Relationship Between Femoral Vascular Closure Devices and Short-Term Mortality From 271 845 Percutaneous Coronary Intervention Procedures Performed in the United Kingdom Between 2006 and 2011

A Propensity Score–Corrected Analysis From the British Cardiovascular Intervention Society

Vasim Farooq, MBChB, MRCP, PhD; Dick Goedhart, PhD; Peter Ludman, MA, MD, FRCP; Mark A. de Belder, MA, MD, FRCP; Alun Harcombe, MBChB, MD, FRCP; Magdi El-Omar, BSc, MBBS, MD, MRCP; on behalf of the British Cardiovascular Intervention Society and the National Institute for Cardiovascular Outcomes Research

Background—The impact of vascular closure devices (VCDs) via the femoral arterial access site on short-term mortality in patients undergoing percutaneous coronary intervention is currently unknown.

Methods and Results—The association between femoral arterial vascular access site management (manual pressure [including external clamp] versus VCD) and 30-day mortality was examined in a national real-world registry of 271 845 patients undergoing percutaneous coronary intervention for elective, non–ST-segment–elevation myocardial infarction and ST-segment–elevation myocardial infarction indications in the United Kingdom between 2006 and 2011. Crude and propensity score–corrected analyses were performed using Cox regression, with additional analyses undertaken in clinically relevant subgroups; 40.1% (n=109 001) of subjects were treated with manual pressure and 59.9% (n=162 844) with VCD. Subjects treated with VCD had fewer comorbidities and were less likely to present with ST-segment–elevation myocardial infarction and cardiogenic shock (P<0.001). Crude 30-day mortality was lower in the group treated with VCD compared with manual pressure (hazard ratio [HR], 0.58; 95% confidence interval [CI], 0.54–0.61; 1.4% versus 2.4%, log rank P<0.0001), findings that were substantially reduced but persisted after propensity score correction (HR, 0.91; 95% CI, 0.86–0.97; 1.8% versus 2.0% versus P<0.001). A more pronounced association of VCD with a reduction in 30-day mortality was evident in females (HR, 0.85; 95% CI, 0.77–0.94; P interaction=0.037), presentation with acute coronary syndrome (HR, 0.88; 95% CI, 0.83–0.94; P interaction=0.0027), or recent lysis (HR, 0.63; 95% CI, 0.40–1.01; P interaction=0.0001).

Conclusions—When compared with manual pressure, VCD was associated with a minor short-term (30-day) prognostic benefit after propensity score correction in the global population and clinically relevant subgroups. The potential for residual confounding factors impacting on short-term mortality cannot be excluded, despite the study having measured and balanced all recorded confounder factors. (Circ Cardiovasc Interv. 2016;9:e003560. DOI: 10.1161/CIRCINTERVENTIONS.116.003560.)

Key Words: acute coronary syndrome ◼ cardiogenic shock ◼ mortality ◼ percutaneous coronary intervention ◼ vascular closure device

Major bleeding after percutaneous coronary intervention (PCI) has been clearly linked to short-term mortality, particularly in the setting of acute coronary syndrome.1–7 Although radial catheterization has been shown to be potentially safer compared with femoral catheterization, particularly in high-risk groups such as those presenting with ST-segment–elevation myocardial infarction, femoral catheterization continues to be a widely used arterial access site in patients undergoing PCI.8–16

Historically, it is well established that the incidence of vascular complications after the use of vascular closure devices (VCD) or manual compression is similar, and given other

Received January 2, 2016; accepted April 17, 2016.

From the Department of Cardiology, Manchester Heart Centre, Manchester Royal Infirmary, Central Manchester University Hospitals NHS Trust, Manchester, United Kingdom (V.F., D.G., M.E.-O.); Department of Cardiology, Queen Elizabeth Hospital, Birmingham, United Kingdom (P.L.); Department of Cardiology, The James Cook University Hospital, Middlesbrough, United Kingdom (M.A.d.B.); and Department of Cardiology, Nottingham University Hospitals NHS Trust, Nottingham, United Kingdom (A.H.).

Correspondence to Magdi El-Omar, BSc, MBBS, MD, MRCP, Manchester Heart Centre, Manchester Royal Infirmary, Central Manchester University Hospitals NHS Trust, Manchester, United Kingdom. E-mail Magdi.El-omar@cmft.nhs.uk

© 2016 American Heart Association, Inc.

Circ Cardiovasc Interv is available at http://circinterventions.ahajournals.org

DOI: 10.1161/CIRCINTERVENTIONS.116.003560
advantages, this has led to the widespread adoption of VCDs in conventional PCI practice where a femoral approach is undertaken. The main advantages of VCDs are greater patient comfort and improved cost-effectiveness because of reduced puncture site hemostasis time, bed rest, time to ambulation, and hospital stay compared with manual compression. Although evidence has accrued that VCDs (compared with manual compression) may be of greater value in higher-risk subjects—such as those receiving anticoagulant agents—in terms of reducing bleeding complications, with 1 population-based study (US CathPCI registry, n=1,189,611) associating the most frequently used VCDs with a substantial reduction in bleeding and vascular complications, this has proven to be controversial, particularly because VCDs in themselves have been associated with life-threatening complications. Consequently, the 2010 American Heart Association guidelines give a class IIa recommendation for VCD (reasonable to perform the procedure) to achieve faster hemostasis and improve patient comfort and a class III recommendation (procedure should not be performed because it is not helpful and may be harmful) when used with the intent to reduce vascular complications.

Given the potential association of VCDs with a reduction in vascular-related complications, it is hypothesized that the uniform use of VCD in femoral-based PCI may confer a potential short-term mortality benefit compared with manual pressure, particularly in higher-risk subjects such as those with acute coronary syndrome or receiving more potent anticoagulant therapy. The purpose of this study was to assess the short-term (30-day) mortality of patients undergoing femoral-based PCI treated with VCDs compared with manual compression in a national, all-comers PCI registry for elective, non-ST-segment-elevation myocardial infarction and ST-segment-elevation myocardial infarction indications during a 5-year period in the United Kingdom.

Methods

The British Cardiovascular Intervention Society Database

In an all-comers registry of every PCI procedure performed in all hospitals across the United Kingdom, British Cardiovascular Intervention Society (BCIS) has collected procedural and outcome data under the auspices of the National Institute for Cardiovascular Outcomes Research. By 2005, a full UK wide participation in the electronic collection of PCI data was established by the Central Cardiac Audit Database group. In 2011, >80,000 PCI procedures were recorded in the BCIS database, representing 97.3% of all PCI procedures performed in the United Kingdom. Approximately 113 variables are recorded for every PCI procedure, defining patient demographic features, indication for PCI, procedural details, and outcome data. The data set fields are available at http://www.bcis.org.uk. Data entry is performed locally at each hospital using local software systems by caregivers and data clerks and uploaded to central data servers. Data quality is obtained through local validation, range checks, and consistency assessments during upload. Feedback of data completeness is provided to all units. No external validation of collected data is undertaken. In England and Wales, mortality status is linked to each procedure via the National Health Service central register using a patient’s individual National Health Service number. It is a legal requirement that all deaths in the United Kingdom are registered with this body.

Study Population and Definitions

A retrospective analysis of all PCI procedures recorded in the BCIS database from 2006 to 2011 was undertaken. Subjects with nonfemoral or unknown arterial access site data were excluded. Subjects were divided into 2 cohorts based on femoral arterial access site management, namely manual pressure (including use of an external clamp to provide pressure) or VCD. Patients with missing femoral arterial access site management data were excluded. Stratified analyses were undertaken in clinically relevant subgroups, including age, sex, ethnicity, peripheral vascular disease, clinical presentation, and use of concomitant drugs (recent thrombolysis and periprocedural glycoprotein IIb/IIIa inhibitors). Thirty-day mortality was assessed via the National Health Service central register as described previously.

Definitions

Cardiogenic shock was defined using clinical parameters including blood pressure <100 mm Hg, pulse >100 bpm, with cool peripheries, or requiring inotropes or mechanical circulatory support. Circulatory support is defined as use of inotropes, intra-aortic balloon pump, or other mechanical support. Recent thrombolysis was defined as that given in the last month. The patient’s ethnic group was recorded as that perceived by the treating clinician. Cerebrovascular disease is defined as previous cerebrovascular accident (loss of neurological function caused by an ischemic event with residual symptoms at least 72 hours after onset), reversible ischemic neurological deficit (loss of neurological function caused by an ischemic event with symptoms at least 24 hours after onset but with complete return of function by 72 hours) or transient ischemic attack (loss of neurological function caused by an ischemic event, with abrupt onset and complete return of function within 24 hours). Periperal vascular disease is defined as history or evidence of any of occlusive peripheral vascular or carotid disease, aortic aneurysm, previous vascular surgery, and carotid or femoral bruit. History of renal disease is defined as creatinine >200 micromoles/L at the time of PCI.

Statistical Analysis

Baseline characteristics were compared between manual pressure and VCD femoral arterial access site management. Continuous variables are presented as means±SD and categorical variables as counts (percentages). Differences between the groups were tested using the Student t test for normally distributed continuous variables and Pearson χ2 tests for categorical variables. To control for confounding between manual pressure and VCD, a propensity score was constructed by a multivariate logistic model using the presence of a VCD as the dependent variable and 26 covariates as the independent variables (age at procedure, recent lysis, periprocedural glycoprotein IIb/IIIa use, ECG ischemia, ventilated preop, history of renal disease, smoking status, circulatory support [inotropes, intra-aortic balloon pump (IABP), and cardiopulmonary support], left
ventricular ejection fraction category [good, moderate, and poor], diabetes mellitus status, previous PCI, previous coronary artery bypass graft, previous myocardial infarction, procedural urgency [elective, emergency, salvage, and urgent], clinical syndrome, ethnic group, sex, preprocedural cardiogenic shock, use of bivalirudin, peripheral vascular disease, cerebrovascular disease, hypertension, hypercholesterolemia, left main disease, and number of diseased vessels).

The association between femoral arterial access site management (manual pressure versus VCD) and 30-day all-cause mortality was examined using a Cox regression model. Hazard ratios (HRs), with corresponding 95% confidence intervals (CIs), were obtained as an unadjusted crude estimate and an adjusted effect estimate by entering the propensity score into the Cox regression model as a continuous covariate (regression [covariance] adjustment). Regression (covariance) adjustment was used in preference to propensity score matching as a case (VCD n=162 844) to control (manual pressure n=109 001) matching procedure would have resulted in a loss of approximately one third of the analyzable data in the VCD group (53 843 cases). Missing data were recoded to a valid class in the Cox regression model, with and without correction for the propensity score. This methodology allowed the use of all analysable data, under the assumption that the missing data may be related to the decision on which femoral management approach was used. This assumption was confirmed by a change in the propensity score and consequent adjustment of the data. Propensity score correction of the covariates was undertaken in a proportional hazards model in preference to propensity score matching (Kaplan–Meier methodology), the latter of which would have led to loss of information because it allows for 1 case per control. Model diagnostics demonstrated the proportional hazard assumptions were not violated. Cumulative hazard plots are provided for the purpose of graphically displaying the relationship between femoral arterial access site management and 30-day mortality. Comparisons were made with the log-rank test. To assess the robustness of the HRs for 30-day mortality, stratified analyses were performed in clinically relevant subgroups.

Statistical tests were conducted at the 0.05 (2 tailed) level of significance. All analyses were carried out with SPSS (version 22, SPSS, IBM Corporation, Armonk, New York, NY) and SAS system version 9 software or higher (SAS Institute Inc, Cary, NC).

Results

Between 2006 and 2011, 554 614 PCI procedures were performed in England and Wales. After excluding subjects with nonfemoral or unknown arterial access site status, and subjects with missing femoral vascular access site management access, 271 845 PCI procedures were suitable for analysis (Figure 1). Manual pressure (n=109 001) comprised 40.1% of the study population, VCD (n=162 844) 59.9%. Subjects who underwent femoral arterial vascular access management with a VCD were younger (P<0.001), male (P<0.001), with fewer comorbidities (hypertension, diabetes mellitus, history of renal disease, cerebrovascular disease, and lower ejection fraction; P<0.001; Table 1). In addition, subjects implanted with VCD were less likely to present with ST-segment–elevation myocardial infarction (P<0.001), cardiogenic shock preprocedurally (P<0.001) and to have less complex (3 vessel) coronary artery disease (P<0.001; Table 1). The majority of subjects with a VCD underwent implantation with an Angiосeal (St. Jude Medical, St. Paul, MN; 154 752 of 162 844 patients, 95%; Table 2).

Thirty-Day Mortality

Uncorrected analyses demonstrated a significantly lower 30-day mortality in cases treated using VCD compared with manual pressure (HR, 0.58; 95% CI, 0.54–0.61). After propensity score correction, the mortality benefit for VCD compared with manual pressure was substantially reduced but remained significantly lower for VCD compared with manual pressure (HR, 0.91; 95% CI, 0.86–0.97). Thirty-day uncorrected (VCD 1.4% versus manual pressure 2.4%, log rank P<0.0001) and propensity score–corrected (VCD 1.8% versus manual pressure 2.0%, log rank P=0.0037) cumulative hazard plots, stratified by femoral management approach against time to death, illustrate the minor reduction in adjusted 30-day mortality associated with VCD (Figure 2).

Subgroup Analyses

To investigate whether there is a differential risk among certain populations, adjusted analyses were performed in clinically relevant subgroups (Figure 3). The interaction term reached statistical significance (P <0.05) for sex, clinical syndrome (acute coronary syndrome/acute myocardial infarction), cardiogenic shock, and recent lysis. Notably, there was a lower

---

**Figure 1.** Flow chart of patients eligible and excluded from analyses. PCI indicates percutaneous coronary intervention.
30-day mortality associated with VCD compared with manual pressure in females (HR, 0.85; 95% CI, 0.77–0.94; interaction \( P = 0.037 \)), presentation with acute coronary syndrome/acute myocardial infarction (HR, 0.88; 95% CI, 0.83–0.94; interaction \( P = 0.027 \)) or recent lysis (HR, 0.63; 95% CI, 0.40–1.01; interaction \( P = 0.0001 \)). Conversely, the association of a lower 30-day mortality with VCD was shown to be in subjects

Table 1. **Demographic Characteristics of the Population \((n=271845)\) Presented as Mean (95% CI) or Number (%) Stratified by Femoral Management Approach (Manual Pressure \([n=109001]\) Versus Vascular Closure Device \([n=162844]\)) for All Patients Undergoing PCI (BCIS Data 2006–2011)

<table>
<thead>
<tr>
<th>Clinical</th>
<th>Manual Pressure, 109001 (40.1%)</th>
<th>Vascular Closure Device, 162844 (59.9%)</th>
<th>(P) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>65.6±13.7</td>
<td>64.8±14.2</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Sex (male)</td>
<td>76392 (70.1)</td>
<td>119727 (73.5)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Ethnic group</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>74133 (68.0)</td>
<td>97981 (60.2)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Black</td>
<td>608 (0.6)</td>
<td>1089 (0.7)</td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>6263 (5.7)</td>
<td>8987 (5.7)</td>
<td></td>
</tr>
<tr>
<td>Oriental</td>
<td>147 (0.1)</td>
<td>204 (0.1)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>3446 (3.2)</td>
<td>9260 (5.9)</td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>57029 (52.3)</td>
<td>80142 (49.2)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>20571 (18.9)</td>
<td>28110 (17.3)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Insulin-treated diabetes mellitus</td>
<td>16749 (16.3)</td>
<td>22378 (14.9)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Smoking status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>33390 (30.6)</td>
<td>49941 (30.7)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Ex-smoker</td>
<td>38467 (35.3)</td>
<td>55392 (34.0)</td>
<td></td>
</tr>
<tr>
<td>Current</td>
<td>21243 (19.5)</td>
<td>31163 (19.1)</td>
<td></td>
</tr>
<tr>
<td>Known hypercholesterolemia</td>
<td>58973 (54.1)</td>
<td>87329 (53.6)</td>
<td>0.015</td>
</tr>
<tr>
<td>History of renal disease</td>
<td>3367 (3.1)</td>
<td>3945 (2.4)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Previous MI</td>
<td>31305 (28.7)</td>
<td>40691 (25.0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Previous CABG</td>
<td>12001 (11.0)</td>
<td>17111 (10.5)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Previous PCI</td>
<td>24213 (22.2)</td>
<td>36019 (22.1)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Known PVD</td>
<td>6200 (5.7)</td>
<td>5667 (3.5)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>3710 (3.4)</td>
<td>4608 (2.8)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Left ventricular ejection fraction</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Good (&gt;50%)</td>
<td>32808 (30.1)</td>
<td>58154 (35.7)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Fair (30% to 49%)</td>
<td>11172 (10.2)</td>
<td>17920 (11.0)</td>
<td></td>
</tr>
<tr>
<td>Poor (&lt;30%)</td>
<td>3964 (3.6)</td>
<td>4655 (2.9)</td>
<td></td>
</tr>
<tr>
<td>Not recorded</td>
<td>61057 (56.0)</td>
<td>82115 (50.4)</td>
<td></td>
</tr>
<tr>
<td>Procedural</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indication for PCI</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stable/Elective</td>
<td>48529 (44.5)</td>
<td>74006 (45.4)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>ACS/AMI</td>
<td>60443 (55.5)</td>
<td>88777 (54.5)</td>
<td></td>
</tr>
<tr>
<td>STEMI</td>
<td>19408 (17.8)</td>
<td>27597 (16.9)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Bivalirudin antithrombotic</td>
<td>2748 (2.5)</td>
<td>2595 (1.6)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

ACS indicates acute coronary syndrome; AMI, acute myocardial infarction; BCIS, British Cardiovascular Intervention Society; CABG, coronary artery bypass graft; CI, confidence interval; MI, myocardial infarction; PCI, percutaneous coronary intervention; PVD, peripheral vascular disease; and STEMI, ST-segment-elevation myocardial infarction.

30-day mortality associated with VCD compared with manual pressure in females (HR, 0.85; 95% CI, 0.77–0.94; interaction \( P = 0.037 \)), presentation with acute coronary syndrome/acute myocardial infarction (HR, 0.88; 95% CI, 0.83–0.94; interaction \( P = 0.027 \)) or recent lysis (HR, 0.63; 95% CI, 0.40–1.01; interaction \( P = 0.0001 \)). Conversely, the association of a lower 30-day mortality with VCD was shown to be in subjects

Table 2. **Type of Femoral Vascular Closure Device Recorded in the BCIS Database 2006 to 2011**

<table>
<thead>
<tr>
<th>Vascular Closure Device ((n=162844))</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angioseal</td>
<td>154752</td>
<td>95.0</td>
</tr>
<tr>
<td>Starclose</td>
<td>4325</td>
<td>2.7</td>
</tr>
<tr>
<td>Perclose</td>
<td>1464</td>
<td>0.9</td>
</tr>
<tr>
<td>Exoseal</td>
<td>702</td>
<td>0.4</td>
</tr>
<tr>
<td>Vasoseal</td>
<td>447</td>
<td>0.3</td>
</tr>
<tr>
<td>Mynx</td>
<td>100</td>
<td>0.06</td>
</tr>
<tr>
<td>Prostar</td>
<td>22</td>
<td>0.01</td>
</tr>
<tr>
<td>Duett</td>
<td>5</td>
<td>0.003</td>
</tr>
<tr>
<td>Clo-Sur PAD (Medtronic)</td>
<td>3</td>
<td>0.002</td>
</tr>
<tr>
<td>Mixed*</td>
<td>123</td>
<td>0.08</td>
</tr>
<tr>
<td>Unknown</td>
<td>901</td>
<td>0.6</td>
</tr>
</tbody>
</table>

BCIS indicates British Cardiovascular Intervention Society; and PAD, pressure applied dressing.

*More than 1 type of vascular closure device.
Figure 2. Thirty-day uncorrected (A) and propensity score–corrected (B) cumulative hazard plots stratified by femoral management approach (manual pressure vs VCD) against time to death. *P* values were calculated by the log-rank test. A, Uncorrected 30-day cumulative hazard plot. B, Propensity score–corrected* 30-day cumulative hazard plot. *Propensity score correction for age at procedure, recent lysis, periprocedural glycoprotein IIb/IIIa use, ECG ischemia, ventilated preop, history of renal disease, smoking status, circulatory support (inotropes, intra-aortic balloon pump, and cardiopulmonary support), left ventricular ejection fraction category (good, moderate, and poor), diabetes mellitus status, previous percutaneous coronary intervention, previous coronary artery bypass graft, previous myocardial infarction, procedural urgency (elective, emergency, salvage, and urgent), clinical syndrome, ethnic group, sex, preprocedural cardiogenic shock, use of bivalirudin, peripheral vascular disease, cerebrovascular disease, hypertension, hypercholesterolemia, left main disease, and number of diseased vessels. VCD indicates vascular closure device.
without cardiogenic shock (HR, 0.81; 95% CI, 0.76–0.88), compared with a neutral effect in subjects with cardiogenic shock (HR, 1.04; 95% CI, 0.93–1.15; interaction $P=0.0078$).

**Discussion**

In a population-based study involving 271,845 PCI procedures performed in England and Wales between 2006 and 2011, the use of a VCD (compared with manual pressure) was associated with a minor reduction (0.9-fold) in 30-day mortality after propensity correction. Stratified analyses in clinically relevant subgroups demonstrated this association to be more pronounced in females, presentation with acute coronary syndrome or recent lysis.

Historically manual compression, including the use of femoral clamps, has remained the gold standard for achieving femoral arterial hemostasis,\(^43,44\) and despite >20 years of use of VCDs, their safety remains controversial.\(^21,30–35\)

As described in the Figure 3. Stratified analyses in clinically relevant subgroups for 30-day mortality. Adjusted hazard ratios (manual pressure vs VCD) with 95% 2-sided CIs, and interaction $P$ values are shown. ACS indicates acute coronary syndrome; AMI, acute myocardial infarction; CI, confidence interval; PCI, percutaneous coronary intervention; STEMI, ST-segment–elevation myocardial infarction; and VCD, vascular closure device.

Adding to this field is the reported outcomes of VCDs during a 5-year period in a population-based study from the BCIS database. Strikingly, it was shown that VCDs were systematically implanted in lower-risk subjects. After propensity score correction, an association of VCDs with lower short-term mortality persisted. Although the potential for unmeasured confounding factors is entirely plausible, the findings of this study demonstrated the association of VCDs with a significantly greater reduction in 30-day mortality in higher-risk groups, such as those presenting with acute coronary syndrome, recent administration of thrombolytic agents and women, where the bleeding risk is well established to be higher.\(^5–7,45\) In addition, the current results support previous studies demonstrating VCDs to be of greater value in patients receiving anticoagulant agents by reducing bleeding complications.\(^5,28\) Conversely, although VCDs have been associated with life-threatening complications,\(^21,30–35\) this study did not demonstrate any signal of an adverse mortality impact in any of the prespecified subgroups, and indeed showed a more pronounced effect in the higher-risk groups, with the exception of cardiogenic shock where the effect was neutral.

It is however important to emphasize that VCDs have been associated with an increased risk of vascular complications compared with manual pressure, in particular leg ischemia, the need for surgical repair, and groin sepsis.\(^43\) As described in the
limitations of the study, because of systematic underreporting of vascular-related complications in the BCIS database, with the potential for bias in reporting in either arm, it was not possible to correlate vascular complications with short-term mortality. In addition, the systematic use of femoral angiography to screen for a diseased femoral vessel and avoidance of puncture site-related factors, is well established to lead to optimal positioning of the femoral sheath and reduction in vascular complications associated with VCD.46,47 It is highly plausible that this may account for some of the differences in baseline characteristics in this study, and that the presence of peripheral vascular disease was not associated with any impact on mortality (interaction P=0.28, Figure 3).

Notably, findings from the US national CathPCI registry (n=1819611) provide important mechanistic insights into the potential reduction in mortality seen in the BCIS registry—having associated the most frequently used VCDs (Angioseal, Perclose, StarClose and Boomerang Closure wire) with a substantial reduction in bleeding and vascular-related complications. In addition, 2 randomized trials of >5500 subjects undergoing femoral-based angiography have equated VCDs with at least no increased harm compared with manual compression. In consideration of the above findings, perhaps the time has come for the 2010 American Heart Association guidelines to be revisited, particularly since a class III recommendation (procedure should not be performed because it is not helpful and may be harmful) is currently given for VCDs when used with the intent to reduce vascular complications.37

Given the association of radial catheterization with improved clinical outcomes compared with femoral-based PCI, there has been a progressive increase in radial-based PCI in contemporary PCI practice, particularly with ST-segment–elevation myocardial infarction.10,14–16 Notably, it has been recently shown within the BCIS data set that even with the use of a VCD, radial-based PCI remains safer,30 supporting the practice that radial-based PCI should remain the cornerstone of contemporary PCI. Conversely, the maintenance of skills to safely conduct femoral-based PCI is of absolute importance, given that the femoral approach to PCI is still widely practiced, and particularly given recent evidence suggesting that radial operators have potentially more vascular-related complications in femoral-based PCI compared with predominantly femoral-based operators.30

Limitations

The main limitations of this study are those inherent to all registries, namely, the inability to exclude unmeasured confounding despite the study having measured and balanced all recorded confounder factors. Second, although statistical methods were used to correct for missing data, the possibility of confounding factors from missing data to have affected the results cannot be excluded. Third, outcomes related to vascular-related complications and bleeding were not possible because of systematic underreporting in the BCIS database, with the potential for bias in either arm. Conversely, mortality data were collected with accuracy because it is a legal requirement that all deaths in the United Kingdom are registered with the National Health Service central register (see methodology). Fourth, we could not correct for potential confounders related to whether the IABP was inserted in the same femoral-access site as to which the PCI procedure was performed, or if an alternative femoral access was used, as this was not reliably recorded in the database. Finally, comparisons of 30-day mortality based on VCD types was not possible because of 95% of all devices used being an Angioseal, consequently this study should not be interpreted as having a class-effect across all types of VCDs.

Conclusions

The use of a VCD (compared with manual pressure) was associated with a minor (0.9-fold) 30-day prognostic benefit after propensity score correction, findings which were much more pronounced in females, presentation with acute coronary syndrome or patients who had recently been administered thrombolytic therapy. The potential for residual confounding factors impacting on short-term mortality cannot be excluded, despite the study having measured and balanced all recorded confounder factors.

Disclosures

None.

References

Femoral Vascular Closure Devices and 30-Day Mortality


Relationship Between Femoral Vascular Closure Devices and Short-Term Mortality From 271 845 Percutaneous Coronary Intervention Procedures Performed in the United Kingdom Between 2006 and 2011: A Propensity Score–Corrected Analysis From the British Cardiovascular Intervention Society

Vasim Farooq, Dick Goedhart, Peter Ludman, Mark A. de Belder, Alun Harcombe and Magdi El-Omar

on behalf of the British Cardiovascular Intervention Society and the National Institute for Cardiovascular Outcomes Research

Circ Cardiovasc Interv. 2016;9:
doi: 10.1161/CIRCINTERVENTIONS.116.003560

Circulation: Cardiovascular Interventions is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Copyright © 2016 American Heart Association, Inc. All rights reserved.
Print ISSN: 1941-7640. Online ISSN: 1941-7632

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://circinterventions.ahajournals.org/content/9/6/e003560