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Trends in Major Entry Site Complications from Percutaneous Coronary Intervention (From the Dynamic Registry)

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Abstract

Several factors contribute to the risk of percutaneous coronary intervention (PCI) related major entry site complications (MES). We sought to examine the trends in MES among unselected patients during the stent era. Data from the Dynamic Registry including five distinct recruitment waves from 1997 to 2006 (N=10,932) were used to assess baseline characteristics and MES among consecutive patients undergoing PCI. MES was defined as bleeding requiring transfusion, pseudoaneurysm, arterial thrombosis or dissection, vascular complication requiring surgery, or retroperitoneal bleed. Uncomplicated hematomas were not included. Several trends were observed in baseline characteristics including an increase from wave 1 to wave 5 in BMI >30 kg/m² (30.2% to 40.4%), renal disease (3.5% to 9.1%), diabetes (28.0% to 34.1%), and hypertension (59.4% to 78%) ($p_{\text{trend}} < 0.001$ for all). Use of a thienopyridine increased significantly from wave 1 (49.7%) to wave 5 (84%) whereas glycoprotein (GP) IIb/IIIa inhibitor use peaked in wave 3 (53.1%) and then decreased ($p < 0.001$). Access site was predominately femoral but radial access increased over time (0.3% wave 1, 6.6% wave 5) ($p = < .0001$). The rates of MES (2.8% to 2.2%, $p_{\text{trend}} = 0.01$) and MES requiring transfusion (2.0% to 0.74%, $p_{\text{trend}} < 0.001$) were low and decreased with time. The trend in lower risk for MES in later time periods remained after adjustment. In conclusion, MES has decreased over time however opportunity for bleeding avoidance strategies still exists.

Keywords

percutaneous coronary intervention; complications; bleeding; arterial access

Local complications at the site of vascular access are among the most common complications following percutaneous coronary intervention (PCI).¹ Robust data links

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vascular access site complications to both morbidity and mortality following PCI.²⁻⁵ The influence of access site bleeding events and transfusion on mortality and resource utilization is particularly significant.^{6,7} Multiple risk factors for vascular complications following PCI have been identified, including both patient and procedural characteristics.⁸⁻¹⁰ In an attempt to minimize vascular complications associated with PCI, bleeding avoidance strategies have been advocated. Such measures include use of smaller arterial sheaths, radial artery access, use of safer and more predictable anticoagulation regimens, and closure devices.¹¹ Data in support of these strategies are emerging. In this analysis, we sought to investigate the rates and trends in major entry site complications (MES) in a large prospective multicenter PCI Registry in order to characterize changes in patient and procedural factors and specific types of MES complications.

Methods

The National Heart, Lung, and Blood Institute (NHLBI)-sponsored Dynamic Registry was a multicenter prospective study of consecutive patients undergoing PCI in North America and has previously been described.¹² The Dynamic Registry includes five distinct recruitment waves of patients enrolled from 1997 to 2006 (N=10,965). All patients enrolled in this observational study provided informed consent for inclusion of data used in this analysis. This current analysis excludes 9 patients with missing data age and 24 patients missing information on the components that define MES complications leaving a patient population of 10,932.

MES complication was defined as access site bleeding requiring transfusion, development of pseudoaneurysm, arterial thrombosis or dissection, vascular complication requiring surgery, or retroperitoneal bleeding. Uncomplicated hematomas were not included in the primary MES endpoint. Data collection for closure devices use was captured only in waves 4 and 5. Non-access site bleeding was defined as gastrointestinal bleeding, genital- urinary bleeding, or other bleeding remote from the access site. Two of the authors (JDA, KY) independently determined whether bleeding events were access or non-access site related. In the event of disagreement a third reviewer was used (FS).

PCI patients were grouped by recruitment wave and descriptive statistics were summarized as means for continuous variables and percentages for categorical variables. Differences between proportions were assessed for temporal trend using Cochran-Mantel-Haenszel or the Jonckheere-Terpstra test, where appropriate. Similar methods were used for the individual components that defined MES bleeding complications. Logistic regression was used to estimate the independent effect of clinically relevant factors on in-hospital risk of MES. Risk factors in the model included age, sex, procedural indication, cardiogenic shock, prior PCI, history of congestive heart failure, chronic kidney disease, peripheral vascular disease, GP IIb/IIIa inhibitor use, access site and recruitment wave. Goodness-of-fit was assessed using the Hosmer-Lemeshow method, and the model was considered to be adequate ($p>0.05$). All statistical analyses were performed with the use of SAS software, version 9.3, and a two-sided p-value of 0.05 or less was considered to indicate statistical significance.

Results

Significant trends in baseline characteristics were observed with increasing comorbidities over time (Table 1). The prevalence of prior myocardial infarction, however, fell over the ten year period. Significant trends in procedural characteristics were also observed (Table 2). Entry site location was predominantly femoral with increasing use of radial access over time. Anticoagulation and antiplatelet regimens varied considerably over time. Notably, use

of a thienopyridine significantly increased while the use of a GP IIb/IIIa inhibitor peaked in wave 3 and decreased by wave 5. Overall use of procedural and post-procedural heparin fell significantly from wave 1 to wave 5. Within the procedural period, use of unfractionated heparin fell while more low molecular weight heparin rose during the study period ($p_{\text{trend}} < 0.001$ for both). Bivalirudin use, reported in waves 4 and 5 only, was 31.9% and 32.0%, respectively. Pre-procedure aspirin use was high and there was no significant change over the 10 year period. Closure devices were used in 30.9% of patients in wave 4 and 40.2% in wave 5 ($p < 0.001$).

The trends in MES and bleeding outcomes are presented in Figure 1. The absolute decrease in MES over time was small but the trend was significant, from 2.8% in wave 1 to 2.2% in wave 5 ($p_{\text{trend}} = 0.015$). Transfusions related to access site MES decreased over time. Among patients that experienced bleeding ($n = 426$), the access site was the cause in 74.4%, 72.0%, 60.0%, 49.4% and 71.4% of cases in waves 1 to 5. Rates of pseudoaneurysm did not vary over time (from 0.71% in wave 1 to 0.97% in wave 5, $p_{\text{trend}} = 0.45$). Complications including arterial thrombosis and surgery of the access site were rare and similar over time (data not shown).

Several variables were identified as independently associated with MES (Table 3). Older age, female sex, acute myocardial infarction as indication, cardiogenic shock and procedural GP IIb/IIIa inhibitor use were all associated with a higher risk of MES. Prior PCI and radial access, on the other hand, were associated with a significantly lower risk of MES. Compared to recruitment wave 1, there was a trend towards a lower risk of MES in subsequent waves and this reached statistical significance in wave 4.

Discussion

This analysis of nearly 11,000 patients in the Dynamic PCI Registry confirms a small decrease in MES complications including those requiring blood transfusion over the time period of 1998 to 2006 in unselected patients. This occurred despite an increase in high risk patient characteristics over time, including obesity, renal insufficiency, diabetes mellitus and hypertension. The improvement may be explained by the uptake of strategies known to reduce bleeding, including radial access and anticoagulation with bivalirudin, or more attentiveness to femoral arterial access, hemostasis and closure.

Our results are in keeping with other reported single center and multicenter registry analyses surveying bleeding and other vascular complications in patients undergoing PCI. In 14,239 patients undergoing PCI from the femoral artery approach at Wake Forest University, vascular complications decreased from 3.1% to 1.0% from 1998 to 2007.¹³ In the National Cardiovascular Data (NCDR) CathPCI Registry between 2004 and 2008 the overall rate of bleeding was 2.0%, similar to our observation.¹⁴ In another NCDR analysis of over 1.7 million patients between 2005 and 2009, a 20% reduction in post-PCI bleeding was observed, however rates remained the highest in STEMI patients and no improvement was seen in this subgroup.¹⁵

Peri-procedural anticoagulation clearly influences MES bleeding complications. Use of alternative anticoagulants to unfractionated heparin alone or in combination with a GP IIb/IIIa receptor antagonist, is associated with lower rates of bleeding complications during PCI in various patient subsets.^{16,17} A change in practice patterns, with the adoption of bivalirudin over time, was observed in the NCDR Cath PCI Registry with use increasing from 17% to 30% from 2005 to 2009.¹⁵ We began collecting data on bivalirudin use after wave 3, which ended in 2002. In waves 4 and 5 of the Dynamic Registry, 2004 to 2006, bivalirudin use was similar at 32%. We also observed a decline in the use of GP IIb/IIIa

inhibitor after 2002. Periprocedural use of a GP IIb/IIIa inhibitor was found to be an independent predictor of MES in our study.

The trends we observed in radial access are also similar to other registries.¹⁵ By 2006, radial access was used in 6.6% of PCI procedures in the Dynamic Registry. This is double the rate observed in the NCDR Registry through 2009 which remained below 3%. In the subset of patients with STEMI, however, the use of radial increased from 0.9% to 6.4% from 2007 to 2011.¹⁸ The majority of randomized controlled trials supporting the radial over femoral approach for the reduction in bleeding were published later in time and may result in further increases in transradial PCI.^{19,20} We observed a significantly lower risk of MES in patients undergoing PCI via the radial approach. Previous trials have reported on the contribution of non-access site bleeding to major bleeding events. In the current study, the access site was responsible for bleeding in 49% to 75% of patients in each wave. An analysis of over 14,000 patients in randomized trials of PCI found that both access and non-access site bleeding were independently associated with mortality at 1 year.²¹

Several independent predictors of MES were identified such as female sex, peripheral vascular disease, acute myocardial infarction and cardiogenic shock. Bleeding avoidance strategies such as radial access and bivalirudin may be particularly effective at reducing bleeding complications in patients with one or more of these risk factors.

This prospective study is subject to limitations. MES was site determined and not independently adjudicated. All bleeding events however were reviewed by two of the authors to determine whether they were access or non-access site related. The severity of bleeding was not defined according to previously published criteria; however requirement of transfusion was collected. We were unable to evaluate several variables known to influence the risk of bleeding as they were not prospectively collected in the registry; including sheath size, venous access, and baseline hematocrit. Data on vascular closure device use was restricted to the later waves. Other limitations include the lack of data concerning additional techniques such as micropuncture use, and fluoroscopic or ultrasound guidance for femoral artery entry. Additionally, transfusion was at the discretion of the physicians and the threshold for transfusion may have changed over time with a higher threshold. Therefore, our results may be confounded by other factors that effectively lower MES bleeding complications and transfusions other than those explored in this analysis. Lastly, we did not assess the relationship between MES and clinical outcomes.

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Figure 1. Major entry site complications by recruitment wave

Table 1
Baseline characteristics of study population by recruitment wave

Characteristic	1 (N=2500)	2 (N=2099)	3 (N=2045)	4 (N=2111)	5 (N=2177)	p-value
Age, mean, median (years)	62.6, 63	63.0, 63	64.4, 65	63.7, 64	63.9, 64	<0.001
Female	35.5%	36.4%	36.0%	32.5%	32.8%	0.005
White	80.1%	78.2%	79.3%	77.0%	75.1%	0.99
Black	7.6%	12.0%	12.8%	14.7%	16.4%	
Asian	4.8%	3.9%	3.8%	3.0%	2.2%	
Hispanic	7.2%	5.7%	4.0%	5.3%	5.8%	
Other race/ethnicity	0.2%	0.2%	0.1%	0.0%	0.7%	
Body mass index (kg/m ²), mean, median	28.2, 28	28.8, 28	29.3, 28	29.2, 28	29.6, 29	<0.001
Prior percutaneous coronary intervention	28.5%	30.5%	33.0%	31.6%	35.2%	<0.001
Prior coronary bypass	16.6%	17.1%	18.6%	19.8%	18.0%	0.03
Prior myocardial infarction	39.1%	32.4%	27.6%	25.9%	22.6%	<0.001
Diabetes mellitus	28.0%	28.5%	30.1%	33.5%	34.1%	<0.001
Prior heart failure	9.9%	9.6%	12.5%	9.3%	10.1%	0.94
Hypertension	59.3%	64.6%	74.7%	77.1%	78.1%	<0.001
Hypercholesterolemia	61.0%	63.4%	71.4%	74.8%	79.1%	<0.001
Smoker						
Never	34.5%	32.5%	33.2%	37.6%	36.0%	0.04
Current	25.3%	26.7%	24.0%	22.5%	25.7%	
Former	40.2%	40.7%	42.8%	39.9%	38.3%	
Renal disease	3.5%	5.0%	7.3%	8.8%	9.2%	<0.001
Peripheral vascular disease	7.2%	7.3%	9.2%	8.8%	7.4%	0.24

* Baseline clinical variables were based on patient self-reports, physician diagnosis or pharmacologic therapy

Table 2

Procedural data and outcome by recruitment wave

Characteristic	1 N=2500	2 N=2099	3 N=2045	4 N=2111	5 N=2177	p-value
Device access site						
Femoral	99.4%	97.5%	96.0%	96.1%	93.2%	<.0001
Brachial	0.3%	0.5%	0.2%	0.5%	0.2%	
Radial	0.3%	2.0%	3.8%	3.4%	6.6%	
Meds <24hrs. Prior or During Procedure						
Aspirin	91.9%	81.0%	94.1%	92.2%	86.7%	0.88
Clopidogrel or Ticlopidine	49.8%	41.4%	67.6%	85.7%	84.0%	<.0001
GPIIb/IIIa inhibitor	24.3%	31.7%	53.1%	33.7%	37.4%	<.0001
Bivalirudin	-	-	-	31.9%	32.0%	0.77
Heparin	97.4%	94.6%	95.8%	75.6%	71.9%	<.0001
Unfractionated heparin	n/a	93.6%	95.0%	73.2%	68.8%	<.0001
Low molecular weight heparin	n/a	3.9%	3.7%	4.7%	7.3%	<.0001
Meds used after the procedure						
Heparin	38.6%	21.6%	10.6%	9%	10.6%	<.0001

The type of heparin used was not collected in Wave 1.

Table 3
Variables associated with major entry site complications in the Dynamic Registry

Effect	Odds Ratio	95% Confidence Limits		p-value
Age (years)	1.037	1.026	1.049	<0.001
Female sex	1.989	1.550	2.551	<0.001
Acute myocardial infarction*	1.391	1.051	1.841	0.02
Cardiogenic shock	3.091	1.788	5.346	<0.001
Peripheral vascular disease	1.560	1.072	2.269	0.02
Procedural glycoprotein IIb/IIIa inhibitor	1.480	1.144	1.914	0.003
Prior percutaneous coronary intervention	0.696	0.518	0.936	0.017
Radial access (versus femoral and brachial)	0.123	0.017	0.880	0.037
Recruitment Wave (versus wave 1)				
wave2	1.042	0.736	1.477	0.82
wave3	0.776	0.534	1.128	0.18
wave4	0.564	0.374	0.852	0.007
wave5	0.756	0.517	1.105	0.15

* versus other indication for percutaneous coronary intervention