

# Relationships among patient characteristics, comorbidities, and vascular complications post-percutaneous coronary intervention

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**BACKGROUND:** The incidence of vascular complications (VCs) after femoral sheath removal following a percutaneous coronary intervention procedure (PCIP) occurs variably (5%-30%) depending on gender, body size, and comorbidities. VCs after a PCIP are distressful for subjects and increase costs and nursing care. Evidence on which subject characteristics contribute to VCs is inconsistent.

**OBJECTIVES:** The study objective was to determine which subject characteristics and comorbidities contribute to VCs post-PCIP.

**METHODS:** This correlational study included 306 subjects. Groin areas were assessed for the presence of VCs before, immediately after compression released, and 12 and 24 hours after femoral sheath removal for the presence of VCs. Subject characteristics and comorbidities were recorded.

**RESULTS:** The most frequently occurring VCs were ecchymosis, hematoma, and oozing. Age was significantly associated with ecchymosis, whereas hypertension was associated with a decreased level of ecchymosis. Body surface area significantly influenced hematoma formation.

**CONCLUSIONS:** Nurses caring for subjects' post-PCIP who are older and have a smaller body surface area may require extra vigilance and tailoring of nursing care to prevent development of VCs. (Heart Lung® 2008;37:190-195.)

More than one million percutaneous coronary intervention procedures (PCIPs) were performed in 2000 as a primary method for treating coronary heart disease, the leading cause of death in the United States.<sup>1</sup> PCIPs include angioplasty, atherectomy, laser angioplasty, stents, and radiation therapy for in-stent restenosis. To gain access to the coronary arteries and cardiac chambers, a femoral arterial sheath is inserted into the groin in the

cardiovascular (CV) laboratory. Anticoagulation is required during PCIPs to prevent acute thrombotic closure of coronary vessels, which can occur during insertion of interventional devices.

Bed rest is maintained before and after femoral sheath removal for 4 to 6 hours to promote healing of the arterial puncture site.<sup>2</sup> The femoral sheath is removed when the whole blood thrombin is less than 120 seconds, generally within 4 to 6 hours after the last dose of heparin. Compression of the femoral artery after sheath removal following a PCIP is a nursing responsibility in many acute and critical care settings. Nurses select one of three methods to achieve hemostasis (manual pressure, FemoStop [Radi Medical Systems, Uppsala, Sweden], or C-clamp). Regardless of the method to achieve hemostasis, compression of the femoral artery can lead to the development of vascular complications (VCs); however, the literature is inconclusive when determining which factors influence the development of VC. The purpose of this study was to determine which individual patient factors contribute to VC.

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## FACTORS CONTRIBUTING TO VASCULAR COMPLICATIONS AFTER FEMORAL SHEATH REMOVAL

Risks associated with femoral sheath removal include inadequate hemostasis resulting in VCs such as oozing, ecchymosis, hematoma, development of pseudoaneurysm, arteriovenous fistulas, thrombosis, arterial dissection, thromboemboli, and retroperitoneal bleeding. VCs are responsible for increased morbidity, length of stay, patient distress, and decreased patient comfort.<sup>3</sup> Serious VC rates after PCIP have been reported to range from 11% to 65%;<sup>3-7</sup> approximately 2% to 3% require surgical intervention.<sup>4</sup> Nursing care intensity is increased when VCs occur because of the numerous interventions required.

Lumsden et al,<sup>8</sup> in a prospective evaluation of surgically treated groin complications after PCIP, found that advanced age, small body size, and female gender may increase the risk of VC. Overall, complication rates were .6% for cardiac catheterization, 15% for percutaneous transluminal coronary angioplasty (PTCA), and 2.2% for atherectomy. Complication rates for coronary stent placement were 16% with a significant association ( $P < .0001$ ) with groin complications; however, these data are dated from 1990 to 1991, and coronary intervention equipment and techniques have changed in the past decade.

In a prospective study of 5042 patients, Waksman and colleagues<sup>4</sup> defined VC as a pseudoaneurysm, an arteriovenous fistula, a femoral laceration requiring surgical repair, a retroperitoneal hematoma, and significant bleeding. Groin complications were significantly more common in older ( $P < .0001$ ), female ( $P < .0001$ ), and heavier ( $P < .001$ ) subjects those with unstable angina ( $P < .036$ ) and hypertension ( $P < .0001$ ), and those with no history of PCIP ( $P < .0001$ ). The researchers theorized that those with higher systolic blood pressure on admission may reflect higher pressure during sheath removal, although this was not measured during removal and the presence of unstable angina may require prolonged administration of heparin. There was no difference in body mass index between men and women in this study.

Skillman and colleagues<sup>9</sup> described factors associated with arterial complications to be the size of catheter or sheath, use of anticoagulant and/or antiplatelet drugs, site and method of sheath puncture, presence and extent of peripheral vascular disease (PVD), and obesity. Other subject characteristics were not cited.

Muller et al<sup>10</sup> described relationships between complex PCIP and increased VC. Subjects with an increase in risk factors for atherosclerotic disease and PVD, and lower incidence of increased body weight showed a tendency for increased VC. Statistically significant variables were PVD and age more than 65 years.

Hamner and Stegall<sup>11</sup> studied predictors of complications after PCIP, looking at subject characteristics, type of procedure, intraprocedure variables, and post-insertion variables. The only subject characteristics that were significant were decreased ( $P < .0152$ ) weight and partial thromboplastin time greater than 60 seconds ( $P < .0093$ ).

Nasser et al<sup>12</sup> published a review of current English language literature on the incidence, diagnosis, prevention, and treatment of VCs after PCI. Complications were defined as hematomas, pseudoaneurysms, arteriovenous fistulae, acute arterial occlusions, cholesterol emboli, and infections. Subject characteristics that were found to be major predictors of VC were advanced age, female, repeat procedures, PVD, level of anticoagulation, use of intraprocedural thrombolytic agents, and increased creatinine levels. Minor predictors were level and length of time of anticoagulation, use of thrombolytic agents, elevated creatinine levels, low platelet counts, long periods of anticoagulation, and larger femoral sheath size.

In summary, factors that contribute to the development of VC are inconsistent in the research literature. Characteristics of lower weight, female sex, PVD, level of anticoagulation, and sheath size seem to be more consistently found in the literature as predictors of VC. Knowledge gaps remain as to what subject characteristics are significantly associated with VC. Nurses caring for these subjects need to know who may be more susceptible to VC so they may more appropriately plan care. To gain a clearer picture on which factors contribute to the development of VC, the following study was conducted.

## METHOD

### Design

The primary aim of this study was to determine whether certain subject characteristics and comorbidities contribute to VC post-PCIP. A correlational design was used to address the study aim. This is a secondary analysis of data from another study with the primary aim of determining which groin compression method produces the fewest VCs and subject symptoms after PCIP. These results are reported elsewhere.<sup>13</sup>

## Setting

Approval for the use of human subjects in research was obtained from the University of XX and XX Health System Institutional Review Boards. Investigators approached potential subjects about participation before any anxiolytic medications were administered, and subjects were informed of the purpose of the study, what they would be asked to do if they agreed to participate, and that they would not continue in the study if they did not have a PCIP while in the CV laboratory.

Participants were recruited from inpatient units and the Same Day Intervention Unit contained in the XX Heart Hospital (HH) of X Hospital (XH) from June 2001 to December 2003. XH is a 532-bed tertiary care center located in the urban Midwest. The HH consists of 135 beds within XH and is a busy comprehensive cardiac care center. In 2002, 7351 patients were admitted to HH with 1095 PCIPs performed.

## Sample

Any subject admitted to the Same Day Intervention Unit or in patient care unit at XXHH scheduled for an angiogram and possible PCIP who was alert, was age 18 years or older, could read and write English, and was undergoing an elective PCIP for treatment of unstable angina or acute myocardial infarction was invited to participate. Only subjects who actually had a PCIP while in the CV laboratory, met the inclusion criteria, and were admitted to the designated nursing care unit postprocedure were included in the final sample. Any subject undergoing a PCIP who was hemodynamically unstable, required an intra-aortic balloon pump, was intubated and ventilated, received thrombolytic therapy within 24 hours before or during the PCIP (streptokinase, alteplase recombinant, reteplase recombinant, tenecteplase, or other thrombolytics), had a known groin pathology, was admitted to an intensive care unit postprocedure, or had a documented mental incompetence contained in the medical record (eg, Alzheimer disease) was not approached or included in the final sample. A convenience sample of 306 subjects was recruited on the basis of power analysis calculations for the original study.<sup>13</sup>

A core group of 30 experienced registered nurses (RNs) were trained as study nurses. These RNs attended a formal education session that focused on the protocol, demonstration, and verification of skill in groin compression techniques, and orientation to subject assessment, data collection and data re-

coding. Only trained RNs cared for enrolled study subjects.

The study RN assessed the groin area for the presence or absence of any VCs before sheath removal, immediately after compression was released, and 12 and 24 hours after femoral sheath removal. VCs included oozing (presence of any leakage of blood from the puncture site), ecchymosis (presence of any skin discoloration without a mass), hematoma (presence of a nonpulsatile mass > 4 cm), or pulsatile mass (presence of a palpable mass with movement corresponding to systole and diastole).

Data were collected before and after the PCIP from subjects and abstracted from the medical record regarding age, gender, ethnicity, presence of documented comorbidities (hypertension, angina and diabetes), current medications, current blood pressure, body surface area (BSA), type of PCIP and any complications during procedure, length of PCIP, size of femoral sheath, use of oral anticoagulants, medications administered during the PCIP, and medications administered before and after femoral sheath removal.

## Analysis

All data were entered and managed in a Microsoft Access database (Microsoft Corp, Redmond, Wash). Descriptive data were presented as counts and percentages for categorical data and means with standard deviations for interval data. Outcomes were defined as the number of times during the four assessment periods the complication occurred. Final counts indicated that few subjects had experienced any complication at all four time periods. Therefore, the final outcome variables were categorized as 0, 1, 2, 3, or 4. One subject who experienced a pulsatile mass was not included in analysis. Associations of variables of interest were first analyzed with the 4 VC counts using bivariate analysis. Because of the non-normal distribution of the variables, associations between interval variables were analyzed using a Spearman's correlation. Associations of categorical independent variables and outcomes were analyzed using a Mann-Whitney *U* test. Stepwise ordinal logistic regression was used to generate the most parsimonious model of independent variables significantly associated with VC. Ordinal regression assumes that there is the same proportional increase in risk from one count to the next higher count at every level. This assumption was tested for each model using a Score test. There was no indication of violation of this assumption for any of the models. SPSS (SPSS Inc, Chicago, Ill) or

SAS (SAS Institute Inc., Cary, NC) was used for data analysis.

## FINDINGS

### Demographic and baseline data

The mean age of subjects was 62.3 years. The majority of subjects were male (77%). Ethnicity was predominantly white and Hispanic ( $n = 9$ ; 2.9%) and other ( $n = 2$ ; .7%). The incidence of comorbidities was hypertension (62%), angina (47%), and diabetes (26.5%). PTCA with stent placement was the most common PCIP followed by brachytherapy with stent and PTCA, PTCA alone, stent placement alone, atherectomy, and other. The majority of subjects had a 6.0F femoral sheath placed in the CV laboratory, followed by 8.0F, 4.0F, and 7F. Table I describes all data collected. There were no documented medical complications for any subject while in the CV laboratory. No patients were lost to follow-up.

### Incidence of vascular complications

The presence of VCs before femoral sheath removal (Table II) included 58 subjects (19%) with oozing, 57 subjects (18%) with ecchymosis, and 59 subjects (19.3%) with hematoma. The incidence of pulsatile mass after sheath removal was limited to one subject and was not considered in further analysis. Overall, presence of vascular complications in subjects ranged from 2-37% (Table III). The incidence of oozing trended downward after sheath removal across all groin compression methods. Ecchymosis increased at each assessment point after sheath removal. Hematoma increased slightly between immediate femoral sheath removal and the 12-hour assessment period.

### Relationships among subject characteristics, comorbidities, and vascular complications

**Bivariate analysis of subject characteristics and vascular complications.** Age was found to be significantly correlated with the incidence of ecchymosis ( $r_s = .14$ ;  $P = .01$ ). BSA was significantly, negatively related to the number of periods of hematoma ( $r_s = -.13$ ;  $P = .004$ ). No other variables were found to be significantly related to VCs (Table IV).

**Multivariate analysis of subject characteristics and vascular complications.** Oozing: No subject characteristics or comorbidities were found to influence the incidence of oozing. Hematoma: BSA was the only variable found to be significantly associated

**Table I**  
Subject characteristics

Total N	306
Age (y)	33–90
Mean	62.3 (11.43)
Gender	
Men	(77%)
Women	(23%)
Ethnicity	
White	(96.4%)
Hispanic	(2.9%)
Other	(.7%)
Blood pressure (mm Hg)	126/70
Body surface area (m <sup>2</sup> )	Range 1.02–3.08
Type of PCIP	
PTCA with stent	(62%)
Brachytherapy with stent	(12%)
PTCA alone	(11%)
Stent alone	(8%)
Atherectomy and other	(7%)
Intraprocedural complications	None
Average length of PCIP (min)	(SD)
	69.5 (34.8)
Size of femoral sheath (French)	
4.0	(1.7%)
6.0	(90%)
7.0	(.3%)
8.0	(8%)
Aspirin use	95.4%

PTCA, Percutaneous transluminal coronary angioplasty; PCIP, percutaneous coronary intervention procedure; SD, standard deviation.

with the number of incidences of hematoma formation, which is consistent with the bivariate results. For every .1 increase in BSA, a subject was .88 times less likely to develop a hematoma. Ecchymosis: Age was found to be significantly associated with ecchymosis. For each increased year of age, a subject was 3% more likely to have an increased number of observation periods with ecchymosis. Subjects who had hypertension were half as likely to experience an increased number of observation periods with ecchymosis than those without hypertension.

**Table II**

Incidence of vascular complications (n = 306)

Vascular complications	Before sheath removal	After compression released	12 h after removal	24 h after removal or at discharge
Hematoma	59 (19.3%)	54 (17.6%)	60 (19.6%)	45 (14.7%)
Oozing	58 (18.9%)	32 (10.5%)	19 (6%)	6 (2%)
Ecchymosis	57 (18.6%)	64 (21%)	112 (36.6%)	107 (35%)
Pulsatile mass	0	0	1 (.3%)	1 (.3%)

**Table III**

Relationships of patient characteristics and comorbidities with number of periods with vascular complications

Patient characteristics and comorbidities	Hematoma		Oozing		Ecchymosis	
	Correlations	P value	Correlations	P value	Correlations	P value
Age	.07	.21	.06	.28	.14	*.01
Body surface area	-.13	*.004	*-.05	.35	*-.02	.72

  

No. of periods	Hematoma			Oozing			Ecchymosis		
	Mean (range)	No	Yes	Mean (range)	No	Yes	Mean (range)	No	Yes
Hypertension	.72 (0-3)	.65 (0-3)	*.41	.44 (0-2)	.38 (0-2)	.33	1.2 (0-3)	.83 (0-3)	*.02
Diabetes	.73 (0-3)	.51 (0-3)	.14	.44 (0-2)	.30 (0-2)	.12	1.0 (0-3)	.83 (0-3)	.29
Angina	.57 (0-3)	.78 (0-3)	*.10	.33 (0-2)	.49 (0-2)	.08	.84 (0-3)	1.1 (0-3)	.11

\*Statistically significant.

## DISCUSSION

Assessment and management of VC and symptoms are important nursing care responsibilities for patients undergoing PCIP. The purpose of this correlational study was to determine which subject characteristics were related to VC post-PCIP. VCs in this study were higher than reported in the literature. Complications of oozing, hematoma, and ecchymosis were all present before sheath removal. Ecchymosis was the most frequent complication seen after sheath removal and increased over time. Hematoma and oozing tended to decrease over time after sheath removal. Older patients had an increased number of observation periods with ecchymosis, and smaller patients had an increased number of observation periods with hematoma. Normal or lower blood pressure may play a role in the development of ecchymosis. The relationship between increased age and increased incidence of ecchymosis may be related to increased friability of

vasculature, resulting in increased subcutaneous oozing. The relationship of smaller BSA and hematoma is unclear; perhaps increased adipose tissue in the subcutaneous area plays a role in improving hemostasis.

The definitions of complications in this study differ from those reported in the medical literature in that they are more conservative and therefore capture more complications. Complications cited in the literature are typically those that require medical intervention, such as increased length of stay or blood transfusions because of blood loss related to groin bleeding. The outcomes of this study are consistent with previous studies in identifying age and female sex being associated with a higher incidence of VC. Although these complications may not require medical or surgical intervention, nursing care is intensified. Discomfort and distress may also increase with the development of complications, requiring pharmacologic intervention.

**Table IV**

Stepwise ordinal regression of patient characteristics and comorbidities with number of periods with vascular complications

Patient characteristics and comorbidities	Hematoma		Ecchymosis	
	OR (95% CI)	P value	OR (95% CI)	P value
Age			1.03 (1.01–1.05)	.004
Body surface area	.88 (.80–.98)	.03		
Hypertension			.53 (.33–.82)	.006

OR, Odds ratio; CI, confidence interval.

No significant predictors of periods of oozing.

## Directions for future research

This study was limited to examination of only the subject characteristics of age, gender, BSA, and three common comorbidities identified in the medical record: hypertension, diabetes, and angina. There may be other factors contributing to VC. Although ecchymosis was the most frequent complication observed and significantly associated with age, there may be other factors that impact ecchymosis and warrant further investigation. Further study of the clinical significance of VC, the relationship of BSA and normotension or hypertension, and cost-effectiveness of managing the defined complications are needed to determine appropriate interventions.

## Implications for nursing practice

Nurses need to be more vigilant in the care of subjects with VC before sheath removal, with advanced age, and with smaller BSA. The anticipation of VC by nurses recognizing those patients at higher risk for VC may alter nurses' frequency of groin assessment, individualize patient education on postprocedure care, and alter staffing patterns. Education about the types of VC is required for subjects at risk to enlist their cooperation in activity restrictions after sheath removal. Evidenced-based guidelines need to be developed to guide nursing practice in sheath removal, assessment, and care post-sheath removal.

## CONCLUSIONS

Subjects who are older in age and smaller in size have an increased risk for VC after PICP. Ecchymosis is associated with advanced age, whereas those with a lower BSA have an increased risk for hematoma development. The association of hypertension and decreased levels of ecchymosis is not clear. Anticipating the potential for

VCs in older and smaller subjects should be incorporated in caring for subjects after PCIP.

## REFERENCES

- Heart disease and stroke statistics. Vol. 2004. Dallas, TX: American Heart Association; 2004.
- Interdisciplinary management of the interventional patient. In: Apple S, Lindsay J, eds. Principles and practice for interventional cardiology. Baltimore. Lippincott Williams & Wilkins; 2000:229-47.
- Pracyk J, Wall T, Longabaugh P, et al. A randomized trial of vascular hemostasis techniques to reduce femoral vascular complications after coronary intervention. *Am J Cardiol* 1998; 81:970-6.
- Waksman R, King S, Douglas J, et al. Predictors of groin complications after balloon and new-device coronary intervention. *Am J Cardiol* 1995;75:886-9.
- Kresowik T, Khoury M, Miller B, et al. A prospective study of the incidence and natural history of femoral vascular complications after percutaneous transluminal coronary angioplasty. *J Vasc Surg* 1991;13:328-35.
- Lehmann K, Heath-Lange S, Ferris S. Randomized comparison of hemostasis techniques after invasive cardiovascular procedures. *Am Heart J* 1999;138:1118-25.
- Rudisill P, Williams L, Craig S, Schopp P. Study of mechanical versus manual/mechanical compression following various interventional cardiology procedures. *J Cardiovasc Nurs* 1997;11:15-21.
- Lumsden A, Miller J, Kosineki TF, Salam A, Smith R. A prospective evaluation of surgically treated groin complications following percutaneous cardiac procedures. *Am Surg* 1994;60:132-7.
- Skillman J, Kim D, Baim D. Vascular complications of percutaneous cardiac interventions. *Arch Surg* 1988;123:1207-12.
- Muller D, Shamir K, Ellis S, Topol E. Peripheral vascular complications after conventional and complex percutaneous coronary interventional procedures. *Am J Cardiol* 1996;69:63-8.
- Hamner J, Stegall G. Predictors of complications after sheath removal following percutaneous coronary interventional procedures. *Adv Pract Nurs Q* 1996;2:23-30.
- Nasser T, Mohler E, Wilensky R, Hathaway D. Peripheral vascular complications following coronary interventional procedures. *Clin Cardiol* 1995;18:609-14.
- Chlan L, Sabo J, Savik K. Effects of three groin compression methods on patient discomfort, distress, and vascular complications following a percutaneous coronary intervention procedure. *Nurs Res* 2005;54:391-8.