)	0.298*
Bleeding	6 (0.8)	2 (0.5)	0 (0.0)	2 (0.5)	0 (0.0)	2 (3.7)	0.297*
Hematoma	6 (0.8)	2 (0.5)	0 (0.0)	2 (0.5)	0 (0.0)	2 (3.7)	

CAG=percutaneous transluminal coronary angiography, PCI=percutaneous coronary intervention, Fr.=french, Q1=1st quartile, Q3=3rd quartile, SBP=systolic blood pressure, DBP=diastolic blood pressure, mmHg.=millimeters of mercury

*X² test **Wilcoxon's rank sum test

Table 4 Procedure and characteristics of patients with vascular complications

Vascular complication	Total (n=784)	Yes (n=12)	No (n=772)	p-value
Courses of treatments				0.805*
Day case	387 (49.4)	5 (1.3)	382 (98.7)	
Admit	397 (50.6)	7 (1.8)	390 (98.2)	
Patients characteristics				
Sex				1.000*
Male	547 (69.8)	8 (1.5)	539 (98.5)	
Age (yrs) [median (Q1-Q3)]	61 (54.0-70.0)	54 (50.0-67.6)	61 (54.0-70.0)	0.207**
BMI	23.8 (21.3-26.7)	23.2 (21.1-24.1)	23.8 (21.3-26.7)	0.309**
Underlying disease				
No Known underlying disease	321 (40.9)	4 (1.2)	317 (98.8)	0.807*
DM	28 (3.6)	0 (0.0)	28 (100.0)	1.000*
HT	104 (13.3)	3 (2.9)	101 (97.1)	0.548*
DLP	99 (12.6)	2 (2.0)	97 (98.0)	1.000*
DM+HT	54 (6.9)	0 (0.0)	54 (100.0)	0.708*
DM+DLP	12 (1.5)	0 (0.0)	12 (100.0)	1.000*
HT+DLP	103 (13.1)	2 (1.9)	101 (98.1)	1.000*
DM+HT+DLP	63 (8.0)	1 (1.6)	62 (98.4)	1.000*
Procedure				0.040*
CAG	456 (58.2)	3 (0.7)	453 (99.3)	
PCI	328 (41.8)	9 (2.7)	319 (97.3)	
Vascular access site				1.000*
Femoral	750 (95.7)	12 (1.6)	738 (98.4)	
Radial	34 (4.3)	0 (0.0)	34 (100.0)	
Sheath size				
Sheath 5 Fr.	331 (42.2)	3 (25.0)	328 (42.5)	0.356*
Sheath 6 Fr.	436 (55.6)	8 (66.7)	428 (55.4)	0.628*
Sheath 7 Fr.	17 (2.2)	1 (8.3)	16 (2.1)	0.632*
Heparin (units)	5,000	6,000	5,000	0.208*
(median (Q1-Q3))	(5,000-6,000)	(6,000-6,000)	(5,000-6,000)	
SBP (mmHg.) [median (Q1-Q3)]	141 (126.0-161.0)	147 (131.0-155.0)	141 (126.0-162.0)	0.799**
DBP (mmHg.) [median (Q1-Q3)]	82 (73.0-90.5)	89 (82.0-93.0)	81 (73.0-90.0)	0.190**
Hemostasis method after sheath removal				<0.001*
Manual compression	693 (88.4)	6 (0.9)	687 (99.1)	
Vascular closure device (proglide®)	57 (7.3)	6 (10.5)	51 (89.5)	

yrs=years, Q1=1st quartile, Q3=3rd quartile, BMI=body mass index, DM=diabetes mellitus; HT=essential hypertension, DLP=dyslipidemia, CAG=percutaneous transluminal coronary angiography, PCI=percutaneous coronary intervention, Fr.=french, SBP=systolic blood pressure, DBP=diastolic blood pressure; mmHg.=millimeters of mercury

*X² test **Wilcoxon's rank sum test

Discussion

This study supported that: day case CAG/PCI was as safe as inpatient CAG/PCI. Only 12 cases developed vascular complications. The proportion of patients with vascular complications did not differ significantly between the day case group (1.3%, 95% CI: 0.72–1.87) and inpatient group (1.8%, 95% CI: 1.10– 2.42). Associated factors with the occurrence of vascular complications were: coronary interventions and hemostasis, with vascular closure devices used.

The incidence of vascular complications in our study was low (about 1.3% and 1.8%) in both day cases and inpatient groups. The systematic review, from a randomized control trial by Brayton et al.⁵, reported similar numbers of incidence. The same study also reported that: the vascular complications of the patients after CAG/PCI were not different between day case patients and inpatients.⁵ Similar studies by Shoff et al, Abdelaal et al. and Koch also found similar results, in that the complications were low in both patient groups.^{8,20,21} Brayton et al. found that patients with hypertension, receiving dual antiplatelet drugs, coronary interventions, receiving heparin, introducer sheath size and use of Glycoprotein IIb/IIIa inhibitors during the procedure were related to vascular complications.⁵ Our research did not find any relationship between these factors and vascular complications; with the exception of coronary interventions and the vascular closure device used.

A possible explanation for the relationship between coronary intervention and vascular complications might be procedural factors. In our subgroup analysis stratifying patients undergoing CAG or PCI, the patients having undergone PCI received higher doses of Heparin, additionally the size of the sheath used were generally larger than the patients undergoing CAG (Table 3). Therefore, those factors might explain why patients undergoing coronary intervention had higher incidence of vascular complications.

Using a vascular closure device (Proglide® (Abbott, USA)), as the homeostasis after the CAG/PCI, increased the risk of vascular complications, when compared to manual compression. Manual compression has been the conventional method for hemostasis after sheath removal for the femoral artery access site since 1953.²² Various studies have shown that vascular closure devices were effective for stopping bleeding after cardiovascular procedures.^{22,23} Studies also reported that suture mediated vascular closure devices have a similar numbers of patients with complications as that of manual compression.^{15,24} These devices are used to reduce the waiting time in mobilizing patients; however, compared to using the device, as a homeostasis, manual compressions are cheaper and do not require special equipment.^{25,26} In contrast to these studies, we found that vascular complications were higher in patients who used vascular closure devices. This might be due to the lack of skills and inexperience of healthcare personal. The device has been available, but has only been utilized for only about 2 years in the heart center before the data collection of this study.

From our reviews, this study is the first study to examine complications of day case CAG/PCI in Thailand, as well as which the sample size was relatively large, compared to other studies in Thailand. However, due to its retrospective design, confounding factors by indication, such as only low risk case being selected for the day case patients could not be avoided. In addition, the number of patients with vascular complications was small, so we could not perform multivariate regression analysis to assess the relationship between associate factors with the occurrence of vascular complications while controlling for confounders. Therefore, our result should be interpreted with caution, due to the above mentioned limitations.

Nevertheless, this study shows that the incidences of vascular complications in the day case group were as low as those in the inpatient group.⁸ Hence, CAG/PCI can

be performed as a day case procedure in selective patients safely, without the added risks of vascular complications.

Conclusion

Day case CAG/PCI can be performed with a low risk of vascular complications. CAG/PCIs should be performed as day cases, so as to reduce the expenditures for patients, increase hospital bed turnover rates and reduce the reimbursements from universal healthcare coverage of the Ministry of Health. However, patients undergoing PCI, and using vascular closure devices should be closely observed before discharge.

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Conflict of Interest

None declared.

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