Major Femoral Bleeding Complications After Percutaneous Coronary Intervention

Incidence, Predictors, and Impact on Long-Term Survival Among 17,901 Patients Treated at the Mayo Clinic From 1994 to 2005

Brendan J. Doyle, MB, BCH, Henry H. Ting, MD, MBA, Malcolm R. Bell, MBBS, FRACP, Ryan J. Lennon, MS, Verghese Mathew, MD, Mandeep Singh, MD, David R. Holmes, MD, Charanjit S. Rihal, MD

Rochester, Minnesota

Objectives The purpose of this study was to evaluate secular trends and factors associated with major femoral bleeding after percutaneous coronary intervention (PCI) in routine clinical practice during the past decade and to assess the impact of these complications on outcomes including mortality.

Background Significant changes in patient demographic data, adjunctive pharmacotherapy, and access site management have occurred during the coronary stent era. Trends in major vascular complications after PCI during this time have not been well characterized.

Methods Consecutive patients who underwent transfemoral PCI from 1994 to 2005 at the Mayo Clinic (n = 17,901) were studied. Patients were divided into 3 groups: Group 1 (1994 to 1995, n = 2,441); Group 2 (1996 to 1999, n = 6,207); and Group 3 (2000 to 2005, n = 9,253).

Results The incidence of major femoral bleeding complications decreased (from 8.4% to 5.3% to 3.5%; p < 0.001). Reductions in sheath size, intensity and duration of anticoagulation with heparin, and procedure time were observed (p < 0.001), and multivariate analysis confirmed each as an independent predictor of complications (p < 0.001). Adverse outcomes of major femoral bleeding included prolonged hospital stay (mean 4.5 vs. 2.7 days; p < 0.0001) and increased requirement for blood transfusion (39% vs. 4.7%; p < 0.0001). Major femoral bleeding and blood transfusion were both associated with decreased long-term survival, driven by a significant increase in 30-day mortality (p < 0.001 for both).

Conclusions We noted a marked decline in the incidence of major femoral bleeding after PCI over the past decade. Mortality associated with these bleeding complications and with blood transfusion remains a significant issue. (J Am Coll Cardiol Intv 2008;1:202–9) © 2008 by the American College of Cardiology Foundation
Since the introduction of coronary stents in the late 1980s, significant changes in the anticoagulation protocols have resulted in varying rates of stent thrombosis and bleeding complications (1–9). The impact of these changing trends on bleeding after percutaneous coronary intervention (PCI) and its relationship to adverse cardiovascular outcomes is less well studied. To address the hypothesis that changes in PCI practice have altered the incidence of major femoral bleeding complications and that these complications have a clinically meaningful impact on morbidity and mortality, we studied a cohort of 17,901 consecutive patients treated with PCI from 1994 to 2005.

**Methods**

Major vascular complications among 17,901 patients undergoing transfemoral PCI from 1994 through June 2005 were identified with the Mayo Clinic PCI database. In this database, major vascular complications are recorded prospectively at the time of hospital dismissal. For the present study, patients were divided into 3 groups on the basis of the year they underwent PCI: Group 1 (1994 to 1995, n = 2,443), the early stent era with intensive anticoagulation and antiplatelet regimens during and after PCI including warfarin, dextran, prolonged intravenous heparin, aspirin, and dipyridamole; Group 2 (1996 to 1999, n = 6,212), a period of transition from intense anticoagulation regimens to dual anti-platelet therapy with aspirin and ticlopidine and initial use of periprocedural glycoprotein (GP) IIb/IIIa inhibitors; Group 3 (2000 to 2005, n = 9,253), the contemporary era with routine use of aspirin and clopidogrel, frequent use of GP IIb/IIIa inhibitors but reduced intensity and duration of anticoagulation with unfractionated heparin. Low molecular weight heparin and bivalirudin are not used in our PCI practice.

Upon completion of the PCI procedure, the femoral sheath is sutured in place and connected to a flush system. An obturator 1 French size smaller than the sheath is placed below 45° (increasing patient comfort) while waiting for the activated clotting time (ACT) to fall. When the ACT is below 180 s the sheath is removed, hemostasis is secured with manual compression for 10 to 15 min, and the patient remains lying flat in bed for 2 h. Between 2 to 4 h after sheath removal, patients can lie on their sides in bed. Between 4 and 6 h after sheath removal the patient is allowed to sit upright in bed and is then allowed to ambulate after 6 h. This protocol has not changed significantly during the study period.

Institutional review board approval was obtained for this study. Patients who denied research authorization to their medical records were excluded, as required by State of Minnesota statute (n = 335). Interventions with brachial or radial artery access were also excluded.

**Definitions.** The primary end point of this study was major femoral bleeding complications after PCI, which included any of the following: femoral hematoma, femoral bleed, and retroperitoneal hematoma. Significant femoral hematoma was defined as >4 cm in diameter that required blood transfusion, surgery, or prolonged hospital stay. Femoral bleed was defined as external bleeding from the femoral artery requiring blood transfusion or surgery. Retroperitoneal hematoma was identified with abdominal ultrasound or computed tomography scan. Blood transfusion was defined as the administration of whole blood or packed red blood cells within 7 days of PCI. Severe renal impairment was defined as creatinine >3.0 mg/dl, on dialysis or previous renal transplant. Peripheral vascular disease was defined as a history of claudication or peripheral vascular surgery (including non-traumatic amputation) or angioplasty. Myocardial infarction (MI) before PCI was diagnosed if 2 or more of the following criteria were met: prolonged chest pain >20 min, cardiac biomarker elevation >2 times the upper limit of normal (creatinine kinase, creatine kinase-myocardial band, or relative index), ST-segment T-wave changes, or new Q waves on serial electrocardiograms indicative of myocardial damage. Procedural success was defined as <50% residual stenosis in the treated segment and no in-hospital death, Q-wave MI, or emergency coronary artery bypass surgery.

**Statistical analysis.** Continuous variables are summarized as mean ± SD unless otherwise noted. Discrete variables are presented as frequencies and group percentages. Missing values were not included in the denominator for percentage calculation. Kaplan-Meier estimates were used to describe long-term survival. Group distributions were compared by 1-way analysis of variance or Pearson’s chi-square test or the log-rank test. All tests were 2-tailed with a 0.05 type 1 error rate, except for multiple testing situations. A Bonferroni adjustment to a 0.025 significance level was used when Groups 1 and 2 were compared with Group 3. Multiple logistic regression was used to estimate partial associations between clinically relevant risk factors and the combined bleeding end point. Non-linear associations between continuous covariates and the end point were inspected. The continuous covariates with non-linear associations were then collapsed into groups for ease of interpretation. Generalized estimating equations were used to account for correlation between different procedures on the same patient assuming an exchangeable correlation structure.

**Abbreviations and Acronyms**

- ACT = activated clotting time
- BMI = body mass index
- CI = confidence interval
- GP = glycoprotein
- MI = myocardial infarction
- OR = odds ratio
- PCI = percutaneous coronary intervention
- Q = quinidine
- SD = standard deviation

**Coronary Artery Disease**
Multiple Cox proportional hazard models were used to estimate the partial hazard ratios (HRs) between those who did and those who did not have a bleeding complication or a blood transfusion. Follow-up analyses were restricted to the first PCI/unique patient within the study period. The proportional hazards assumption was assessed by plotting a scatterplot smoother through scaled Schoenfeld residuals. Violation of the proportional hazards assumption was handled by allowing for separate effects at different follow-up intervals. Age was treated as a time-dependent covariate (in 3-month intervals) to allow for a nonlinear association. Other risk factors in the model were gender, urgency of PCI, pre-PCI shock, pre-PCI MI, body mass index (BMI), smoking status, congestive heart failure on presentation, left ventricular ejection fraction, diabetes, severe renal impairment, peripheral vascular disease, American Heart Association/American College of Cardiology type C lesion, number of diseased coronary vessels, prior coronary bypass surgery, and prior PCI.

Results

Patient characteristics. The majority of patients treated were men, with no significant change from Group 1 to Group 3 (72%, 70%, and 70%; p > 0.05). Mean age rose from Group 1 to Group 3 (64.4 years, 65.9 years, and 66.9 years; p < 0.001). The proportion of patients treated for acute MI (occurring < 24 h before PCI) also rose from Group 1 to Group 3 (13%, 14%, and 19%; p < 0.001). Changes in other patient characteristics are detailed in Table 1.

Procedural characteristics. Procedural characteristics are summarized in Table 1. Mean sheath size decreased significantly from Group 1 to Group 3 (8.2-F, 7.8-F, and 6.4-F; p < 0.001), and concomitant use of a venous sheath also declined between these time periods (13%, 12%, and 6%; p < 0.001). Use of GP IIb/IIIa receptor blockers rose significantly from Group 1 to Group 3 (1%, 41%, and 58%; p < 0.001). Use of individual agents in Groups 1 to 3 was as follows: abciximab 1%, 39%, and 18%; eptifibatide 0%, 1%, and 38%; and tirofiban 0%, 1%, and 2%. Intensity of anticoagulation with heparin decreased from Group 1 to Group 3, as assessed by peak intraprocedural activated clotting time (405 s, 339 s, and 312 s; p < 0.001; Hemochron assay) and by use of post-procedure heparin infusions (80%, 36%, and 27%; p < 0.001). Mean procedure duration decreased from Group 1 to Group 3 (1.7 to 1.4 h; 1.4 to 1.2 h).

Table 1. Changes in Clinical and Procedural Characteristics of Patients Undergoing PCI

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Age (yrs)</td>
<td>64.4 ± 11.7*</td>
<td>65.9 ± 11.9*</td>
<td>66.9 ± 12.2</td>
</tr>
<tr>
<td>Men</td>
<td>1,749 (72%)</td>
<td>4,354 (70%)</td>
<td>6,474 (70%)</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>531 (22%)*</td>
<td>1,381 (22%)*</td>
<td>2,408 (26%)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>1,372 (57%)*</td>
<td>3,774 (62%)*</td>
<td>6,573 (75%)</td>
</tr>
<tr>
<td>Hypercholesterolemia</td>
<td>1,216 (57%)*</td>
<td>3,679 (65%)*</td>
<td>7,072 (84%)</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>28.6 ± 5.1*</td>
<td>29.0 ± 5.2*</td>
<td>29.7 ± 5.6</td>
</tr>
<tr>
<td>Moderate/severe renal impairment</td>
<td>91 (4%)</td>
<td>215 (3%)</td>
<td>323 (4%)</td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td>276 (11%)</td>
<td>705 (12%)</td>
<td>904 (10%)</td>
</tr>
<tr>
<td>Unstable angina</td>
<td>1,809 (74%)*</td>
<td>4,087 (66%)*</td>
<td>5,120 (55%)</td>
</tr>
<tr>
<td>Myocardial infarction &lt;24 h prior</td>
<td>319 (13%)*</td>
<td>878 (14%)*</td>
<td>1,704 (19%)</td>
</tr>
<tr>
<td>Type of PCI</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elective</td>
<td>789 (32%)</td>
<td>2,521 (41%)</td>
<td>2,875 (31%)</td>
</tr>
<tr>
<td>Urgent</td>
<td>1,248 (51%)</td>
<td>2,623 (42%)</td>
<td>4,578 (49%)</td>
</tr>
<tr>
<td>Emergency</td>
<td>402 (16%)</td>
<td>1,056 (17%)</td>
<td>1,797 (19%)</td>
</tr>
<tr>
<td>Sheath size (F)</td>
<td>8.2 ± 0.7*</td>
<td>7.8 ± 0.9*</td>
<td>6.4 ± 0.8</td>
</tr>
<tr>
<td>Venous sheath</td>
<td>312 (13%)*</td>
<td>719 (12%)*</td>
<td>563 (6%)</td>
</tr>
<tr>
<td>Glycoprotein IIb/IIIa inhibitor</td>
<td>27 (1%)*</td>
<td>2,536 (41%)*</td>
<td>5,328 (58%)</td>
</tr>
<tr>
<td>Peak ACT (s)</td>
<td>405 ± 110*</td>
<td>339 ± 79*</td>
<td>312 ± 61</td>
</tr>
<tr>
<td>Mean systolic blood pressure (mm Hg)</td>
<td>137 ± 27*</td>
<td>136 ± 29*</td>
<td>131 ± 27</td>
</tr>
<tr>
<td>Mean diastolic blood pressure (mm Hg)</td>
<td>74 ± 12*</td>
<td>71 ± 12*</td>
<td>68 ± 12</td>
</tr>
<tr>
<td>Duration of procedure (h)</td>
<td>1.7 ± 1.3*</td>
<td>1.4 ± 1.0*</td>
<td>1.4 ± 0.9</td>
</tr>
<tr>
<td>Heparin use post-procedure</td>
<td>1,955 (80%)*</td>
<td>2,215 (36%)*</td>
<td>2,456 (27%)</td>
</tr>
<tr>
<td>Vascular closure device</td>
<td>0</td>
<td>315 (5%)</td>
<td>433 (5%)</td>
</tr>
</tbody>
</table>

*p < 0.001 versus Group 3.

ACT = activated clotting time; PCI = percutaneous coronary intervention.
p < 0.001). Vascular closure devices were first used in Group 2 (5% of patients; Angioseal 1.9%, Perclose 3.1%), and use remained low in Group 3 (5% of patients; Angioseal 1.8%, Perclose 3.2%). Mean systolic and diastolic blood pressure during the procedure declined from Group 1 to Group 3 (137/74 mm Hg, 136/71 mm Hg, and 131/68 mm Hg; p < 0.001).

**In-hospital outcomes.** Procedural success was obtained in 94.4% of all patients. In-hospital mortality was 1.9%. Use of emergency coronary artery bypass surgery, and stroke fell from 5.7% in Group 1 to 2.6% in Group 3 (p < 0.001). The incidence of major femoral bleeding declined significantly from 8.4% in Group 1, 5.3% of patients in Group 2, and 3.5% of patients in Group 3 (p < 0.001). Significant reductions were observed for all individual bleeding complications (Table 2); femoral hematoma, femoral bleed, and retroperitoneal bleed all declined by at least 50% from the earliest (Group 1) to the most recent (Group 3) time period.

Rates of blood transfusion declined significantly from Group 1 to Group 3 (8.5%, 7.8%, and 5.6%; p < 0.001) (Table 2). This change was driven by a decrease in the frequency of large-volume blood transfusions of 3 or more units (Group 1 = 4.5%, Group 2 = 3.2%, Group 3 = 1.8%; p < 0.001). There was no significant change in the frequency of small-volume blood transfusions of 1 to 2 units from the earliest to the contemporary time period (4.0% vs. 3.8%; p > 0.05). Among patients with major femoral bleeding, 43% did not require a blood transfusion; 60% of patients with major femoral hematoma did not require transfusion. In addition, 72% of patients who required post-PCI transfusion did not meet the definition for major femoral bleeding.

**Multiple regression analysis.** A multiple regression model was used to identify variables independently associated with the composite end point of any femoral bleeding complication (Fig. 2). Sheath size above 6-F was identified as a significant independent predictor of major femoral bleeding (p < 0.001) (odds ratio [OR] 1.38 for 7- to 8-F, OR 1.65 for 9-F, OR 2.48 for >9-F). The absolute risk of complications by sheath size was as follows: 5-F = 2.4%, 6-F = 3.2%, 7-F = 4.2%, and >7-F = 6.3% (p < 0.001 for trend). Other predictors of major femoral bleeding included age >65 years (in particular those >75 years [OR 2.64; 95% confidence interval (CI) 1.98 to 3.52]), female patient (OR 1.64; 95% CI 1.38 to 1.94), severe renal impairment (OR 2.29; 95% CI 1.69 to 3.08), GP IIb/IIIa inhibitor use (OR 1.54; 95% CI 1.29 to 1.84), peak activated clotting time (OR 1.47; 95% CI 1.16 to 1.87), use of post-procedure heparin (OR 2.29; 95% CI 1.93 to 2.73), and procedure duration (OR 1.19; 95% CI 1.07 to 1.32). Use of a vascular closure device was associated with increased risk for major femoral bleeding (OR 1.58, 95% CI 1.09 to 2.29). Patients with mildly (25 to 30 kg/m²) and moderately (30 to 35 kg/m²) elevated BMI exhibited lower risk for complications when compared with patients with BMI in the normal range (OR 0.76 for BMI 25 to 30 kg/m², OR 0.75 for BMI 30 to 35 kg/m²). Diabetes (OR 0.80; 95% CI 0.67 to 0.97) was associated with lower risk for major femoral bleeding complications (p = 0.023). Peripheral vascular disease was associated with a trend toward lower risk for these complications (OR 0.79; 95% CI 0.62 to 1.01, p = 0.063).

**Association of major femoral bleeding with outcomes.** Patients who had major femoral bleeding after PCI had a

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**Table 2. Changing Incidence of Major Femoral Bleeding and Blood Transfusion After PCI**

<table>
<thead>
<tr>
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<tbody>
<tr>
<td><strong>Groups</strong></td>
<td>(n = 2,443)</td>
<td>(n = 6,207)</td>
<td>(n = 9,253)</td>
</tr>
<tr>
<td>Femoral hematoma</td>
<td>172 (7.0%)*</td>
<td>236 (3.8%)*</td>
<td>257 (2.8%)*</td>
</tr>
<tr>
<td>Femoral bleed</td>
<td>60 (2.5%)*</td>
<td>76 (1.2%)*</td>
<td>54 (0.6%)*</td>
</tr>
<tr>
<td>Retroperitoneal bleed</td>
<td>20 (0.8%)*</td>
<td>19 (0.3%)*</td>
<td>26 (0.3%)*</td>
</tr>
<tr>
<td>Blood transfusion</td>
<td>207 (8.5%)*</td>
<td>482 (7.8%)*</td>
<td>516 (5.6%)*</td>
</tr>
<tr>
<td>1 to 2 U</td>
<td>98 (4.0%)*</td>
<td>288 (4.6%)*</td>
<td>347 (3.8%)*</td>
</tr>
<tr>
<td>3+ U</td>
<td>109 (4.5%)*</td>
<td>194 (3.1%)*</td>
<td>169 (1.8%)*</td>
</tr>
</tbody>
</table>

*p < 0.005 versus Group 3.

PCI = percutaneous coronary intervention.

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**Figure 1. Changing Incidence of Major Femoral Bleeding Complications From 1994 to 2005**

The incidence of major femoral bleeding declined significantly from the earliest (8.4%) to the contemporary time period (3.5%).
significantly longer post-procedure hospital stay than patients without vascular complications (mean 4.5 days vs. mean 2.7 days; p < 0.0001). Blood transfusion was required more frequently after a major vascular complication (39.0% vs. 4.7%; p < 0.0001).

Patients experiencing major femoral bleeding had significantly higher mortality during long-term follow-up. This difference was driven by significant excess mortality in the first 30 days after PCI (HR 14.2; 95% CI 9.95 to 20.3, p < 0.01); the risk of death was not significantly different between patients with and without a major femoral bleeding complication (HR 1.10; 95% CI 0.95 to 1.28, p = 0.20). Excess 30-day mortality remained significant after adjustment for baseline patient and procedural characteristics as described in Statistical Analysis (adjusted HR 16.4 to 75.1, p < 0.001). For all 3, the effect of the complication on mortality after 30 days was non-significant. Kaplan-Meier curves in Figure 3 demonstrate worse long-term survival for patients with: (panel A) any bleeding complication versus no bleeding complication, (panel B) retroperitoneal bleeding versus no retroperitoneal bleeding, (panel C) major femoral bleeding versus no major femoral bleeding, and (panel D) major hematoma versus no major hematoma. Over time, 30-day mortality associated with major femoral bleeding seemed to decline (Group 1 HR 16.1, 95% CI 8.8 to 29.5; Group 2 HR 9.8, 95% CI 5.4 to 17.9; Group 3 HR 6.9, 95% CI 3.5 to 13.4), although this trend did not reach statistical significance (p = 0.065).

Blood transfusion within 7 days of PCI was associated with increased mortality at 30-day follow up. This risk was dose-dependent, with transfusion of 3 or more units independently associated with greater risk (adjusted HR 18.1; 95% CI 13.7 to 24.0, p < 0.0001) when compared with transfusion of 1 or 2 U (adjusted HR 8.9; 95% CI 6.3 to 12.6, p < 0.0001). Excess mortality associated with blood transfusion persisted through long-term follow-up: Kaplan-Meier estimated long-term survival for patients receiving: 1)
no post-PCI blood transfusion; 2) 1 to 2 U blood transfusion; and 3) ≥3 U blood transfusion is shown in Figure 4.

Discussion

The main findings of this study were: 1) there has been a significant decline in rates of major femoral bleeding complications after PCI in the contemporary era; 2) this downward trend in adverse events has occurred despite the performance of PCI on older patients and despite increased use of intravenous GP IIb/IIIa inhibitors; 3) use of smaller sheaths, reduced intensity and duration of periprocedural anticoagulation with heparin, and shorter procedures have contributed to the reduction in complications; 4) major femoral bleeding complications are associated with prolonged hospital stay and markedly increased requirement for blood transfusion; and 5) major femoral bleeding complications and blood transfusion are both associated with increased mortality during long-term follow-up.

Changes in procedural technique and risk of complications.

The findings of the multivariate analysis suggest that risk of major femoral bleeding complications might be minimized by judicious use of smaller sheaths, careful titration of intraprocedural anticoagulation, and avoidance of post-procedure heparin infusions. Improved efficiency leading to shorter procedures might also reduce complications by minimizing sheath dwell time (10,11). It is likely that the passing out of favor of techniques such as directional atherectomy (that required larger sheath sizes and prolonged procedure times) have contributed to the decline in the incidence of major vascular complications over the past decade. Incorporation of GP IIb/IIIa inhibitors into routine practice has been achieved, however, while bleeding complications have continued to decrease. The level of concomi-
tant anticoagulation is an important determinant of the absolute bleeding risk associated with GP IIb/IIIa inhibitor use (12–14), and it is likely that the effect of these agents on complication rates in this study was attenuated by a downward trend in the intensity of anticoagulation.

Vascular closure devices are used infrequently in our practice (only 5% in Groups 2 and 3), and so the association between use of these devices and increased risk for major femoral bleeding (OR 1.58, p < 0.016) should be interpreted with caution. Nonetheless, previous studies have suggested that such devices might increase risk of hematoma, pseudo-aneurysm formation, retroperitoneal hemorrhage, and rare but catastrophic infectious and ischemic complications (15–20). Our findings re-emphasize the need for large-scale randomized studies of these devices to definitively address these safety concerns.

Outcome of major femoral bleeding complications. A number of mechanisms might underlie the association between major femoral bleeding and blood transfusion, with increased risk for major femoral bleeding (OR 1.58, p = 0.016) should be interpreted with caution. Nonetheless, previous studies have suggested that such devices might increase risk of hematoma, pseudo-aneurysm formation, retroperitoneal hemorrhage, and rare but catastrophic infectious and ischemic complications (15–20). Our findings re-emphasize the need for large-scale randomized studies of these devices to definitively address these safety concerns.

Outcome of major femoral bleeding complications. A number of mechanisms might underlie the association between major femoral bleeding, blood transfusion, and increased mortality. Severe hemorrhage could directly increase risk of death by causing hemodynamic compromise, particularly in patients with poor cardiac reserve or other severe comorbidities. The need to stop antithrombotic therapies within hours or days of PCI because of major bleeding could also play an indirect role, by increasing risk of ischemic coronary complications. Notably, accumulating data suggest a possible direct link between blood transfusion and adverse outcomes for a variety of critical illnesses and major surgical procedures (21,22). Pro-inflammatory and -thrombotic effects of red blood cell transfusion have been demonstrated (23), and use of a restrictive transfusion policy has been associated with improved outcomes for patients with critical illness (24). Our data support the latter finding, because transfusions of ≥3 U were associated with worse outcomes when compared with transfusions of 1 to 2 U. Nevertheless, it must be emphasized that a causal relationship between post-PCI blood transfusion and subsequent excess mortality will be impossible to establish outside of a randomized clinical trial comparing a traditional with a more restrictive transfusion policy. Moreover, it is possible that, despite the findings of our multivariate analysis, major femoral bleeding and blood transfusion might simply be surrogates for patients with more complex coronary disease and more extensive comorbidities and that the associations with mortality might be due to unmeasured variables.

Study limitations. Although the data were prospectively gathered, this was a retrospective study and is subject to the limitations of this design. Outcomes are reported from a single high-volume center using transfemoral access, and our use of vascular closure devices is low by comparison with some other centers. Therefore, our results might not be applicable to centers with lower volume or centers where use of vascular closure devices or radial access is more frequent. Finally, our definition of major femoral bleeding complications did not incorporate measurement of pre- and post-procedure hemoglobin (used in the Thrombolysis In Myocardial Infarction bleeding classification system). Therefore, although stringent criteria for defining major femoral bleeding—including the need for blood transfusion, vascular surgery, and/or prolonged hospital stay—were used in this study, caution should be exercised before making direct comparisons between absolute bleeding risk observed in this study and rates reported elsewhere.

Conclusions

In this single-center study, we have noted a significant fall in the incidence of major femoral bleeding complications over the past decade. These improvements have been achieved without the use of bivalirudin and with relatively infrequent use of vascular closure devices. The association of major femoral bleeding and blood transfusion with increased long-term mortality remains a strong impetus for further improvements in access strategies for patients undergoing PCI.

Reprint requests and correspondence: Dr. Charanjit S. Rihal, Director, Cardiac Catheterization Laboratory, Mayo Clinic, 200 First Street SW, Rochester, Minnesota 55905. E-mail: rihal.charanjit@mayo.edu.

REFERENCES


