Predictors of Vascular Complications Post Diagnostic Cardiac Catheterization and Percutaneous Coronary Interventions

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Care of patients after cardiac catheterization and/or percutaneous coronary intervention is largely the responsibility of nurses. The identification of risk factors for vascular complications from these procedures is important for the development of protocols to prevent complications. This article describes a retrospective, descriptive, and correlational study of 11,119 patients who underwent cardiac catheterization and/or percutaneous intervention, with femoral artery access, in the years 2001 to 2003. Increased risk for vascular complications was found in patients who were older than 70 years, were female, had renal failure, underwent percutaneous intervention, and had a venous sheath.

Keywords: Cardiac catheterization, Percutaneous coronary intervention, Risk factors, Vascular complications

According to the American Heart Association statistics and the goals of Healthy People 2010, the number of people in the United States who undergo diagnostic cardiac catheterization (CC) and/or percutaneous coronary intervention (PCI) is approaching 3 million per year. The percutaneous femoral arterial approach used for CC and PCI presents a risk of vascular access complications in these patients. The American College of Cardiology’s benchmark for the incidence of all complications, major adverse cardiac events, stroke, death, renal failure (RF), and vascular complications is no more than 1% for diagnostic CC and 3% for PCI. However, the incidences of vascular access complications alone have been reported to be anywhere from 0.1% to 61%, depending
on the definition of complications and covariates, including the type of procedure, anticoagulation, closure devices, age, sex, and comorbidities. An estimate of 3% incidence of vascular access site complications in nearly 3 million procedures would mean that almost 90,000 patients are affected annually in the United States. Nurses need to develop safe protocols of care for patients post CC and PCI that are research and evidence based.

**LITERATURE REVIEW**

To date, most practice guidelines for this care are based on expert opinion and are not evidence based. Guidelines differentiating care for high-risk patients are not available. Preliminary work in this area suggested that increased age, repeated intervention using the same vascular access site, and anticoagulation may be important factors contributing to the incidence of vascular complications. Other researchers have added female gender, past medical history of peripheral vascular disease (PVD), past medical history of hypertension (HTN), and undergoing a PCI to the list of potentially significant risk predictors for vascular complications. The presence of a venous sheath has also been suspected of, but not validated as, increasing the risk.

Attempts have been made to determine the best nursing interventions to prevent vascular complications after CC and PCI. A descriptive, correlational study of nursing care interventions after coronary procedures was conducted by joining the multicenter IMPACT II trial studying the effects of eptifibatide versus placebo in 4,010 patients. This research showed that many nursing interventions after PCI are not research based and that most nursing interventions aimed at decreasing vascular complications increase nursing workload but do not significantly affect the incidence of complications. This study confirmed the need for further clinical research studies to validate nursing practice in the care of these patients.

The trend in healthcare reimbursement results in decreased length of stay and higher costs for hours in specialty units such as the CC in PCI recovery area. Researchers have demonstrated that 2 to 4 hours of bed rest post femoral artery sheath removal may be safe for some patients. One report on the use of an arterial closure device stated that the vascular complication rate was only 0.78%, the time to hemostasis was 1.3 minutes, and the time to ambulation was within 5.5 minutes. Although this may have been true for a selected group of patients, there is a population of patients who require much longer initial compression time, longer time in bed, and careful selection of the method of vascular closure. Research is needed to clearly define which patients can safely be ambulated and discharged quickly versus which patients require more conservative protocols of care. As healthcare evolves, new devices and drugs are continuously introduced, bringing with them new risks. The identification of high-risk patients will be important when trials for new products are implemented. Risk analysis may provide support for reimbursement for longer stays in a recovery area for high-risk patients.

**CASE REPORT**

Although the incidence of vascular complications may be low, an analysis of the impact of these complications on individual patients and the healthcare system demonstrates the need to continue to find ways to decrease this incidence further. For example, in 2001, 2 elderly patients were admitted for diagnostic CC at a Mid Atlantic medical center. They were the same age, white, and had the same elective diagnostic procedure. One patient was female and the other was male. Both of these patients had 3 chronic disease processes. The female patient had a history of HTN, hyperlipidemia, and RF. The male patient had a history of HTN, hyperlipidemia, and PVD. The body mass indexes (BMI) of these 2 patients were 36 and 38, respectively; both had a venous and an arterial sheath placed, and they were treated by the same physician and the same catheterization laboratory staff. Both received the usual care at this institution, including a 6F sheath for a diagnostic catheterization, manual sheath removal by a nurse with 15 minutes of initial compression, a Syvek patch covered by a 2×2-in gauze, and Tegaderm as a dressing over the site, followed by bed rest for 4 hours with the affected leg immobilized and the head of the bed elevated no more than 60°. Both patients received the same post procedure explanation and teaching regarding immobility and splinting.

However, the recovery of these 2 patients was drastically different. The female patient developed 2 vascular complications, a hematoma and a pseudoaneurysm. Happily, both patients were discharged home, but the length of stay for the female patient was 8 days, with a total cost of $13,363.00, compared with a 2-day length of stay and a total cost of $6,627.00 for the male patient with no complications.
In light of this case report, we should ask ourselves what the differences are between patients that should alert us to use more conservative protocols to prevent vascular complications after CC and PCI. Should the treatment plan for the female patient have been different from the care usually provided? Would a more conservative approach to initial compression, in length of bed rest, have resulted in a more positive outcome?

**METHODS**

**Research Questions**

The purpose of the current study was to provide baseline data on the number and type of vascular complications post CC and PCI experienced at this institution and the significance of risk predictors for these complications. The findings of this study will lead to a prospective study of risk predictors. The research questions for this current study were the following: (1) What was the incidence of vascular complications post CC and PCI at the University of Virginia Heart and Vascular Center during the years 2001 through 2003? (2) Which patient demographic, comorbid, and procedural variables are statistically predictive for vascular access complications?

*The findings of this study will lead to a prospective study of risk predictors.*

**Design**

This was a retrospective, descriptive, and correlational study. Data from the records of patients who had undergone CC or PCI between 2001 and 2003 were retrieved from the Clinical Automated Office Solutions database.

**Sample**

This was a convenience sample of 11,119 patients who underwent CC or PCI in the years 2001 to 2003 at a large university medical center. Inclusion criteria were age more than 21 years, the use of the femoral artery for percutaneous access, and the routine standard of care for sheath removal in this institution. This standard of care included the use of a 6F sheath for CC and a no more than 8F sheath for PCI, activated clotting time of 180 seconds or less before sheath removal, manual pull with initial compression of 15 minutes, dressing of the groin site with a Syvek patch covered by a 2×2-in gauze and Tegaderm, and bed rest for 4 hours with the affected leg immobilized and the head of the bed elevated no more than 60°. In addition, preprocedural explanations and teaching regarding immobility and splinting of the groin site were done. Demographics are summarized in Table 1.

**Definitions**

For the purpose of this study, vascular access site complications included the following: hematoma, arteriovenous fistula (AVF), pseudoaneurysm, bleeding from the access site, other bleeding, femoral artery dissection, and loss of pulse to the distal extremity. The procedures of interest were (1) percutaneous diagnostic CC and (2) PCI, including CC and an intervention to open an occluded artery with balloon angioplasty, directional atherectomy, intracoronary stent placement, and/or vascular brachytherapy.

The American College of Cardiology National Cardiovascular Data Registry criteria for hematoma are (1) a hematoma greater or equal to 10 cm and (2) a drop in hemoglobin greater than 3.0 g/dL requiring

<table>
<thead>
<tr>
<th>TABLE 1</th>
<th>Demographic, Comorbid, and Procedural Characteristics of the Sample</th>
</tr>
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<tbody>
<tr>
<td>Age</td>
<td>62.8 (SD = 12)</td>
</tr>
<tr>
<td>BMI</td>
<td>29.4 (SD = 6)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age ≥70 years</td>
</tr>
<tr>
<td>Sex Male</td>
</tr>
<tr>
<td>Female</td>
</tr>
<tr>
<td>Race White</td>
</tr>
<tr>
<td>Black</td>
</tr>
<tr>
<td>Hispanic</td>
</tr>
<tr>
<td>Asian</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td>Comorbidities Hypertension</td>
</tr>
<tr>
<td>Diabetes</td>
</tr>
<tr>
<td>RF</td>
</tr>
<tr>
<td>PVD</td>
</tr>
<tr>
<td>Hypercholesteremia</td>
</tr>
<tr>
<td>Myocardial infarction</td>
</tr>
<tr>
<td>Aortic insufficiency</td>
</tr>
<tr>
<td>Aortic stenosis</td>
</tr>
<tr>
<td>Procedures Percutaneous coronary intervention</td>
</tr>
<tr>
<td>Venous sheath</td>
</tr>
</tbody>
</table>

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blood transfusion. Small hematoma was any hematoma smaller than the American College of Cardiology National Cardiovascular Data Registry definition.

**Procedure and Statistical Analysis**

In compliance with the Health Insurance Portability and Accountability Act and protection of human subjects, applications for the creation of a new data base and exempt status were submitted to, and approved by, the Human Investigations Committee. Data were downloaded from the existing database and stripped of all identifiers. After deleting those with missing and mis-coded data, the remaining sample consisted of 11,119 patients. Data on demographic variables, comorbidities, and procedural variables were entered into the Statistical Package for Social Sciences 11.5 for analysis.

First, descriptive statistics were calculated to determine the characteristics of the sample as well as the incidence and types of complications in this population. χ² Tests were performed to determine which patient demographic, comorbid, and procedural variables were significant between these patients with and without complications.

Hierarchical logistic regression was used to determine the significance of variables in predicting complications. The dependent variable was complication status (yes or no). Selected variables were entered into the hierarchical logistic regression in 3 blocks. Block 1 included demographic data: age (in 3 categories, 21–49, 50–69, and 70–99 years), BMI, and sex. Block 2 included comorbidities: diabetes mellitus (DM), history of HTN, RF, and PVD. Block 3 included procedural variables: whether or not the patient had a PCI and the presence or absence of a femoral venous sheath.

**Results**

The descriptive statistics for the demographic, comorbid, and procedural characteristics are reported in Table 1. Two thirds of the sample were men and 32% of the sample were older than 70 years. The most prevalent comorbidities were HTN (68%) and hypercholesterolemia (68%). Only 32% were documented as having DM, 11% PVD, and 9% RF. Twenty-nine percent of the population underwent PCI, and the remainder had diagnostic CC alone.

Vascular complications were documented in 189 (1.7%) patients. The incidence and types of complications are reported in Table 2. The incidence of vascular complications in patients who underwent PCI was 2.2%, and for CC, 1.5%. The most common complication was groin hematoma.

χ² Tests between the demographic, comorbid, and procedural variables and the presence of any complication were performed to identify variables that should be included in the logistic regression analysis. Age greater than 70 years, being female, HTN, RF, and PCI were all found to be significant predictors of any complication (P < .05; Table 3). Diabetes mellitus, PVD, BMI, and venous sheath were not found to be significant predictors by χ² test. Diabetes mellitus and PVD were included in the regression despite the lack of significant χ² because these variables have a known pathophysiologic effect on vascular integrity and have been found significant in other studies.6,9 Body mass index was

<table>
<thead>
<tr>
<th>TABLE 2</th>
<th>Incidence and Types of Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All Procedures</td>
</tr>
<tr>
<td></td>
<td>N</td>
</tr>
<tr>
<td>Any complication</td>
<td>189</td>
</tr>
<tr>
<td>Artery dissection</td>
<td>3</td>
</tr>
<tr>
<td>Arteriovenous fistula</td>
<td>3</td>
</tr>
<tr>
<td>Pseudoaneurysm</td>
<td>29</td>
</tr>
<tr>
<td>Loss of pulse</td>
<td>11</td>
</tr>
<tr>
<td>Bleeding at site</td>
<td>8</td>
</tr>
<tr>
<td>Other bleeding</td>
<td>20</td>
</tr>
<tr>
<td>Hematoma by American College of Cardiology definition</td>
<td>51</td>
</tr>
<tr>
<td>Small hematomas</td>
<td>95</td>
</tr>
</tbody>
</table>

Complications do not add up to 100% because some patients had more than one complication. Any complication is the number of patients who had complications and did not specify if they had more than one.
included because conflicting evidence of the role it plays in complications has been cited in other research.\textsuperscript{8,14} The presence of a venous sheath was included because it has been anecdotally suspected by clinical experts as a risk predictor.

In block 1 of the logistic regression model, the demographic variables of age greater than 70 years (odds ratio [OR] = 2.4, \(P < .01\)), female gender (OR = 1.6, \(P < .01\)), and higher BMI (OR = 5.8, \(P < .05\)) were found to be significant predictors of complications. In block 2, with the addition of the comorbidities, age and sex remained significant. The only comorbidity found significant was RF (OR = 1.8, \(P > .01\)). In the final block of the regression, age, sex, and RF continued to be significant, and PCI (OR = 1.8, \(P > .01\)) and venous sheath (OR = 1.4, \(P < .05\)) added significance to the model. The \(R^2\) for the total logistic regression model was 0.04.

Only 32\% of the sample were older than 70 years, but they represented 49\% of those with complications. Women made up only 37\% of the sample but represented 50\% of the patients with complications. Patients with RF represented 9\% of the sample but 15\% of those with complications. The variables BMI, HTN, DM, and PVD were not significant in this regression model.

\section*{DISCUSSION}

The findings from this study support previous researchers’ conclusions that advanced age, being female, and PCI increase the risk of femoral artery vascular access site complications. New evidence has been found implicating the comorbidity of RF and the presence of a venous sheath as significant risk predictors. However, the \(R^2\) for the current logistic regression model was 0.04, meaning that this model only accounts for approximately 4\% of the explanation of vascular complications in these patients. Therefore, there are other variables that contribute to the incidence of vascular complications that have not been identified by this model.

\begin{table}[h]
\centering
\begin{tabular}{|l|c|c|}
\hline
\textbf{Variable} & \textbf{\(\chi^2\)} & \textbf{\(P\)} \\
\hline
Age \geq 70 years & 24.174 & <.01 \\
Gender & 14.046 & <.01 \\
History of hypertension & 4.046 & .05 \\
History of diabetes & 0.006 & NS \\
History of RF & 7.846 & <.01 \\
History of PVD & 0.019 & NS \\
Hypercholesteremia & 2.112 & NS \\
Myocardial infarction & 0.183 & NS \\
PCI & 7.503 & <.01 \\
Venous sheath & 1.997 & NS \\
\hline
\end{tabular}
\caption{Effect of Variables on the Presence of a Complication by Chi-square Analysis}
\end{table}

\textsuperscript{NS} indicates nonsignificant \(P\) value >.05.

\section*{LIMITATIONS}

The major limitations of this study reside in the use of a retrospective analysis, a secondary data base, and the lack of reliability testing for the data stored in the database. Data on medication use and anticoagulation were not available through this database; thus, the influence of these factors could not be examined in this study. Other variables that may influence vascular complications after CC and PCI remain elusive, such as provider error and lack of cooperation by individual patients. In addition, these findings may be generalizable to other large teaching institutions performing similar numbers of CC and PCI procedures but may not be applicable to smaller institutions with fewer procedures.

\section*{CONCLUSION}

This analysis identified a significantly higher risk of vascular complications occurring in patients 70 years or older, who are female, have a history of RF, have undergone a PCI, and who have had the addition of a venous sheath. However, the low \(R^2\) for the study points to the fact that there are still significant variables that have not been considered. These findings, and those of previous researchers, support the need for prospective studies specifically designed to clearly identify specific patient and procedural characteristics contributing to a high-risk profile for vascular complications after CC and PCI. The identification of the factors that contribute most to the risk of complications will lead to the development of more individualized patient-specific protocols for the care of high-risk patients. The aging of the population will ultimately result in more patients older than 70 years who are at higher risk when undergoing these procedures. This information will also provide critical support for the justification to third-party payers.
for the costs of longer times of compression, longer times in bed, and longer times of observation in recovery units for patients identified as high risk.

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References


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