Impact of Femoral Vascular Closure Devices and Antithrombotic Therapy on Access Site Bleeding in Acute Coronary Syndromes

The Acute Catheterization and Urgent Intervention Triage Strategy (ACUITY) Trial

Timothy A. Sanborn, MD; Ramin Ebrahimi, MD; Steven V. Manoukian, MD; Brent T. McLaurin, MD; David A. Cox, MD; Frederick Feit, MD; Martial Hamon, MD; Roxana Mehran, MD; Gregg W. Stone, MD

Background—The Acute Catheterization and Urgent Intervention Triage Strategy (ACUITY) trial demonstrated that bivalirudin monotherapy significantly reduces major bleeding compared with heparin (unfractionated or enoxaparin) or bivalirudin plus a glycoprotein IIb/IIIa inhibitor in acute coronary syndromes. Whether vascular closure devices (VCD) impact these results is unknown. Therefore, this study sought to determine whether VCD impact major access site bleeding (ASB) in patients with acute coronary syndromes undergoing early invasive management by the femoral approach.

Methods and Results—Major ASB in ACUITY was defined as ASB requiring interventional or surgical correction, hematoma ≥ 5 cm at the access site, retroperitoneal bleeding, or hemoglobin drop ≥ 3 g/dL with ecchymosis or hematoma < 5 cm, oozing blood, or prolonged bleeding (> 30 minutes) at the access site. Stepwise logistical regression was performed to identify the independent determinants of ASB. Of 11 621 patients undergoing angiography with or without percutaneous coronary intervention by the femoral approach, 4307 (37.1%) received a VCD and 7314 (62.9%) did not. Rates of major ASB were lower with VCD compared with no VCD (2.5% versus 3.3%, relative risk, 0.76; 95% CI, 0.61 to 0.94; P = 0.01) and were lowest in patients treated with bivalirudin monotherapy and a VCD (0.7%). Stepwise logistic regression revealed that a VCD (odds ratio, 0.78; 95% CI, 0.61 to 0.99; P = 0.04) and bivalirudin monotherapy (odds ratio, 0.35; 95% CI, 0.25 to 0.49; P < 0.0001) were both independent determinates of freedom from major ASB.

Conclusion—In patients with acute coronary syndromes undergoing an early invasive management strategy by the femoral approach, the use of a VCD, bivalirudin monotherapy, or both minimizes rates of major ASB.

Clinical Trial Registration—URL: http://www.clinicaltrials.gov. Unique Identifier: NCT00093158.

Key Words: angioplasty ■ anticoagulants ■ myocardial infarction ■ stents ■ vascular closure devices

Vascular closure devices (VCD) have been shown to significantly reduce hemostasis and ambulation times after diagnostic coronary angiography and percutaneous coronary intervention (PCI); however, several meta-analyses and a large registry from the American College of Cardiology-National Cardiovascular Data Registry have reported conflicting data on whether VCD increase, decrease, or do not alter the risk of access site bleeding (ASB).1-7 The prospective, multicenter, randomized Acute Catheterization
antithrombotic regimen on rates of ASB, we analyzed patients with ACS managed invasively by the femoral access site from the large-scale contemporary ACUITY trial.

Methods

Study Design

The ACUITY trial study design has been previously described in detail. Briefly, patients older than 18 years with symptoms of unstable angina lasting for at least 10 minutes within the preceding 24 hours were eligible for enrollment if 1 or more of the following criteria were met: (1) new ST-segment depression or transient elevation of at least 1 mm; (2) elevated troponin I, troponin T, or creatine kinase-MB (CKMB) levels; (3) known coronary artery disease; or (4) all 4 other thrombosis in myocardial infarction risk criteria. Exclusion criteria included acute ST-segment–elevation myocardial infarction or shock; bleeding diathesis or major bleeding within 2 weeks; thrombocytopenia; creatinine clearance <30 ml/min; and recent administration of abciximab, bivalirudin, or >1 dose of low-molecular-weight heparin. The study was approved by institutional review boards or ethics committees at each center, and all patients gave informed written consent.

Randomization and Study Procedures

The ACUITY trial randomized 13,819 patients to receive heparin (unfractionated or enoxaparin) plus GPI, bivalirudin plus GPI, or bivalirudin monotherapy in an open-label fashion. Unfractionated heparin was administered intravenously (IV) as a 60 IU/kg bolus plus 12 IU/kg/h infusion to achieve an active partial thromboplastin time of 50 to 75 seconds before angiography and an activated clotting time of 200 to 250 seconds during PCI. Enoxaparin was administered 1 mg/kg subcutaneously twice daily before angiography with a 0.3-mg/kg IV bolus immediately before PCI if the last subcutaneous dose was >8 hours earlier or 0.75 mg/kg if >16 hours earlier. Bivalirudin was administered IV as a 0.1 mg/kg bolus plus 0.25 mg/kg/h infusion, with a bolus of 0.5 mg/kg and an increase in the infusion to 1.75 mg/kg/h before PCI. Patients assigned to 1 of the GPI arms were further randomized in a 2 x 2 factorial design to either upstream GPI immediately after randomization or deferred (before PCI). Provisional GPI was permitted in deferred GPI or bivalirudin monotherapy patients for severe breakthrough ischemia and during PCI in bivalirudin monotherapy patients for prespecified criteria. The GPI was administered per labeling and continued 12 to 18 hours after PCI. Per protocol, angiography was intended in all patients within 72 hours of randomization with subsequent triage to PCI, coronary artery bypass graft surgery (CABG), or medical management. Aspirin was administered daily during hospitalization (300 to 325 mg PO or 250 to 500 mg IV). Thienopyridine dosing and timing were left to the discretion of the investigator; however, the protocol required a clopidogrel loading dose of 300 mg or more within 2 hours after PCI in all cases. Clopidogrel (75 mg daily) was recommended for 1 year in all patients undergoing PCI, and aspirin (75 to 325 mg daily) was indefinitely recommended. The choice of the arterial access site, the decision whether to use a vascular closure device, and which device to use were left to the discretion of the physician investigator. Although the performance of femoral angiography is recommended before the use of a VCD, this information was not collected in this analysis. Sheath removal, manual compression, and ambulation protocols were determined by the individual institutions.

End Points and Statistical Analyses

End points were assessed at 30 days. For the purpose of the present analysis, major ASB (not related to CABG) was defined as ASB requiring interventional or surgical correction, hematoma ≥5 cm at the access site, retroperitoneal bleeding, or hemoglobin drop ≥3 g/dL with ecchymosis or hematoma ≤5 cm, oozing blood or prolonged bleeding (>30 minutes) at the access site. All analyses are by intention to treat. Stepwise logistical regression was performed to identify the independent determinants of ASB. The variables used in the regression model were age ≥75 years, anemia, baseline elevation CKMB/troponin, creatinine clearance <60 ml/min, closure device use, diabetes, baseline ST-segment deviation, gender, hyperlipidemia, hypertension, prior myocardial infarction, prior PCI, prior CABG, randomization to bivalirudin versus heparin plus GPI, randomization to bivalirudin plus GPI versus heparin plus GPI, and thienopyridine use before angiography/PCI. A P value of <0.05 was required for statistical significance. Statistical analyses were performed by SAS version 8.2 (SAS Institute Inc, Cary, NC).

Results

Patient Population

Between August 23, 2003, and December 5, 2005, 13,819 patients with ACS were enrolled at 450 academic and community-based centers in 17 countries and randomized to heparin (unfractionated or enoxaparin) plus GPI, bivalirudin plus GPI, or bivalirudin monotherapy. Access site information was only collected for the first coronary angiography procedure. Patients undergoing deferred PCI, in whom a different access site was potentially used, were therefore excluded from the present analysis (n = 28), as were patients with brachial access (n = 90), radial access (n = 798) or those whose records lacked access site (n = 914) or VCD use (n = 368) information. After excluding these patients, the study population consisted of 11,621 patients who underwent coronary angiography with or without PCI by the femoral approach.

Of the 11,621 patients in the study population, 4,307 (37.1%) received a VCD (2,971 AngioSeal, 1,113 Perclose, 109 VasoSeal, 33 Duett, and 81 other or unknown) and 7,314 (62.9%) did not. Baseline characteristics and demographics are presented in Table 1. Patients who received a VCD were generally a lower risk population compared with those who did not; they were younger in age and had lower rates of diabetes, hypertension, anemia, baseline renal insufficiency, prior myocardial infarction, and prior CABG. Furthermore, patients who received a VCD were less likely to have elevated biomarkers at baseline.

VCD and Major ASB

The rates of major ASB were significantly lower in patients who received a VCD compared with those who did not (2.5% versus 3.3%; relative risk, 0.75; 95% CI, 0.61 to 0.94; P = 0.01). Furthermore, because major ASB represented >60% of ACUITY non-CABG major bleeding, ACUITY non-CABG major bleeding was also lower in those patients who received a VCD compared with those who did not (3.9% versus 5.3%; relative risk, 0.72; 95% CI, 0.61 to 0.86; P = 0.0003). The individual components of major ASB occurred with similar frequency in patients with and without a VCD, except for ASB requiring interventional or surgical correction and hematoma ≥5 cm at the puncture site, which occurred significantly less often in those patients with a VCD (Table 2). Unadjusted rates of major ASB were 3.0% for AngioSeal, 1.4% for Perclose, and 1.3% for VasoSeal, Duett, and other or unknown VCD (P = 0.006 for the comparison of AngioSeal with Perclose). In terms of the individual components of major ASB, there was an unadjusted trend toward more hematoma ≥5 cm at the puncture site with AngioSeal compared with Perclose (1.6% versus 0.8%, P < 0.064). All other components of major ASB were similar.
No significant differences were observed in the baseline characteristics of patients in the 3 randomized antithrombin groups with or without VCD usage (data not shown). The rates of major ASB were significantly lower in patients treated with bivalirudin monotherapy compared with heparin plus GPI, regardless of whether a VCD was used (0.7% versus 3.3%, respectively, P<0.001) or was not used (1.9% versus 4.2%, respectively, P<0.0001; Figure 1).

The impact of VCD on major ASB overall and among the 3 randomized treatment arms was also evaluated in the subset of patients in whom PCI was immediately performed after diagnostic angiography (n=6606, VCD used in 2451 [37.1%] patients and not used in 4155 [62.9%] patients). Among patients undergoing PCI, a trend was present toward reduced rates of major ASB among patients who received a VCD versus those who did not (3.6% versus 4.5%, P=0.08; Figure 2). As observed in the overall population, ASB requiring interventional or surgical correction and hematoma ≥5 cm occurred significantly less often in patients undergoing PCI when a VCD was used (0.4% versus 0.8%, P=0.05 and 1.9% versus 2.7%, P=0.03, respectively). Also consistent with the overall population, in patients undergoing PCI who received

### Table 1. Demographics and Baseline Characteristics

<table>
<thead>
<tr>
<th></th>
<th>VCD (N=4307), n/N (%)</th>
<th>No VCD (N=7314), n/N (%)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, median (range), y</td>
<td>61 (21 to 92)</td>
<td>64 (20 to 95)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Female</td>
<td>1301 (30.2)</td>
<td>2243 (30.7)</td>
<td>0.60</td>
</tr>
<tr>
<td>Renal insufficiency*</td>
<td>662/4014 (16.5)</td>
<td>1405/6918 (20.3)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Diabetes</td>
<td>1108/4279 (25.9)</td>
<td>2096/7264 (28.9)</td>
<td>0.0006</td>
</tr>
<tr>
<td>Current smoker</td>
<td>1263/4242 (29.8)</td>
<td>2046/7184 (28.5)</td>
<td>0.14</td>
</tr>
<tr>
<td>Prior MI</td>
<td>1290/4217 (30.6)</td>
<td>2308/7134 (32.4)</td>
<td>0.05</td>
</tr>
<tr>
<td>Prior PCI</td>
<td>1731/4270 (40.5)</td>
<td>2855/7250 (39.4)</td>
<td>0.22</td>
</tr>
<tr>
<td>Prior CABG</td>
<td>729/4299 (17.0)</td>
<td>1408/7301 (19.3)</td>
<td>0.002</td>
</tr>
<tr>
<td>Family history of coronary artery disease</td>
<td>1991/3776 (52.7)</td>
<td>3256/6251 (52.1)</td>
<td>0.53</td>
</tr>
<tr>
<td>Hypertension</td>
<td>2805/4289 (65.4)</td>
<td>5035/7286 (69.1)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>2412/4233 (57.0)</td>
<td>4176/7156 (58.4)</td>
<td>0.15</td>
</tr>
<tr>
<td>High risk†</td>
<td>2828/4037 (70.1)</td>
<td>5058/6978 (72.5)</td>
<td>0.006</td>
</tr>
<tr>
<td>Baseline CKMB/troponin elevation</td>
<td>2203/3917 (56.2)</td>
<td>4104/6786 (60.5)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>ST-segment deviation</td>
<td>1417/4304 (32.9)</td>
<td>2530/7312 (34.6)</td>
<td>0.07</td>
</tr>
<tr>
<td>Anemia‡</td>
<td>598/4063 (14.7)</td>
<td>1231/6964 (17.7)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Thrombocytopenia (baseline platelet count &lt;100 000)</td>
<td>12/4052 (0.3)</td>
<td>15/6939 (0.2)</td>
<td>0.41</td>
</tr>
</tbody>
</table>

MI indicates myocardial infarction.
*Renal insufficiency was defined as calculated creatinine clearance <60 mL/min.
†High risk was defined as either CKMB or troponin elevation or ST-segment deviation.
‡Anemia was defined using the World Health Organization definition (hemoglobin <13 g/dL for men and <12 g/dL for women).

### Table 2. Major ASB at 30 Days According to Vascular Closure Device Use

<table>
<thead>
<tr>
<th></th>
<th>VCD (N=4307), n (%)</th>
<th>No VCD (N=7314), n (%)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major ASB (non-CABG)</td>
<td>109 (2.5)</td>
<td>245 (3.3)</td>
<td>0.01</td>
</tr>
<tr>
<td>Access site hemorrhage requiring interventional or surgical correction</td>
<td>16 (0.4)</td>
<td>48 (0.7)</td>
<td>0.048</td>
</tr>
<tr>
<td>Hematoma ≥5 cm at puncture site</td>
<td>58 (1.3)</td>
<td>154 (2.1)</td>
<td>0.004</td>
</tr>
<tr>
<td>Retroperitoneal bleeding</td>
<td>25 (0.6)</td>
<td>29 (0.4)</td>
<td>0.16</td>
</tr>
<tr>
<td>Hgb drop ≥3 g/dL and ecchymosis</td>
<td>12 (0.3)</td>
<td>33 (0.5)</td>
<td>0.15</td>
</tr>
<tr>
<td>Hgb drop ≥3 g/dL and hematoma &lt;5 cm at the puncture site</td>
<td>18 (0.4)</td>
<td>47 (0.6)</td>
<td>0.12</td>
</tr>
<tr>
<td>Hgb drop ≥3 g/dL and oozing blood at the puncture site</td>
<td>15 (0.3)</td>
<td>33 (0.5)</td>
<td>0.40</td>
</tr>
<tr>
<td>Hgb drop ≥3 g/dL and prolonged (&gt;30 min) bleeding at the puncture site</td>
<td>2 (&lt;0.1)</td>
<td>8 (0.1)</td>
<td>0.28</td>
</tr>
</tbody>
</table>

Hgb indicates hemoglobin.

![Figure 1](https://sanbornetal.com/closure-devices-and-bleeding-in-acuity.png)

Figure 1. Thirty-day major ASB by randomized antithrombin treatment in patients with and without VCD use.
a VCD, major ASB was more frequent with AngioSeal compared with Perclose (4.3% versus 2.1%, \( P = 0.01 \)). ASB was lowest in patients who received bivalirudin monotherapy compared with heparin plus GPI regardless of whether a VCD was used (0.8% versus 4.7%, \( P < 0.0001 \)) or was not used (2.4% versus 5.7%, \( P < 0.0001 \)).

As shown in Table 3, a stepwise logistic regression revealed that treatment with bivalirudin monotherapy rather than heparin plus a GPI was the strongest predictor of freedom from major ASB (odds ratio, 0.35; 95% CI, 0.25 to 0.49; \( P < 0.0001 \)). The use of a VCD was also independently associated with freedom from major ASB (odds ratio, 0.78, 95% CI, 0.61 to 0.99; \( P = 0.04 \)). When age was inserted into the multivariate model as a continuous rather than a discrete variable, VCD use was borderline significant (odds ratio, 0.80; 95% CI, 0.62 to 1.02; \( P = 0.066 \)). In addition, female sex, age \( \geq 75 \) years, elevated baseline cardiac biomarkers, thienopyridine use before angiography or PCI, and no prior PCI were independently associated with major ASB. Other variables in this model that were not independently associated with major ASB included anemia, baseline renal insufficiency (creatinine clearance <60 mL/min), diabetes mellitus, ST-segment deviation at baseline, hyperlipidemia, prior myocardial infarction, and prior CABG.

**Discussion**

The ACUITY trial demonstrated that compared with anti-thrombin regimens containing a GPI, bivalirudin monotherapy significantly reduces major and minor bleeding complications, including ASB, without increasing ischemic complications in patients with moderate and high-risk ACS managed with an early invasive strategy. Although femoral VCD were initially demonstrated to reduce time to hemostasis and ambulation,2–4 data regarding their impact on bleeding from the access site has been in variance.5–8 Several of the early meta-analyses examining the rate of vascular complications with VCD5–7 were based on early reports of first-generation devices with many of the operators still in the “learning curve” phase. Closure devices have considerably improved in terms of their size and ease of use since these early reports, as have operator experience and technique with VCD. Antiplatelet and anticoagulant regimens during angiography and PCI have also evolved since these early reports. The present analysis was therefore performed to evaluate the impact of femoral VCD on major ASB in a contemporary clinical trial of moderate and high-risk patients with ACS undergoing an early invasive management strategy.

In this analysis of patients undergoing angiography with or without PCI from the femoral approach, there was a significant reduction in the incidence of major ASB and ACUITY non-CABG major bleeding when a VCD was used. In terms of the individual components of major ASB, both ASB requiring interventional or surgical correction and hematoma \( \geq 5 \) cm at the puncture site occurred significantly less often in those patients with a VCD. Furthermore, the lowest rate of ASB (<1%) was observed when patients were treated with bivalirudin monotherapy and a VCD. Stepwise logistic regression revealed significantly reduced risks in the odds of major ASB with bivalirudin monotherapy or VCD usage (65% and 22%, respectively). The magnitudes of these results in the setting of a clinical trial are very similar and concordant to those recently reported from the large Northern New England PCI Registry in which the relative risk reduction in bleeding and vascular complications with bivalirudin and VCD use during PCI was 52% and 25%, respectively.11 Because bleeding has been found to be a powerful independent predictor of 30-day mortality in patients with ACS managed invasively in the ACUITY, the Organization to Assess Ischemic Syndromes Registry, and the Clopidogrel in Unstable Angina to Prevent Recurrent Events randomized trials, the present findings of reduced major ASB and ACUITY non-CABG major bleeding using femoral VCD in concert with bivalirudin may have significant clinical implications for future improvements.12–13 We have also reported that the use of the radial artery access site is associated with a significantly lower rate of major bleeding complications in comparison with the more conventional femoral artery access route, and that bivalirudin monotherapy compared with heparin plus GPI significantly reduced access site-related bleeding with femoral but not radial artery access.14 Unfortunately, the use of VCD was not examined in this prior study. Although a cost analysis is beyond the scope of this study, it was previously reported in the ACUITY trial that bivalirudin monotherapy resulted in reduced hospital costs compared with heparin plus GPI mainly because of reduced bleeding complications.15 The potential contribution of VCD-related bleeding reduction to overall cost estimates in this patient population remains to be
determined; however, it has been reported that routine use of the AngioSeal VCD was associated with a net cost savings as compared with mechanical compression. Thus, several strategies may be undertaken in the future to reduce major ASB in patients with ACS managed with an invasive strategy. Several limitations of this study deserve comment. First, this was a nonrandomized, post hoc subgroup analysis that should be considered hypothesis generating for future definitive investigation. The timing of the major ASB was not recorded in ACUITY. If a major ASB developed during the angiographic or PCI procedure, it may have influenced the decision to use or not to use a VCD and may have contributed to more ASB in the non-VCD group. Second, the use of a VCD was not randomized and was left to the operator’s discretion, which may have introduced a potential for selection bias and nonadjustment for unmeasured confounders, including the presence of peripheral vascular disease that was not captured in ACUITY. Several characteristics of the VCD population are associated with lower rates of bleeding. This is a limitation that should also be considered. There were 450 centers in the ACUITY trial, and the decision to use a VCD as well as the choice of which particular VCD to use was not randomized and was probably related to the preferences and experience at the individual centers. A wide range of operator experience with the various VCD also could have influenced the rates of major ASB among the various devices. The PCI subset was also underpowered to determine a significant benefit with VCD, although the risk reduction was similar to the overall population, and a trend toward lower rates of major ASB was present. Large randomized studies are also required to definitively determine the relative rates of major ASB among the currently available VCD. Finally, this study examined only major ASB, and not other vascular complications such as pseudoaneurysm, arteriovenous fistula, and limb ischemia, the relative occurrence of which with and without VCD must be considered when determining whether to use VCD. In summary, in the large-scale ACUITY trial, the rates of major femoral ASB were significantly lower with (1) VCD use compared with manual compression and (2) bivalirudin monotherapy compared with GPI-containing antithrombin regimens regardless of VCD usage. Major ASB rates were lowest (<1%) in patients who received both a VCD and bivalirudin monotherapy. These results suggest that the combined use of bivalirudin and a VCD may reduce major ASB in patients with ACS managed with an early invasive strategy from the femoral approach.

Sources of Funding
The ACUITY trial was sponsored by The Medicines Company (Parsippany, NJ).

Disclosures
Dr Sanborn received honoraria from and is a member of speaker’s bureau of The Medicines Company and Merck. Dr Ebrahimi received honoraria from and is a member of speaker’s bureau of The Medicines Company and Abbott. Dr Manoukian received honoraria from and is a member of speaker’s bureau of The Medicines Company and Abbott. Dr McLean has no financial support to disclose. Dr Cox received honoraria from and is a member of speaker’s bureau of Abbott, The Medicines Company, and Boston Scientific and is a consultant and a member of the advisory board of Abbott and Boston Scientific. Dr Feit holds an ownership interest in Johnson & Johnson, Lilly, and The Medicines Company and received honoraria and is a member of the speaker’s bureau of The Medicines Company. Dr Hamon received honoraria from and is a member of the speaker’s bureau of The Medicines Company and is a consultant and a member of the advisory board of The Medicines Company. Dr Mehran received honoraria from and is a member of speaker’s bureau of The Medicines Company, Boston Scientific, Regards, Therox, Sanofi-Aventis/BMS, Lilly, Gabert, Abiomed, Cordis, Medtronic, and Abbott; is a consultant and a member of the advisory board of The Medicines Company, Boston Scientific, Sanofi/Aventis/BMS, Cordis, Medtronic, BRACCO, and Abbott; and received other research support (receipt of drugs, supplies, equipment, or other in-kind support) and research grant (principal investigator, collaborator or consultant, and pending or already received grants) from Boston Scientific. Dr Stone received other research support (receipt of drugs, supplies, equipment, or other in-kind support) and research grant (principal investigator, collaborator or consultant, and pending or already received grants) from The Medicines Company, Boston Scientific, and Abbott and received honoraria from and is a member of speaker’s bureau of St Jude and Lilly.

References
CLINICAL PERSPECTIVE

Vascular closure devices (VCD) have been shown to significantly reduce hemostasis and ambulation times after diagnostic coronary angiography and percutaneous coronary intervention; however, there is conflicting data on whether VCD increase or decrease the risk of access site bleeding (ASB). To assess the impact of VCD and the antithrombotic regimen on the rates of ASB, we analyzed patients with acute coronary syndrome invasively managed from the large-scale contemporary Acute Catheterization and Urgent Intervention Triage Strategy (ACUITY) trial. In this analysis of patients undergoing angiography with or without percutaneous coronary intervention from the femoral approach, there was a significant reduction in the incidence of major ASB and ACUITY non–coronary artery bypass graft major bleeding when a VCD was used. In terms of the individual components of major ASB, both ASB requiring interventional or surgical correction and hematoma ≥5 cm at the puncture site occurred significantly less often in those patients with a VCD. Furthermore, the lowest rate of ASB (<1%) was observed when patients were treated with bivalirudin monotherapy and a VCD. A stepwise logistic regression revealed significantly reduced risks in the odds of major ASB with bivalirudin monotherapy rather than heparin plus a glycoprotein IIb/IIIa inhibitor and VCD usage (65% and 22%, respectively). Because bleeding is a powerful independent predictor of 30-day mortality in patients with acute coronary syndrome invasively managed, the present findings suggest that the combined use of bivalirudin and a VCD may reduce major ASB in patients with acute coronary syndrome managed with an early invasive strategy from the femoral approach.
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_Circ Cardiovasc Interv._ 2010;3:57-62; originally published online January 26, 2010;
doi: 10.1161/CIRCINTERVENTIONS.109.896704

_Circulation: Cardiovascular Interventions_ is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231

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Print ISSN: 1941-7640. Online ISSN: 1941-7632

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