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Trends in Vascular Complications After Diagnostic Cardiac Catheterization and Percutaneous Coronary Intervention Via the Femoral Artery, 1998 to 2007

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Objectives This study sought to evaluate trends in vascular complications after diagnostic cardiac catheterization (CATH) and percutaneous coronary intervention (PCI) from the femoral artery from 1998 to 2007.

Background Vascular complications have been recognized as an important factor in morbidity after CATH and PCI. Whether strategies to reduce vascular complications performed from the femoral artery in the past decade have improved the safety of these procedures, however, is uncertain.

Methods A total of 35,016 consecutive diagnostic cardiac catheterization (n = 20,777) and percutaneous coronary intervention procedures (n = 14,239) performed via a femoral access at a single site (Wake Forest University Baptist Medical Center) between 1998 and 2007 were evaluated. Annual rates of vascular complications were evaluated. Covariate effects on the risk of vascular complications were evaluated by logistic regression and risk-adjusted trend analysis.

Results Overall, the incidence of any vascular complication decreased significantly for CATH, 1.7% versus 0.2%, and PCI, 3.1% versus 1.0%, from 1998 to 2007, both $p < 0.001$ for trend. Favorable trends in procedural covariates affecting vascular complications were mainly responsible for the decrease in the incidence of vascular complications, including fewer closure device failures and use of smaller sheath sizes.

Conclusions In this large, single-center, contemporary observational study, the safety of CATH and PCI performed from the femoral artery improved significantly from 1998 to 2007. Reductions in the prevalence of adverse procedural factors contributed to the decrease in the incidence of vascular complications, suggesting that strategies to reduce vascular complications can be effective in improving the safety of these procedures. (J Am Coll Cardiol Intv 2008;1:317–26) © 2008 by the American College of Cardiology Foundation

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Recent studies have identified bleeding after diagnostic cardiac catheterization (CATH) and percutaneous coronary intervention (PCI) procedures (1–4), particularly retroperitoneal bleeding (5,6), as a significant source of morbidity and mortality after these procedures. Although not all of the bleeding can be directly attributed to complications at the procedure access site, access site complications remain a significant factor in post-procedural bleeding (7–9). Although medical and PCI treatments have been modified to minimize access site bleeding from anticoagulant and antiplatelet therapies (8,10), their use as pre-procedural treatment has increased substantially in the past decade, which could increase the risk of vascular complications. At the same time, strategies aimed at reducing femoral artery access site complications, such as use of fluoroscopy to guide femoral artery access (11), utilization of vascular closure devices (VCDs), and use of smaller sheath sizes, have been introduced into practice. Whether the awareness of the importance of access site complications on overall procedural outcomes (12–14), or utilization of VCDs (15,16) and smaller sheath sizes (12,17,18), or changes in medical and PCI practice (8,10) have had an effect on the incidence of vascular complications in the past decade is not clear. Accordingly, we assessed trends in the incidence of vascular complications after CATH and PCI procedures performed from the femoral artery from 1998 to 2007. We also evaluated trends in patient and procedural covariates that may have affected the risk of developing a vascular complication from these procedures.

Abbreviations and Acronyms

CATH = diagnostic cardiac catheterization
GP = glycoprotein
MC = manual compression
PCI = percutaneous coronary intervention
VCD = vascular closure device

Methods

All patients at our institution undergoing percutaneous CATH and PCI were evaluated for this study, which was approved by the Institutional Review Board. A total of 23,157 patients underwent 35,016 procedures from January 1998 to March 2007. Choice of the access site was at the discretion of the physician performing the case. Preference was for femoral artery access, with radial and brachial access obtained when femoral access could not be obtained; 22,846 patients underwent 34,556 procedures using the femoral approach, 79 patients underwent 105 procedures from the radial artery, and 232 patients underwent 355 procedures from the brachial approach, and form the basis for this study. Data from some of these patients have been included in a prior publication (19).

For patients undergoing procedures via femoral artery access, CATH patients received unfractionated heparin after sheath insertion at the discretion of the cardiologist performing the procedure. For patients undergoing procedures via radial or brachial access, 3,000 to 5,000 units of heparin were given immediately after sheath insertion. Anticoagulation after sheath insertion for PCI patients was obtained using unfractionated heparin with a target activated clotting time of 200 to 250 s if used in conjunction with glycoprotein (GP) IIb/IIIa inhibitors, or 250 to 300s otherwise (10), or bivalirudin per standard protocol (8). Patients in the study received GP IIb/IIIa receptor inhibition also according to usual protocol with abciximab or eptifibatide (20). Post-PCI patients were treated with aspirin (81 to 325 mg/day) and clopidogrel (300 or 600 mg as a loading dose followed by 75 mg/day) if stents were placed.

Access site management. The method of arterial access management was chosen by the cardiologist performing the procedure. Manual compression was obtained by physicians performing the procedure, or trained catheter laboratory and nursing unit personnel. The VCD placement was performed by physicians trained in their use. Brachial artery sheaths were removed immediately after the procedure, and hemostasis was obtained by manual compression. Radial artery sheaths also were removed immediately after the procedure with hemostasis obtained using Hemoband compression (Hemoband Corp., Portland, Oregon). The VCDs were placed only after a femoral arteriogram was performed via the arterial sheath. Patients did not undergo arterial closure with a VCD if: 1) the arteriotomy site was below the femoral bifurcation; 2) the common femoral artery was <5 mm in diameter; 3) extensive calcification or plaque formation was present in the common femoral artery; or 4) extensive scar tissue was present at the access site. Closure was performed using a variety of VCDs at the discretion of the cardiologist performing the procedure including Angioseal (St. Jude Medical, St. Paul, Minnesota), Vasoseal (Datascope Corp., Mahwah, New Jersey), Quikseal (Sub-Q Inc., San Clemente, California), Duett (Vascular Solutions, Minneapolis, Minnesota), and Perclose and Starclose (Abbott Vascular, Redwood City, California) (20). All sheaths were removed soon after the procedure as outlined below. In patients in whom arterial closure was not performed in the laboratory, the sheath was pulled when the activated clotting time was $\leq$180 s in patients who received heparin or $\geq$2 h after the infusion of bivalirudin was completed. Use of a topical thrombin hemostatic patch (D-STAT Dry, Vascular Solutions) to facilitate manual compression was introduced in April 2004 and used on all subsequent manual compressions (21). Ambulation was initiated 2 h after the VCD was placed or D-STAT was used, and 6 h after manual compression alone.

Access site evaluation was routinely done after the procedure and before discharge. The nurse caring for the patient examined the access site for possible vascular complications and recorded the findings in the nurses' notes. The physicians caring for the patient also examined the

access site and recorded the observations in the chart. Before hospital discharge, the patient's chart was abstracted by a clinical research nurse, including the nurses' notes, the medical record, and all tests performed during the hospitalization. The presence and type of vascular complications were recorded in an institutional database (20). Outcomes measures collected conformed to the American College of Cardiology database definitions for vascular complications (22). Minor vascular complications were defined as any of the following: hematoma >10 cm, arteriovenous fistulae, or pseudoaneurysm. Major vascular complications were defined as death caused by vascular complications, vascular repair, major vascular bleeding (>3 g hemoglobin decrease because of access site bleeding or retroperitoneal bleeding), vessel occlusion, or loss of pulse (20,22).

Statistical methods. Descriptive statistics (means and standard deviation of continuous factors, frequency counts and relative frequencies of categorical factors) were calculated and compared for statistical significance across vascular complication groups using the Wilcoxon rank sum test for continuous factors and chi-square testing for categorical factors. Annual trends of baseline covariates and vascular complications were tested by the Cochran-Armitage trend test. Univariate associations between clinical and procedural covariates and vascular complications were examined using the Wald chi-square test. Logistic regression modeling was used to assess multivariate predictors of vascular complications using generalized estimating equations to account for repeated measures (23). All statistically significant ($p < 0.10$) univariate predictors of vascular complications were considered for selection in the multivariate models. All previously known clinically significant independent predictors of vascular complications (i.e., sheath size) were retained in all models. A final predictive model for vascular complications was constructed and used to calculate the average risk-adjusted probability of vascular complications for each year, stratified by closure method, procedure, and sheath size. The SAS statistical software package (version 9.1, SAS Institute, Cary, North Carolina) was used for all statistical analysis.

Results

The vast majority of procedures were performed via femoral artery access (99%), with 0.8% performed via the brachial artery, and 0.2% performed via the radial artery. Access site management was accomplished by manual compression in 76% of CATH and 50% of PCI procedures, whereas VCDs were used in 24% of CATH and 50% of PCI procedures. The baseline clinical and procedural covariates of all CATH and PCI patients with and without vascular complications are shown in Table 1. Meaningful differences in the 2 groups included older age, female gender, and higher body surface area in those with vascular complications compared with those without vascular complications. Meaningful procedural differences in the 2 groups included procedure type (PCI vs. CATH) and larger sheath size in those with compared to those without vascular complications.

There were 453 (1.3%) vascular complications after femoral artery access, 0 (0.0%) after radial artery access, and 16 (4.5%) after brachial artery access, $p < 0.05$ versus femoral artery access. The incidence and trend of specific major and minor vascular complications for CATH and PCI procedures performed from the femoral artery access are shown in Table 2. There was a significant decrease in both major and minor vascular complications over the course of the study, $p < 0.001$ for trend for both, although the decrease was greater for minor than for major vascular complications. Length of stay increased an average of 4 days for those with (6.7 ± 12.1 days) compared to those without (2.7 ± 5.8 days) vascular complications, $p < 0.001$.

Predictors of vascular complications. Independent predictors of vascular complications for the entire study group and for the subgroups undergoing CATH and PCI are shown in Table 3. Failed closure with a VCD, female gender, history of renal failure, peripheral vascular disease, larger sheath sizes, and in-laboratory heparin use (CATH only) were the strongest independent predictors of increased vascular complications over the entire study period. Conversely, successful use of a VCD was the strongest independent predictor of lower vascular complications. Use of bivalirudin was infrequent and was not associated with an increased or decreased risk of vascular complications. Similarly, the use of a brachial or radial artery as access site was infrequent and was not associated with an increased or decreased risk of vascular complications.

Temporal trends in the incidence of vascular complications. The incidence of any vascular complications after femoral artery access by year of procedure, procedure type, and closure method for procedures performed is plotted in Figure 1. The incidence of vascular complications decreased significantly over the course of the study, $p < 0.001$ for trend, both for CATH and PCI procedures. The number of CATH and PCI procedures performed from the radial and brachial arteries was small, and the incidence of vascular complications over the course of the study was not evaluated. The incidence of vascular complications for both manual compression and VCDs also decreased significantly over the course of the study period, $p < 0.01$ for trend, for both CATH and PCI procedures. The incidence of vascular complications by year and VCD type is shown in Figure 2. For both Angioseal and Perclose, there was a significant trend toward a decrease in vascular complications over the study period, most notable for PCI procedures. The incidence of vascular complications for each individual sheath size over the course of the study for both CATH and PCI is plotted in Figure 3. There was a trend toward a decrease in vascular complications for all sheath sizes for both

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Table 1. Baseline Patient and Procedural Characteristics by Vascular Complication Outcomes

Characteristic	Vascular Complications (n = 470)	No Vascular Complications (n = 34,546)	p Value
Demographics			
Age, yrs	66 ± 13	62 ± 12	<0.001
Female gender	56%	39%	<0.001
Medical history			
Heart failure class III or IV	14%	11%	0.027
Current smoker	27%	30%	0.151
Diabetes mellitus	29%	30%	0.559
Hypercholesterolemia	59%	65%	0.004
Hypertension	79%	75%	0.032
History of renal failure	9%	5%	<0.001
Peripheral vascular disease	16%	10%	<0.001
Previous percutaneous coronary intervention	24%	31%	0.002
Body mass index, m^2, median (interquartile range)	1.87 (1.70–2.04)	1.97 (1.80–2.13)	<0.001
Indication for procedure			
Acute coronary syndrome	76%	63%	<0.001
Myocardial infarction within 7 days	32%	22%	<0.001
Stable angina	7%	12%	<0.001
Atypical chest pain, no angina	17%	24%	<0.001
Diagnostic catheterizations	44%	60%	<0.001
Arterial access location			<0.001
Femoral	95%	98%	
Brachial	5%	1.2%	
Radial	0%	0.4%	
Sheath size, F	7.5 ± 1.0	5.8 ± 0.6	<0.001
Medications			
Bivalirudin in-laboratory	0%	0.1%	0.663
Lovenox in-laboratory	0%	0.4%	0.370
Glycoprotein IIb/IIIa inhibitor in-laboratory	9%	6%	0.035
Aspirin at discharge*	88%	76%	0.229
Clopidogrel at discharge*	59%	23%	<0.001
Closure method			0.125
Manual compression	81%	76%	
Vascular closure device	19%	24%	
Failed closure†	7%	1%	<0.001
Percutaneous coronary interventions	56%	40%	<0.001
Arterial access location			0.009
Femoral	98%	99%	
Brachial	2%	0.7%	
Radial	0%	0.2%	
Sheath size, F	7.7 ± 1.0	6.0 ± 0.5	<0.001
Medications			
Bivalirudin in-laboratory	5%	6%	0.547
Lovenox in-laboratory	1%	2%	0.183
Glycoprotein IIb/IIIa inhibitor in-laboratory	93%	92%	0.629
Aspirin at discharge*	80%	92%	0.012
Clopidogrel at discharge*	77%	91%	0.003
Closure method			0.019
Manual compression	58%	50%	
Vascular closure device	42%	50%	
Failed closure†	14%	2%	<0.001

*Data collected starting March 2005 (diagnostic cardiac catheterization n = 3,856; percutaneous coronary intervention n = 2,778). †Femoral compression device required to achieve hemostasis.

Table 2. Vascular Complications by Year of Procedure

Complication	1998 (n = 4,284)	1999 (n = 4,423)	2000 (n = 4,329)	2001 (n = 3,876)	2002 (n = 3,854)	2003 (n = 3,550)	2004 (n = 3,495)	2005 (n = 3,224)	2006 (n = 3,195)	2007 (n = 786)	Trend* p Value
Any vascular complication	94 (2.2%)	73 (1.7%)	67 (1.6%)	58 (1.5%)	41 (1.1%)	35 (1.0%)	42 (1.2%)	25 (0.8%)	31 (1.0%)	4 (0.5%)	<0.001
Major vascular complication	45 (1.1%)	42 (1.0%)	33 (0.8%)	30 (0.8%)	20 (0.5%)	20 (0.6%)	21 (0.6%)	11 (0.3%)	24 (0.8%)	1 (0.1%)	<0.001
Retroperitoneal bleeding	16 (0.4%)	19 (0.4%)	19 (0.4%)	10 (0.3%)	11 (0.3%)	7 (0.2%)	15 (0.4%)	6 (0.2%)	15 (0.5%)	0 (0%)	0.241
Other major bleeding	16 (0.4%)	14 (0.3%)	9 (0.2%)	11 (0.3%)	6 (0.2%)	8 (0.2%)	3 (0.1%)	1 (0.03%)	7 (0.2%)	0 (0%)	<0.001
Occlusion	3 (0.1%)	6 (0.1%)	0 (0%)	1 (0.03%)	1 (0.03%)	3 (0.1%)	1 (0.03%)	1 (0.03%)	0 (0%)	0 (0%)	0.056
Loss of distal pulse	6 (0.1%)	6 (0.1%)	3 (0.1%)	5 (0.1%)	3 (0.1%)	5 (0.1%)	1 (0.03%)	3 (0.1%)	0 (0%)	1 (0.1%)	0.084
Vascular surgery	15 (0.4%)	7 (0.2%)	9 (0.2%)	7 (0.2%)	6 (0.2%)	5 (0.1%)	8 (0.2%)	4 (0.1%)	7 (0.2%)	0 (0%)	0.127
Vascular death	3 (0.1%)	1 (0.02%)	2 (0.1%)	0 (0%)	0 (0%)	2 (0.1%)	1 (0.03%)	2 (0.1%)	1 (0.03%)	0 (0%)	0.749
Minor vascular complication	72 (1.7%)	44 (1.0%)	48 (1.1%)	42 (1.1%)	31 (0.8%)	22 (0.6%)	26 (0.7%)	17 (0.5%)	15 (0.5%)	3 (0.4%)	<0.001
Pseudoaneurysm	21 (0.5%)	10 (0.2%)	10 (0.2%)	10 (0.3%)	10 (0.3%)	7 (0.2%)	10 (0.3%)	10 (0.3%)	5 (0.2%)	2 (0.3%)	0.115
AV fistulae	8 (0.2%)	2 (0.1%)	8 (0.2%)	3 (0.1%)	4 (0.1%)	6 (0.2%)	6 (0.2%)	5 (0.2%)	1 (0.03%)	0 (0%)	0.468
Hematoma >10 cm	47 (1.1%)	36 (0.8%)	32 (0.7%)	34 (0.9%)	20 (0.5%)	11 (0.3%)	13 (0.4%)	3 (0.1%)	10 (0.3%)	2 (0.3%)	<0.001

n = number of procedures. *Cochran-Armitage trend test.

CATH and PCI, with significant differences in 6-F CATH and 10-F PCI. A plot of the risk of vascular complications for all CATH and PCI procedures is depicted in Figure 4, adjusted for covariate effects as identified in the multivariate analysis (Table 3). Over the course of the study, the adjusted risk decreased significantly, $p < 0.01$ for trend for both CATH and PCI, although this was most notable for PCI procedures. Qualitatively similar outcomes were observed for both the CATH and the PCI subgroups.

Trends in factors affecting rates of vascular complications. There were minimal changes in the risk-adjusted rate of vascular complications of individual sheath sizes for both CATH and PCI (Table 4). There did seem to be a progressive increase in the adjusted risk of vascular complications, however, for increasing sheath sizes for both CATH and PCI. A categorical analysis of the risk of vascular complications by sheath size and procedure type is shown in Figure 5. For CATH, the risk of vascular complications was lower for 4-F sheath size compared with all other sheath sizes. For PCI, the risk of vascular complications of 6- and 7-F sheaths were similar, odds ratio 1.09 (95% confidence interval 0.70 to 1.10). However, the risk of vascular complications of 8-, 9-, and 10-F sheaths were all higher than for 6-F sheaths, although the 95% confidence

Table 3. Multivariate Analysis of Vascular Complications

	All Procedures		CATH Only		PCI	
	Odds Ratio (95% CI)	p Value	Odds Ratio (95% CI)	p Value	Odds Ratio (95% CI)	p Value
Increased risk						
Failed closure	7.38 (5.24–10.39)	<0.001	9.15 (4.75–17.63)	<0.001	6.93 (4.63–10.36)	<0.001
Female gender	1.84 (1.44–2.34)	<0.001	1.70 (1.19–2.41)	0.003	1.99 (1.42–2.78)	<0.001
History of renal failure	1.69 (1.21–2.36)	0.002	2.35 (1.52–3.62)	<0.001	1.12 (0.65–1.95)	0.682
Peripheral vascular disease	1.50 (1.15–1.94)	0.003	1.65 (1.14–2.39)	0.008	1.30 (0.90–1.89)	0.167
Glycoprotein IIb/IIIa inhibitor in-laboratory	1.44 (1.10–1.89)	0.008	1.65 (1.00–2.72)	0.048	0.94 (0.35–2.58)	0.911
Bivalirudin in-laboratory*	1.42 (0.78–2.58)	0.250			0.90 (0.28–2.87)	0.859
Hypertension	1.29 (1.00–1.67)	0.048	1.63 (1.08–2.45)	0.019	1.09 (0.78–1.50)	0.622
Sheath size, F	1.29 (1.17–1.41)	<0.001	1.69 (1.40–2.02)	<0.001	1.19 (1.06–1.35)	0.004
Age, yrs	1.02 (1.01–1.03)	<0.001	1.02 (1.01–1.04)	0.002	1.01 (1.00–1.03)	0.035
Heparin in-laboratory†			1.40 (1.04–1.88)	0.025		
Decreased risk						
Body surface area, m^2	0.59 (0.34–1.03)	0.061	0.81 (0.38–1.74)	0.588	0.45 (0.21–0.96)	0.039
Vascular closure device used	0.65 (0.53–0.81)	<0.001	0.65 (0.44–0.97)	0.035	0.65 (0.50–0.84)	0.001
Previous intervention	0.75 (0.60–0.93)	0.011	0.84 (0.59–1.21)	0.354	0.70 (0.52–0.93)	0.015
Hypercholesterolemia	0.80 (0.65–0.98)	0.030	0.68 (0.50–0.93)	0.014	0.91 (0.69–1.19)	0.474

*Not included in CATH-only multivariate model because of low numbers in CATH-only patients and no vascular complications in the procedures with direct thrombin inhibitor used. †All PCI patients had some in-laboratory heparin used, therefore only examined in CATH-only model. CATH = diagnostic cardiac catheterization; CI = confidence interval.

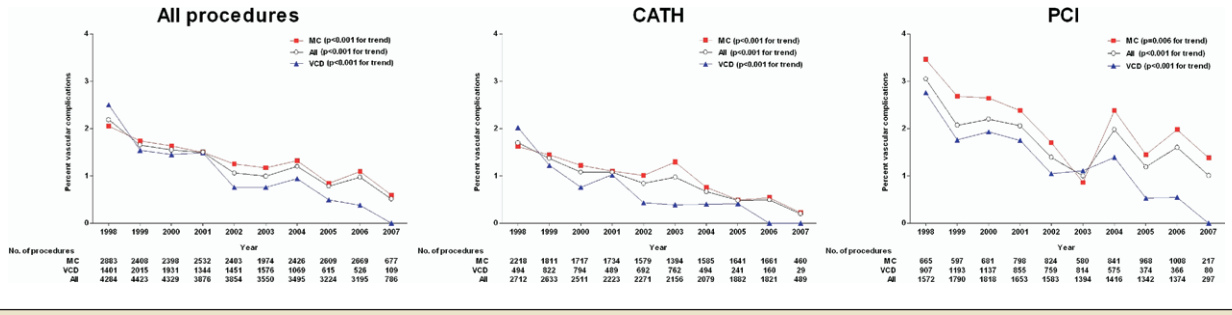

Figure 1. Any Vascular Complications by Procedure and Closure Method

Graph depicting the incidence of any vascular complication by procedure type and closure method from 1998 to 2007. CATH = diagnostic cardiac catheterization; MC = manual compression; PCI = percutaneous coronary intervention; VCD = vascular closure device.

limits were wider for 9- and 10-F sheaths and did not reach statistical significance.

To further examine potential reasons for the decrease in vascular complications observed during the course of the study, we also evaluated the annual frequency of the covariates shown in the multivariate analysis to affect the risk of vascular complications. In 2007, compared with 1998, closure device failure decreased and body surface area (BSA) increased, both of which would be associated with a lower potential risk of vascular complications in 2007 compared with 1998 (Table 5). Use of smaller sheath sizes increased for both CATH and PCI. Changes in other covariates among the CATH and PCI patients from 1998 to 2007 were small.

Discussion

In this large, contemporary, single-center experience, the incidence of vascular complications decreased from 1998 to 2007 for both CATH and PCI procedures performed from the femoral artery. The decrease in vascular complications occurred for both manual compression and VCD management of the femoral artery access site. A decrease in minor vascular complications, predominantly a decrease in hematoma >10 cm, accounted for the greatest proportion of the overall decrease in the incidence of vascular complications. The incidence of major vascular complications also decreased, although the incidence of retroperitoneal bleeding was low and unchanged over the study period. These observations provide strong evidence that CATH and PCI performed from the femoral artery have become safer procedures in the past decade.

We evaluated patient and procedural factors that influenced the risk of vascular complications, as well as their prevalence, over the decade of the study. Adverse patient factors included female gender, history of renal failure or peripheral vascular disease, and low BSA. Failed closure with a VCD, in-laboratory heparin use (CATH only), and larger sheath size were the strongest independent predictors of increased vascular complications, whereas successful use of a closure device and larger BSA were the strongest

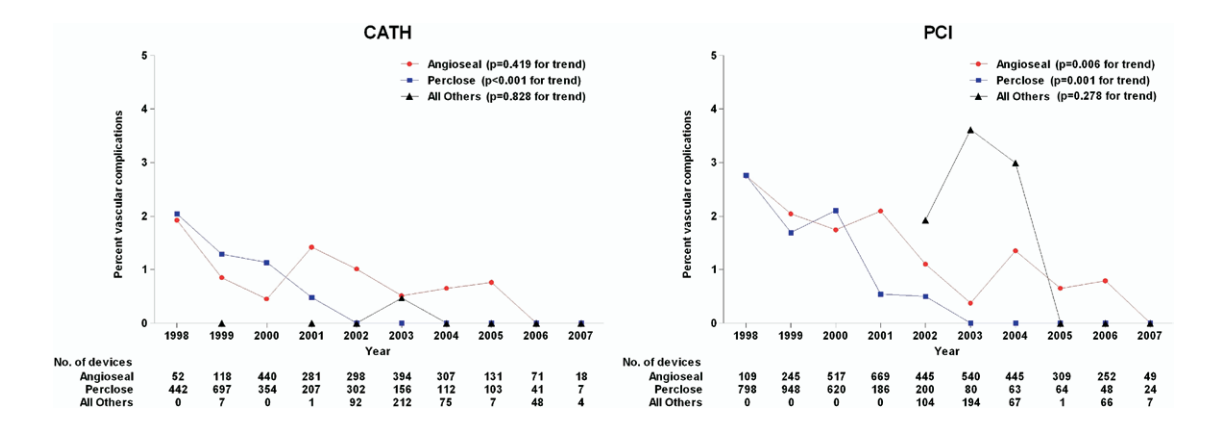

Figure 2. Any Vascular Complications by Vascular Closure Device

Graph of the incidence of any vascular complication by procedure type and vascular closure device from 1998 to 2007. Abbreviations as in Figure 1.

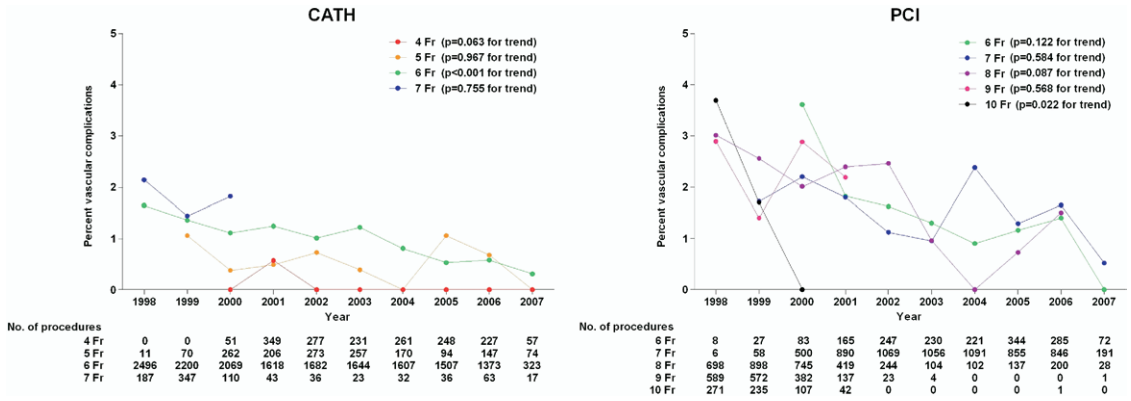

Figure 3. Any Vascular Complications by Sheath Size

Graph of the incidence of any vascular complication for each sheath size for PCI and CATH from 1998 to 2007. Abbreviations as in Figure 1.

predictors of a decrease in vascular complications. There did not seem to be a substantial change in the prevalence of adverse patient variables during the course of the study. However, as a result of changes in practice during CATH and PCI procedures, there was a substantial decrease over the study period in the prevalence of adverse procedural variables including less use of in-laboratory heparin during CATH, fewer failed VCDs, and use of smaller, less harmful sheath sizes. Thus, implementation of procedural strategies to reduce vascular complications after femoral artery access seemed to have resulted in improved safety of CATH and PCI procedures.

Multiple studies have identified factors associated with an increase in the risk of vascular complications during CATH and PCI procedures performed from the femoral artery. In the American College of Cardiology National Cardiovascular Disease Registry female gender, emergency procedures, PCI (vs. CATH), sheath size, and renal failure were found to be independently predictive of increased vascular complications (24,25). Female gender, emergency procedures, and a femoral artery access site at or above the inferior epigastric artery were associated with an increased risk of retroperitoneal bleeding (5,6). We have previously reported that female gender was a strong risk factor for an increased risk of vascular complications during CATH and PCI from a femoral artery access site, but that the risk had decreased from 1998 to 2005 (26). The results of these prior studies, coupled with our observations, suggest that strategies focusing on reducing or eliminating adverse procedural practices may improve the safety of CATH and PCI procedures performed after femoral artery access.

We also performed a detailed analysis of the risk-adjusted incidence of vascular complications per sheath size used over the past 10 years. Although most clinicians would state that smaller sheath sizes are safer during CATH and PCI, there are few large studies directly examining this issue (17,18,27). Moreover, studies developing models to predict vascular complications after CATH or PCI have not included sheath size in their study or predictive models (12,14,28). Our study indicates that the incidence of vascular complications decreased with smaller sheath sizes for both CATH and PCI. Interestingly, the risk-adjusted rate

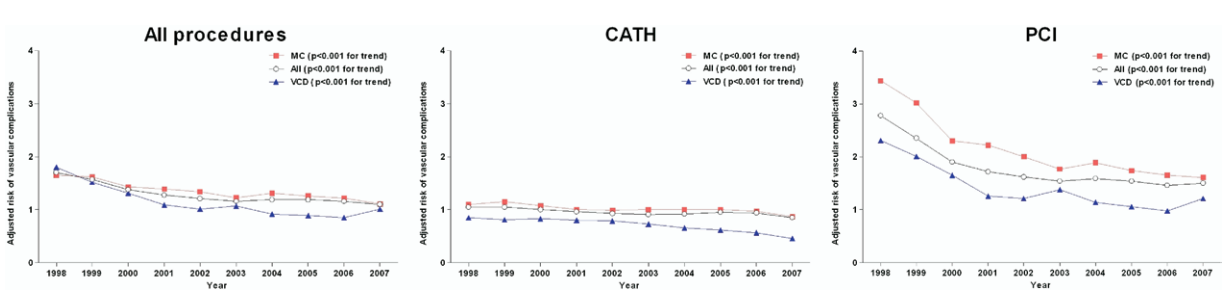

Figure 4. Risk-Adjusted Incidence of Vascular Complications

Graph of the incidence of any vascular complication by procedure type and closure method from 1998 to 2007 adjusted for patient and procedural confounders. Abbreviations as in Figure 1.

Table 4. Risk-Adjusted Incidence of Vascular Complications by Year, Procedure Type, and Sheath Size

Procedure, Sheath Size	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	Trend* p Value
Diagnostic cardiac catheterization											
4-F			0.6%	0.7%	0.6%	0.7%	0.7%	0.7%	0.6%	0.5%	0.905
5-F	1.3%	0.7%	0.7%	0.6%	0.7%	0.7%	0.6%	0.6%	0.6%	0.6%	0.002
6-F	1.0%	1.0%	1.0%	1.0%	0.9%	0.9%	0.9%	0.9%	0.9%	0.8%	0.133
7-F	1.4%	1.3%	1.3%	1.2%	1.2%	0.9%	1.1%	1.1%	1.3%	0.4%	0.418
Percutaneous coronary intervention											
6-F	1.2%	1.7%	1.1%	1.4%	1.3%	1.3%	1.3%	1.2%	1.1%	1.3%	0.932
7-F	3.4%	1.6%	1.5%	1.5%	1.6%	1.5%	1.6%	1.6%	1.5%	1.5%	0.467
8-F	2.4%	2.2%	1.9%	1.8%	2.1%	2.1%	1.9%	2.1%	2.0%	2.2%	0.014
9-F	2.8%	2.5%	2.5%	2.5%	2.5%	3.5%					0.893
10-F	3.7%	2.8%	2.5%								0.044

*Spearman correlation test.

of vascular complications for any given sheath size remained essentially unchanged over the course of the study. These observations taken together provide strong evidence that switching to smaller sheath sizes, which seem to be inherently safer, resulted in improved safety.

Recent randomized clinical trials of PCI outcomes, primarily performed from femoral artery access, have shown a decrease in the rates of bleeding with the use of bivalirudin compared with heparin and a GP IIb/IIIa inhibitor (7). We did not observe a decrease in the incidence of vascular complications with bivalirudin, although it was used in only 5% of PCI cases. Similarly, use of the radial artery as access for CATH and PCI procedures has been associated with lower rates of access site complications compared with the same procedures performed from the brachial or femoral artery (29,30). Radial artery use was infrequent in our experience. In spite of the fact that we did not observe any vascular complications with procedures performed from the radial artery, the numbers were too small to provide a meaningful comparison with complications occurring after femoral artery access. The decrease in rates of access site complications observed with use of the radial artery (29,30), however, makes it one of the modifiable procedural variables that can reduce rates of vascular complications in the cardiac catheterization laboratory.

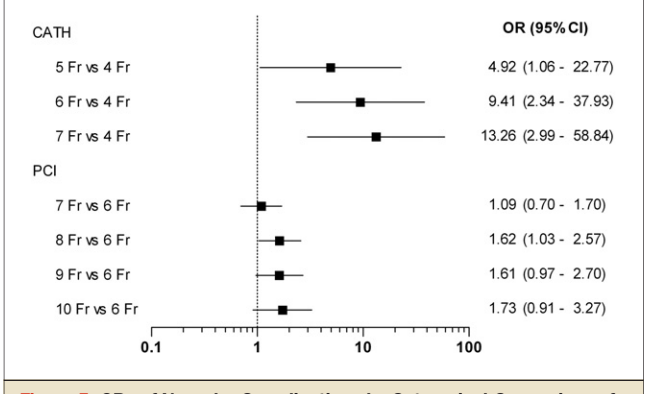

Figure 5. ORs of Vascular Complications by Categorical Comparison of Sheath Sizes

Univariate analysis of the odds ratio of any vascular complication stratified by procedure and sheath size for the entire study period. CI = confidence interval; OR = odds ratio; other abbreviations as in Figure 1.

Study limitations. This study is subject to the limitations of observational studies. The incidence of any vascular complication after diagnostic CATH or PCI in this study was low, approximately 1.5%. This incidence is somewhat less than has been generally reported (1.5% to 4.0%) (15) and likely reflects narrower definitions of vascular complications used in this study (22). Reporting biases because of variations in clinical follow up may have influenced the apparent lower incidence of vascular complications, but are unlikely to have biased the results in favor of one access site management strategy over another. Multivariate analysis adjusted for baseline differences in measured covariates, but did not correct for unmeasured covariates that may have confounded the results. The effect of factors not assessed or measured in this study may have been responsible for the changes observed in this study. Finally, we did not evaluate vascular complications after discharge from the hospital.

Clinical implications. There has been a growing awareness of the importance of peri-procedural CATH and PCI bleeding, particularly because of access site complications. Focus on the complications has increased as the safety of the cardiac procedure itself has improved. Over the past decade, we implemented multiple strategies to reduce vascular complications in the cardiac catheterization laboratory from procedures performed from the femoral artery, including use of fluoroscopy to guide femoral artery access (11), downsizing sheath sizes (12,17,18), use of VCDs (15,16), and minimizing heparin use during CATH procedures. All of

Table 5. Trends in Annual Prevalence of Clinical and Procedural Covariates Associated With Vascular Complications

	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	Trend p Value
Clinical variables											
Age, yrs	62 ± 12	63 ± 12	63 ± 12	63 ± 12	63 ± 12	62 ± 13	62 ± 13	62 ± 13	61 ± 13	61 ± 13	<0.001
Female gender	37%	39%	38%	38%	38%	42%	41%	40%	38%	37%	0.013
History of renal failure	4%	4%	4%	6%	5%	5%	6%	8%	5%	6%	<0.001
Peripheral vascular disease	9%	10%	10%	12%	12%	11%	9%	9%	9%	8%	0.283
Body surface area, m^2, median	1.95	1.95	1.96	1.96	1.97	1.97	1.98	1.98	1.99	2.01	<0.001
Interquartile range	1.80–2.11	1.79–2.11	1.80–2.12	1.80–2.12	1.81–2.13	1.80–2.14	1.81–2.15	1.81–2.15	1.82–2.17	1.84–2.15	
Procedural variables											
Brachial, radial access	1.0%	1.1%	1.2%	1.5%	1.1%	1.1%	1.1%	1.3%	2.1%	4.2%	<0.001
Vascular closure device use, CATH	18%	31%	32%	22%	30%	35%	24%	13%	9%	6%	<0.001
Vascular closure device use, PCI	58%	67%	63%	52%	48%	58%	41%	28%	27%	27%	<0.001
Failed closure, CATH	1.0%	1.3%	1.6%	1.1%	1.5%	1.1%	0.6%	0.4%	0.7%	0.2%	<0.001
Failed closure, PCI	6.2%	3.6%	1.8%	1.5%	2.4%	2.7%	2.1%	1.0%	1.4%	2.0%	<0.001
Bivalirudin in-laboratory	0%	0%	0%	0%	2%	9%	8%	4%	3%	4%	<0.001
Glycoprotein IIb/IIIa inhibitor in-laboratory	37%	41%	45%	46%	43%	35%	37%	41%	44%	37%	0.674
Sheath size, CATH											<0.001
4-F	0%	0%	2%	16%	12%	11%	13%	10%	9%	9%	
5-F	0.4%	3%	10%	9%	12%	12%	8%	4%	7%	15%	
6-F	92%	84%	82%	73%	74%	76%	77%	85%	81%	73%	
7-F	7%	13%	4%	2%	2%	1%	2%	1%	2%	2%	
Sheath size, PCI											<0.001
6-F	0.5%	1%	5%	10%	16%	17%	16%	26%	22%	25%	
7-F	0.4%	3%	28%	54%	68%	76%	77%	64%	63%	65%	
8-F	44%	50%	41%	25%	15%	7%	7%	10%	15%	10%	
9-F	37%	32%	21%	8%	1%	0.3%	0%	0%	0%	0.3%	
10-F	17%	13%	6%	3%	0%	0%	0%	0%	0.1%	0%	

*p value corresponds to Cochran-Armitage trend test for frequency (%) variables; Spearman correlation test for continuous (median) variables.
CATH = diagnostic cardiac catheterization; PCI = percutaneous coronary intervention.

these strategies seemed to contribute to a decrease in the risk of vascular complications after femoral artery access. Our findings should provide reassurance that CATH and PCI have become safer procedures with respect to femoral artery access site complications. Moreover, our findings should provide impetus for transitioning to use of smaller sheath sizes, particularly for CATH procedures, as well as incorporating procedural strategies that reflect optimal use of anticoagulants.

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