Predictors of Complications Following Sheath Removal With Percutaneous Coronary Intervention

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Background and Research Objectives: Complex antplatelet and antithrombotic regimens used in conjunction with percutaneous coronary intervention may increase the risk of vascular complications. The purpose of this study was to examine predictors of vascular complications following sheath removal for percutaneous coronary intervention.

Subjects and Methods: This prospective cohort study enrolled 413 patients during a 7-month period. Data elements collected by chart abstraction. Practice variable included pharmacological agents and method and duration of sheath removal procedure. Patient outcomes included hematoma formation, bleeding occurrence, pseudoaneurysm prevalence, incidence of arteriovenous fistula formation, and thrombosis.

Results and Conclusions: Of the 413 patients, 68 (16.5%) had a complication. Sixty-four (15.5%) developed hematomas ranging in size from 1 to 5 cm (n = 35, 8.5%) to greater than 5 cm (n = 29, 7.0%), 6 experienced bleeding (1.5%), 4 (1%) had arteriovenous fistulas, and 3 (0.7%) developed pseudoaneurysms. There were no significant differences for complications using manual, C-clamp, or arterial vascular closure device. Patients with a higher systolic blood pressure (135 vs 129; df = 410, P = .025) and of older age (66 vs 63; df = 411, P = .016) were significantly more likely to have complications. Clinically significant major vascular complications were low. Arterial closure devices, mechanical C-clamp, and manual compression all provide low and comparable complication risks following sheath removal in the era of antiplatelet and antithrombotic therapies. Patients who are older and those with elevated blood pressure should have their femoral access site closely monitored and be observed for vascular complications.

KEY WORDS: arterial closure devices, hematoma, manual compression, mechanical C-clamp, percutaneous coronary intervention, sheath removal, vascular complications

Percutaneous coronary intervention (PCI) is widely used in the treatment of patients with coronary artery disease and acute coronary syndromes. In 2006, an estimated 1,313,000 PCI procedures were performed.1 Increasingly complex antiplatelet and antithrombotic regimens used in conjunction with PCI may increase the risk of femoral vascular complications associated with PCI. Several methods for sheath removal include manual compression, C-clamp, pneumatic devices, and arterial closure devices. Selecting a method for sheath removal is often dependent on clinician preference, and there is no compelling evidence or widely accepted practice guidelines to favor one approach over another.

Despite advances in technology for PCI, there is no consensus regarding optimal method to achieve vascular hemostasis while minimizing complication rates. Percutaneous coronary intervention complications have been linked to increased consumption of healthcare resources, delays in hospital discharge, and patient dissatisfaction. It was reported that PCI bleeding complications cost an additional US $13,092 and added 4.4 days to a patient's hospitalization,2 and vascular complications cost an additional US $4,830 and 2.1 hospital days.3
The incidence of vascular complications ranges from 5.4% to 37%. Wide variations in reporting these occurrences are attributed to differences among studies for definitions and criteria for complications, assessments of vascular complications, compression techniques, and protocols for sheath removal. For example, some investigations have included ecchymosis and oozing, which do not require medical intervention or affect length of stay. Others limit complications to only the major ones such as significant bleeding that requires transfusion. Regardless of how unfavorable the outcomes with PCI procedures are defined and captured, the potential for serious events has stimulated interest in researching techniques for sheath removal that are associated with the best possible outcomes.

A meta-analysis by Jones and McCutcheon revealed that few studies address techniques performed to attain hemostasis after sheath removal. Furthermore, there are significant gaps in the current state of the science, and researchers have not been able to document relationships, if any, between sheath removal techniques, devices, antiplatelet medications, patient characteristics, and complication rates in PCI patients.

A randomized study of 90 PCI patients by Benson et al found an overall vascular complication rate of 14.4%, and manual sheath removal was associated with significantly fewer complications of rebleeding or hematoma formation compared with the C-clamp or pneumatic device ($\chi^2 P = .04$). In contrast, no significant differences by compression method for vascular complications, discomfort, and distress were detected by Chlan et al when 306 patients were randomized to C-clamp, manual compression, and pneumatic device. A follow-up study on the same 306 patients identified that patients with smaller body surface area had an increased risk for hematoma development, and patients with advanced age had an increased risk for ecchymosis.

Arterial closure devices have the potential to reduce the time to hemostasis, facilitate patient mobilization, decrease hospital length of stay, and improve patient satisfaction. However, their safety with respect to vascular complications remains unclear. Outcomes related to access site complications with arterial closure devices with PCI patients receiving antiplatelet agents showed a 4.2% vascular complication rate and were associated with failed hemostasis. Another randomized controlled trial with 167 PCI patients found a 7% failure rate for maintaining hemostasis with arterial closure device compared with no failures using manual compression, but no significant difference in rates was detected between groups for the development of hematoma. Findings from a meta-analysis from 30 studies involving 37,066 PCI patients favored mechanical compression over arterial closure devices for preventing complications; however, the synthesis of results from multiple studies did find that arterial closure devices improved patient satisfaction and time to ambulation.

Nursing management of patients undergoing PCI is critical to improving outcomes and reducing complications. The development of protocols and procedures for sheath removal must be based on scientific evidence that indicates which practices are the most efficient and effective. Acknowledging that complications exist with all methods and result in increased length of stay and hospital costs, studies must be designed to systematically identify care strategies that are most beneficial as well as predictors of vascular complications in routine clinical settings. We conducted a descriptive correlational study to examine vascular complications associated with 4 different methods of sheath removal practices following PCI and the influence of specific patient factors on outcomes. A secondary outcome was to capture the vascular complication rates after PCI sheath removal and more specifically the incidence and type of vascular complications experienced by patients during the course of routine clinical care.

**Methods**

A prospective, observational case series with a study cohort of patients requiring PCI for the treatment of acute coronary syndrome was conducted. No interventions or study conditions were manipulated as part of this research. Clinical nurses were trained during orientation to the unit on sheath removal using the clamp, manual, and pneumatic device. Each nurse was checked off on the sheath competency after removing 6 sheaths. Clinical nurses were instructed in the importance of: withdrawing about 5 to 10 mL of blood prior to removing the catheters to ensure that there are no clots; they were also instructed to position the hemostasis option (manual or C-clamp) 1 to 2 cm above the site where the arterial sheath enters the skin since the arterial puncture site is superior and medial to the skin puncture site, assess the circulation to the extremity distal to the site of the arterial sheath removal, and palpate the area around the arterial site, maintain bed rest for 6 hours after arterial sheath removal when using manual or C-clamp and 4 hours with closure devices.

Patients were exposed to routine clinical care following their procedure, at the discretion of healthcare providers, and data were subsequently collected on both practice and patient outcomes. Approval from our institutional review board was obtained with waiver of consent for participants because the study involved data collection by chart abstraction, and all participant data were deidentified. Patients who underwent PCI were eligible for inclusion in the...
study the day after their procedure prior to their discharge. Data elements included patient demographics, health status and comorbidities, practice variables (eg, type of sheath removal), and patient outcomes and complications (eg, hematoma formation). This was a 1-time event collected prior to discharge.

### Sample

Patients undergoing PCI at an academic medical center following their procedure were enrolled in the study. These patients were hospitalized on the cardiac intensive care or cardiac intermediate care units. Those who were hemodynamically unstable after PCI (ie, requiring pulmonary artery catheter monitoring or intra-aortic balloon pump therapy) and those having a PCI using the radial artery were excluded from the study.

### Outcomes

A data collection tool was used to record intervention events and outcome variables for all participating patients. Data elements included:

- Patient demographics: body mass index, age, sex, and race.
- Health status and comorbidities: current diagnosis and history of diabetes, hypertension, vascular disease, myocardial infarction, and tobacco use.
- Practice variables: pharmacological agents administered in the course of clinical care, method of sheath removal, sheath size, and duration of sheath removal procedures. All anticoagulant medications given during hospitalization were documented; however, it is important to note that this therapy was given based on physician preference and discretion. The method for sheath removal was not controlled or manipulated as part of this study and solely left to the judgments and practice preference of nurses caring for these patients. Thus, some methods were used more frequently than others. When arterial closure devices were deployed, this was at the discretion of the physician performing the PCI.

### Procedure

The principal investigator provided group and one-on-one education on the purpose of the study, data collection process, and study outcomes to the nurses. The importance of accurately recording all patient events and the sequence of care was emphasized. Nurses were instructed to document which method of sheath removal was used: manual, C-clamp (CompressAR, Advanced Vascular Dynamics, Portland, OR) or pneumatic (FemoStop, Radi Medical Systems AB, St. Jude Medical, Inc., St. Paul, MN) compression. Some patients required 2 different methods of sheath removal. For example, nurses may have initiated hemostasis with a clamp but may have subsequently switched to the manual method if complications were noted. Therefore, only the first sheath removal method used was included in the data analysis. When arterial closure devices (ie, Angio-Seal, Kensey Nash Corporation, Exton, PA; or Perclose, Abbott Laboratories, Abbott Park, IL) were used for hemostasis by physicians in the catheterization laboratory, this information was recorded.

### Table 1 Patient Outcomes and Definitions

<table>
<thead>
<tr>
<th>Outcome Variables</th>
<th>Definitions</th>
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<tbody>
<tr>
<td>Hematoma</td>
<td>Any swelling or palpable mass</td>
</tr>
<tr>
<td>Small hematoma</td>
<td>1–5 cm in diameter</td>
</tr>
<tr>
<td>Large hematoma</td>
<td>&gt;5 cm in diameter</td>
</tr>
<tr>
<td>Bleeding occurrence</td>
<td>&gt;2.0-g point drop from baseline hemoglobin and/or clinical complications (such as retroperitoneal bleed) to indicate bleeding (such as a blood transfusion). Note: Patients who had oozing of blood were not considered having a complication because oozing could not be quantified and did not change the length of stay and did not delay discharge.</td>
</tr>
<tr>
<td>Pseudoaneurysm</td>
<td>Forms outside the arterial wall, is contained by the surrounding tissue, continues to communicate with the artery via the puncture site, is detected by physical examination and confirmed by ultrasound-containing Doppler-detected flow.</td>
</tr>
<tr>
<td>Arteriovenous fistula</td>
<td>Abnormal communication between the femoral artery and vein confirmed by ultrasound-containing Doppler-detected flow.</td>
</tr>
<tr>
<td>Thrombosis</td>
<td>Complete occlusion of the femoral vessel as detected by the absence of distal foot pulses and confirmed by ultrasound-containing Doppler-detecting flow.</td>
</tr>
</tbody>
</table>
Nurses were instructed to measure all hematomas with a tape measure. Hematomas were divided into 2 categories: 5 cm or less for small hematoma and greater than 5 cm for large hematomas. The principal investigator collected all data through ongoing chart abstraction. During the course of the study, nurses were free to use their clinical judgment in selecting the sheath removal method that they believed to be most appropriate and were not biased or influenced by the investigators.

**Power Analysis**

The sample size was calculated based on the primary outcome variable of interest, the rate of hematomas. The average rate of hematoma for all patients was estimated at 16%; however, if only large hematomas were considered, this rate would drop to approximately 8%. For the one primary independent variable of interest, sheath removal method, the total number of patients required for a medium effect size (0.30), a = 0.05 with 80% power, across the range for complications (8%–16%) was 176 to 322. To detect a 1.5-fold increase in the compression times between the 2 outcome groups, with a = .05 and 80% power, 357 patients were needed.

**Data Analysis**

Study data were subjected to both descriptive and inferential statistical analyses. The occurrence of statistically significant differences in outcome variable means and prevalence rates related to intervention variables were determined using the χ2 test, Student t test for independent groups, or Mann-Whitney U tests as appropriate. Only meaningful significant relationships were targeted as part of this investigation.

When appropriate, measurable practice variables and patient outcomes were categorized into nominal level data to achieve the most detailed information. Any practice or patient outcome with less than 5% frequency was not used in further analysis or, if appropriate, was combined with another variable. Furthermore, the same rule was applied to categories within a variable. However, if a category with less than 5% frequency could not be combined with another category, the patients in this group were excluded from further analyses.

Each outcome was separately compared with the outcomes using appropriate statistical methodology. Variable effects with P < .2 were considered for the multivariate model. However, if it was not significant but there was some clinical evidence to support the variable in the model, it was included.

**Results**

During the 7 months from November 2003 through May 2004, 413 patients were enrolled. Baseline demographic and pharmacological agents are shown in Table 2. Patients ranged in age from 38 to 90 years (mean, 63.54 [SD, 10.3] years); 316 (76.5%) were men, and 97 (23.5%) were women. Most were white (n = 320; 77.5%) and had a history of hypertension (n = 312; 75.5%) and myocardial infarction (n = 254; 61.5%). There were no elevated international normalized ratios due to coumadin or liver failure.

Most patients (n = 219; 53%) received a glycoprotein IIb/IIIa inhibitor; heparin, n = 382 (92.5%); aspirin, n = 409 (99%); and clopidogrel, n = 405 (98.1%), for baseline treatment during and after PCI procedure. Heparin was weight-based dosed, at 50 to 70 units/kg, with an activating clotting time goal of 200 to 250 seconds for patients receiving a glycoprotein IIb/IIIa inhibitor and longer than 300 seconds for those not on such agents. Clopidogrel was loaded at 300 or 600 mg, independent of glycoprotein IIb/IIIa inhibitor use, and continued at 75 mg daily. Most patients had a 6F arterial catheter (76%), and sheaths were removed after the activating clotting time was less than 180 seconds.

Of the 413 patients, 68 patients (16.5%) had a complication such as hematoma, bleeding occurrence, pseudoaneurysm, and/or AV fistula. Thrombosis was
not present in any patient. While a subset of patients had more than 1 complication, for example, a hematoma and a pseudoaneurysm, most of the 68 patients experienced a single complication, for example, hematoma. There were a total of 64 hematomas (15.5%), with 35 hematomas 1 to 5 cm (8.5%) and 29 hematomas greater than 5 cm; 6 bleeding occurrences (1.5%); 4 AV fistulas (1%); and 3 pseudoaneurysms (0.7%).

Other potential complications from sheath removal include deep vein thrombosis from prolonged compression time and surgery to repair the pseudoaneurysm, AV fistula, or massive bleeding. To our knowledge, from this prospective, observational case series with a study cohort of patients, there were no documented deep vein thromboses. There were 3 patients who required the operating room: one to repair a pseudoaneurysm; another, an AV fistula; and the third, the femoral artery. Two pseudoaneurysms resolved with thrombin injections.

Using χ² tests, there were no significant statistical differences in complication rates by sex, race, diagnosis, and medical history of diabetes, hypertension, myocardial infarction, smoking, and vascular disease (Table 2). In examining the first method of sheath removal (manual, C-clamp, and arterial vascular closure device), no significant differences in complication rates by removal method (Table 3) were observed.

The use of arterial vascular closure devices was relatively limited in this study; therefore, the 2 types of devices used (Angio-Seal, a collagen plug, n = 62; and Perclose, a percutaneous suture device, n = 19) were combined to form 1 group. The pneumatic device was used only 4 times (1%), so it was excluded from the analyses. There were no significant differences in complications by medications used during or after the procedure. Most hematomas occurred after compression (n = 25; 6.1%), followed by during sheath removal (n = 19; 4.6%). Patients with complications had significantly higher systolic blood pressures (135 vs 129; df = 410, P = .025) and were significantly older (66 vs 63; df = 411, P = .016). Height, weight, body mass index, and body surface area did not affect the complication rates (Table 2).

The method of sheath removal had no statistically significant effect on hematoma size (P = .084) (Table 4). However, arterial vascular closure devices did have a higher proportion of large hematomas (70%) than did manual devices (57.1%) and a higher proportion than did C-clamp (34.4%).

To examine the relationship of compression time to hemostasis, it was necessary to exclude the 68 patients associated with complications as compression time was extended and 23 patients in whom the pneumatic and arterial vascular closure devices were used. For patients without complications, there was a significantly shorter compression time for those exposed to the manual sheath removal method (n = 90) compared with C-clamp device (n = 183) (median, 20 vs 35; P < .001) (Table 5).

### Discussion

Determining sheath removal procedures and care of patients following PCI remain the primary responsibility

### Table 3: Sheath Removal Methods and Complications

<table>
<thead>
<tr>
<th>Type</th>
<th>Frequency, n (%)</th>
<th>Complication Frequency, n (%)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manual</td>
<td>n = 413</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C-clamp</td>
<td>105 (25.4)</td>
<td>17 (25)</td>
<td>.486</td>
</tr>
<tr>
<td>Arterial closure device</td>
<td>223 (54.0)</td>
<td>38 (55.9)</td>
<td>.544</td>
</tr>
<tr>
<td>Collagen closure device*</td>
<td>81 (19.9)</td>
<td>13 (19.1)</td>
<td></td>
</tr>
<tr>
<td>Percutaneous suture closure device*</td>
<td>19 (4.6)</td>
<td>5 (7.4)</td>
<td>.218</td>
</tr>
<tr>
<td>Pneumatic device†</td>
<td>4 (1)</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

*Collagen closure device (Angio-Seal) and percutaneous suture closure device (Perclose) are subgroups of the arterial closure device.

†The pneumatic device was used only 4 times (1%), so it was excluded from analyses.

### Table 4: Sheath Removal Method by All Complications

<table>
<thead>
<tr>
<th>Method</th>
<th>Manual</th>
<th>C-Clamp</th>
<th>Arterial Closure Devices (Collagen/Percutaneous)</th>
<th>All Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hematoma diameter 1–5 cm</td>
<td>8 (1.9)</td>
<td>24 (5.8)</td>
<td>0/3 (0.7)</td>
<td>35 (8.5)</td>
</tr>
<tr>
<td>Hematoma diameter &gt;5 cm</td>
<td>9 (2.2)</td>
<td>13 (3.1)</td>
<td>6 (1.5)/1 (0.2)</td>
<td>29 (7)</td>
</tr>
<tr>
<td>Bleeding occurrence</td>
<td>2 (0.5)</td>
<td>3 (0.7)</td>
<td>1 (0.2)/0</td>
<td>6 (1.5)</td>
</tr>
<tr>
<td>Pseudoaneurysm</td>
<td>2 (0.5)</td>
<td>1 (0.2)</td>
<td>0/0</td>
<td>3 (0.7)</td>
</tr>
<tr>
<td>AV fistula</td>
<td>1 (0.2)</td>
<td>2 (0.5)</td>
<td>1 (0.2)/0</td>
<td>4 (1.0)</td>
</tr>
<tr>
<td>P</td>
<td>.486</td>
<td>.544</td>
<td>.464/.218</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviation: AV, arteriovenous.

*Values are presented as n (%). There were a total of 64 hematomas (15.5%), with 35 hematomas 1 to 5 cm (8.5%) and 29 hematomas greater than 5 cm (7.0%); 6 bleeding occurrences (1.5%); 4 AV fistulas (1%); and 3 pseudoaneurysms (0.7%).

†Collagen closure device/percutaneous suture closure device.

*All complications, per patient; however, some patients had several complications listed such as a hematoma and a pseudoaneurysm, while most had a single complication such as a hematoma.
of nurses. Assessment and management of vascular complications are essential because the use of anticoagulant therapy often administered to patients having PCI affects clotting times. Importantly, independent nursing judgments regarding the methods for sheath removal and frequency of monitoring should be based on current evidence and knowledge of the risks for complications, given the patient characteristics and circumstances surrounding the PCI procedure. Our study identified that patient variables such as age, health status and comorbidities, and nursing practices can have important implications for determining the predictors of vascular complications.

Vascular complications in this study (16.5%) were similar to the rates reported in the literature. Variations in the incidence of vascular complications documented by other investigators can be attributed to differences in how complications are defined and measured. For example, there are striking distinctions in the ways that vascular complications are characterized including the presence of ecchymosis and oozing and size of hematomas or magnitude of bleeding events. If one excludes small hematomas, which are usually clinically insignificant, then of the 413 patients, only 42 patients (10.2%) had a complication defined as large hematoma (>5 cm), bleeding occurrence, pseudoaneurysm, and/or AV fistula. In addition, if we restrict the analysis to those patients who sustained a clinically significant major vascular complication, defined as AV fistula, those who had a pseudoaneurysm, or patients with a bleeding complication requiring transfusion for drop in hemoglobin of 4 g, then major vascular complications occurred in only 13 patients (3.2%).

We were unable to detect major differences in vascular complication rates with manual, C-clamp, and arterial closure device for sheath removal (Table 3). Chlan et al7 also demonstrated no significant differences in vascular complications using pneumatic, C-clamp, or manual compression. However, study procedures were implemented by 30 highly trained nurses who had an average of 12 years of experience. Despite vascular complications (16%) including oozing, ecchymosis, and hematoma, the inability to find differences among sheath removal techniques may have been attributed to nurses being more experienced in the care of patients after PCI. Our investigation was conducted with clinical nurses who had varied experiences and time in practice, and we believe that this is more representative of a naturalistic environment with nurses having various levels of knowledge and expertise.

The C-clamp was used most frequently for sheath removal (54%) by the nurses. The C-clamp provides the application of constant pressure while maintaining limb perfusion and allows for hands-free line removal so nurses can monitor patients while providing appropriate care. While manual compression was used 25.4% of the time, nurses who used this method felt that they had more control than with the C-clamp. If the clamp is not positioned correctly, it may result in failure to achieve hemostasis. Although not statistically significant, investigators observed that if there was a hematoma, the C-clamp produced smaller hematomas, whereas the manual method and arterial closure devices were more likely to have larger hematomas (Table 4).

Manual compression for some practitioners is not an option based on strength and ability to hold a good compression for 15 to 20 minutes. If hand and arm fatigue develops during the procedure, the amount of pressure to the femoral artery may vary, causing vascular complications. When a hematoma developed, compression time increased, making it difficult to assess the effect of compression time. However, patients without complications had a significant difference in compression times. Patients with sheath removal using manual compression had a 15-minute lower compression time, on average, compared with patients with a C-clamp (median, 20 vs 35; P < .001). Similar results were confirmed by Bogart16; mean length of time to hemostasis was 22 minutes in the manual compression group and 31 minutes in the mechanical compression group (P < .001). When providing manual compression to the femoral artery, it is easier to release pressure to examine and assess if hemostasis is achieved. This is not possible with the C-clamp or pneumatic device; nurses may leave it on longer as it is convenient and without opportunities to assess hemostasis.

Arterial closure devices were used in 19.6% of the patients. This technique was at the discretion of the physician performing the procedure. Appropriate patient selection is important and should be placed only after confirmation of the vascular anatomy and

### TABLE 5
**Compression Times (in Minutes) for Patients Without Complications**

<table>
<thead>
<tr>
<th>Typea</th>
<th>n</th>
<th>Mean</th>
<th>SD</th>
<th>Median</th>
<th>Minimum</th>
<th>Maximum</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manual</td>
<td>90</td>
<td>20.29</td>
<td>6.32</td>
<td>20</td>
<td>10</td>
<td>45</td>
<td>.001</td>
</tr>
<tr>
<td>C-clamp</td>
<td>183</td>
<td>37.30</td>
<td>17.01</td>
<td>35</td>
<td>10</td>
<td>110</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>273</td>
<td>31.69</td>
<td>16.45</td>
<td>30</td>
<td>10</td>
<td>110</td>
<td></td>
</tr>
</tbody>
</table>

Note: Patients with a manual sheath removal had a significant 15-minute lower compression time, on average, than subjects with a C-clamp (median, 20 vs 35; P < .001).
in the absence of significant local peripheral arterial disease. Arterial closure devices improve patient satisfaction by reducing the duration of bed rest. However, Tron et al reported that manual compression was significantly \( P < .04 \) better than percutaneous suture devices for hemostasis success, as did Koreny et al based on their meta-analysis of 30 randomized trials.

Older patients were more likely to have complications than were younger patients. This finding was similar to other studies that reported older age was a significant variable associated with vascular complications. Feit et al, in a study of 6,001 patients, identified baseline predictors of major hemorrhage following PCI to be advanced age \( (P < .0001) \) and female sex \( (P < .0001) \). However, Sabo et al were able to show that age was linked to the development of ecchymosis \( (P < .01) \), but not hematoma \( (P = .21) \). In our investigation, we did not monitor ecchymosis because it does not delay discharge and is not clinically significant if it occurs. It is important to note that advanced age was not a predictor for vascular complications in all studies, but despite inconclusive findings about age, nurses should still be cautious and extra diligent when removing sheaths in older patients.

Results showed that patients with higher systolic blood pressures were more likely to have a complication than were patients with lower systolic blood pressures, which is also supported by Waksman et al, who reported that one of the correlates of vascular complications was higher systolic blood pressure \( (140 \text{ SD, 25} \) vs \( 135 \text{ SD, 20 mm Hg; } P < .001) \). However, our study did not find female sex or height and weight to be significant predictors of complications as documented in other studies.

It was evident from our results that all sheath removal methods provide adequate hemostasis. The occurrence of vascular complications may be, in part, due to differences among studies in definitions and clinical protocols that are used to direct practice and less a consequence of the type of sheath removal or compression technique. Thus, it may be safe to say that without compelling evidence in favor of one hemostasis intervention over another, nurses should continue to use the method of sheath removal with which they are experienced and comfortable.

**Study Limitations**

Since the study was conducted, there has been an increase in the use of a 600-mg loading dose of clopidogrel in place of the 300-mg dose. This is expected to result in an earlier onset of action of clopidogrel and could theoretically increase the bleeding risk at the time of sheath removal; however, because most sheath removal occurs at about 4 to 6 hours after the procedure, the effects of either loading dose of clopidogrel would likely be similar. In addition, with the widespread use of early clopidogrel loading, there has been a trend toward less use of glycoprotein IIB/IIA inhibitor. It is possible that one benefit would be less access site bleeding, but this is speculative. Catheter size and use have not changed substantially since the study was conducted.

Because this was a descriptive study using a convenience sample, it was anticipated that there may be some degree of type II statistical error related to limitations from a heterogeneous sample and lack of control over sheath removal interventions. However, our sample size appeared to be adequate for being able to detect statistically significant differences if present. The study, while conducted in a naturalist environment where nurses determine the method of sheath removal, makes our findings more applicable and meaningful to practice. Some may argue that the inability to exert control over the intervention influences our results, yet our analysis was able to account for specific patient characteristics that can affect complications. Furthermore, practice variations do exist in routine clinical care, and it is important to assess outcomes in the context of usual care. Patients in our study did not have an ultrasound of their groin to confirm clinical indicator for hematoma and other vascular complications, so it is possible that asymptomatic patients with a pseudoaneurysm or AV fistula may have gone undetected. To a degree, differences in medication therapies found across institutions may limit the generalizability of study findings.

**Implications for Nursing Practice**

This study provides nurses with research findings to support independent decisions to implement interventions during sheath removal. Despite advances in technology, vascular complications continue to be a problem no matter which method of removing sheaths is used. Vigilance in preventing problems associated with sheath removal can reduce vascular events, which have been known to increase hospital costs and cause discomfort to patients. Our findings contribute important information to the existing body of knowledge and evidence about sheath removal practices following PCI. Importantly, nurses need to be aware that advanced age or hypertension seems to negatively influence patient outcomes, and therefore, these patients require extra vigilance with assessment and management practices. Until universally accepted evidence-based guidelines are developed, institutions should promote practice policies and procedures that are aligned with specific standards of practice regardless of which method is used. Future efforts around the care of these patients should focus on...
on forming consistent definitions for parameters defining what constitutes complications such as bleeding, hemorrhage, and hematoma, so that these can be systematically applied in research studies.

Conclusion

This study concludes that manual compression, C-clamp, and arterial vascular closure devices all provide low complications for sheath removal in conjunction with complex antiplatelet and antithrombotic regimens. These devices can achieve hemostasis; however, manual methods appear to require less time to hemostasis. Older patients and those with elevated blood pressure may be at greater risk for hematoma and thus subsequently require closer monitoring of the femoral access site area and for signs of pending hematoma or bleeding during and after sheath removal.

Acknowledgments

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REFERENCES