A propensity analysis of the risk of vascular complications after cardiac catheterization procedures with the use of vascular closure devices

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Background Complications of vascular access are one of the most common adverse events after coronary angiography and percutaneous coronary intervention (PCI) and are reported to occur in 1% to 9% of cases. There are conflicting reports of the association of vascular complications with the use of vascular closure devices (VCDs). The purpose of this study was to assess femoral arterial access–related vascular outcomes after invasive cardiology procedures with the routine use of VCDs.

Methods A total of 12937 consecutive patients were studied for inhospital outcomes through a prospective registry from January 2002 to December 2005. Of these, 6913 (53%) patients underwent PCI and 9996 (77%) patients received VCDs. Univariate and multivariate logistic regression analyses were used to determine the predictors of vascular complications. A propensity analysis of VCD use was performed to account for potential bias in the likelihood of using such devices.

Results Vascular complications occurred in 0.7% of diagnostic angiography and 2.7% of PCI patients. The risk of vascular complications was significantly lower with closure device use compared with manual compression in both diagnostic angiography (0.5% vs 1.1%, $P = .01$*) and PCI (2.4% vs 4.9%, $P < .001$*) groups. Multivariate logistic regression analysis, after accounting for the propensity to use such devices, revealed that VCD use was associated with a 58% (95% CI 19%-88%) reduction in the risk of vascular complications in diagnostic procedures catheterization and a 42% (95% CI 17%-59%) reduction in PCI patients.

Conclusions In contemporary practice, VCDs offer reduced risk of vascular complications as compared with manual compression in appropriately selected patients undergoing diagnostic and therapeutic cardiac catheterizations. (Am Heart J 2007;153:606-11.)

Vascular access–related complications occur in 0.8% to 1.8% of diagnostic cardiac catheterizations and 1.5% to 9% of percutaneous coronary intervention (PCI) cases when performed via transfemoral access.[1-8] These complications lead to increased length of hospital stay and health care costs.[9-12] Manual or mechanical compression is the standard of care for achieving arteriotomy site hemostasis after invasive procedures. In contemporary practice, there has been an increase in the utilization of various types of vascular closure devices (VCDs) for femoral arteriotomy closure, driven mainly by patient preference, comfort, and reduced length of hospitalization.[10,12] Multiple small randomized controlled trials (RCTs) evaluating the safety of VCDs have generally reported no significant advantage in safety outcomes over manual compression.[13-22] However, a recent meta-analysis of the randomized prospective studies on the use of the Angio-Seal (St Jude Medical, St Paul, MN) vascular sealant device reported a trend toward decreased vascular complication rates as compared with manual compression.[22] Therefore, we sought to evaluate vascular complications associated with femoral arterial access in the setting of routine use of VCDs at our high-volume center, for both diagnostic and therapeutic coronary procedures.

Methods

We prospectively evaluated consecutive patients undergoing cardiac catheterization and PCIs via femoral access at the Brigham and Women's Hospital between January 1, 2002, and

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Table I. Baseline characteristics

	Diagnostic cases (n = 6024)			PCI cases (n = 6913)		
	Manual compression (n = 1990)	VCD (n = 4034)	*P* value	Manual compression (n = 951)	VCD (n = 5962)	*P* value
Age (y)	65.7 ± 13.7	62.9 ± 12.9	<.001*	69.5 ± 12.0	65.0 ± 12.1	<.001*
Female sex	38.2%	35.9%	.08	39.3%	28.5%	<.001
BMI (kg/m^2)	27.4 ± 6.1	28.4 ± 8.8	<.001*	28.3 ± 11.8	28.7 ± 5.5	.08
Diabetes	24.2%	22.5%	.1	35.4%	28.4%	<.001*
Hypertension	69.5%	69.4%	.9	81.4%	78.2%	<.001*
Chronic renal insufficiency	8.0%	4.9%	<.001*	9.6%	4.4%	<.001*
Peripheral vascular disease	12.1%	5.9%	<.001*	24.3%	9.0%	<.001*
Acute MI	6.2%	8.5%	.002*	22.2%	21.6%	.6
ST segment elevation MI	1.3%	2.1%	.02*	7.6%	8.5%	.3
Procedure duration (min)	48.1	45.9	.004*	88.0	80.0	.001*
High-volume operator	97.2%	97.8%	.1	97.7%	98.5%	.06
Venous sheath	40.8%	39.2%	.2	51.1%	39.9%	<.001*
Arterial sheath size >6F	1.16%	0.8%	.1	11.5%	8.7%	.001*
GpIIb/IIIa inhibitors	1.0%	1.2%	.4	38.0%	44.0%	.001*
Bivalirudin	0.3%	0.6%	.1	13.1%	11.5%	.1

High-volume operator means operator had performed >100 VCD deployments. *BMI*, Body mass index; *MI*, myocardial infarction.
*$P < .05$.

December 31, 2005, for the occurrence of inhospital vascular complications. A prospective catheterization laboratory database, based on the American College of Cardiology–National Cardiovascular Data Registry definitions, was used to record clinical and procedural elements for each case.[23] Only patients presenting in cardiogenic shock or requiring intra-aortic balloon counter pulsation were excluded prospectively from this analysis.

Six vascular complications were reviewed, as follows: *groin bleeding* (defined as blood loss at the access site resulting in blood transfusion, increased length of stay, or drop in hemoglobin >3 g/dL), hematoma (size ≥5 cm), pseudoaneurysm (confirmed by ultrasonography), arteriovenous fistula (confirmed by ultrasonography), retroperitoneal hemorrhage (confirmed by computed tomographic scan), limb ischemia (loss of peripheral pulse requiring vascular or surgical evaluation), or any case requiring vascular access–related surgical intervention.

Diagnostic coronary catheterization and PCIs were performed according to standard guidelines. Unless contraindicated, all PCI patients received aspirin, clopidogrel, and weight-adjusted heparin therapy as per the standard American College of Cardiology/American Heart Association recommendations. Periprocedural glycoprotein IIb/IIIa (GpIIb/IIIa) inhibitors and/or bivalirudin was used at the discretion of the treating physician. Anatomical landmarks were identified by preprocedure fluoroscopy, and vascular access was obtained through single-wall common femoral arterial puncture.

The vascular access management strategy at the study site was routine use of VCDs in all PCI cases unless contraindicated, and based upon operator discretion in diagnostic cases. Contraindications to closure device deployment included (1) arteriotomy site at or below femoral bifurcation, (2) common femoral artery with >50% narrowing due to calcification or plaque, and (3) diameter of common femoral artery <5 mm.

Among the VCD group, the most frequently used was AngioSeal; but Perclose (Abbott Vascular, Redwood Shores, CA), VasoSeal (Datascope Corp, Montvale, NJ), and Duett (Vascular Solutions, Minneapolis, MN) were also used. A cine film of the ileofemoral arterial anatomy was taken of all patients before VCD deployment. Sheath removal in PCI cases was performed at an activated clotting time <160 milliseconds when manual compression was used and immediately after the procedure for VCDs. Manual groin compression was performed by the fellows and catheterization laboratory personnel and consisted of 15 to 20 minutes of groin compression followed by placement of mechanical compression device (FemoStop, Radi Medical Systems, Inc., Wilmington, MA) as required. Previous reports in the literature have shown no significant difference in vascular complication rates with FemoStop compared with manual compression.[24-26] Therefore, for the purposes of this analysis, such patients were included under the compression group for the purpose of comparison with VCDs. Ambulation was advised after 4 to 6 hours of bed rest in manual compression patients and 2 to 4 hours after closure device deployment. *Vascular closure device failure* was defined as unsuccessful deployment or failure to achieve hemostasis, and occurred in 1.35% of diagnostic and 2.63% of PCI cases. These cases were included under the closure device category on the basis of intention-to-treat analysis.

All statistical analyses were performed using Stata Intercooled Version 8.0 (Stata Corp LP, College Station, TX). The χ^2 test was used for comparisons of categorical data, and the 2-tailed Student *t* test was used to compare continuous variables. Forward and backward stepwise multiple logistic regression was used to identify independent predictors of vascular complications, and the final models incorporated those covariates with consistent associations of *P* values < .20. The discriminatory power of the logistic models was measured using the area under the receiver-operator curve, and goodness of fit was measured with the Hosmer-Lemeshow C statistic.[27,28] A *P* value > .05 was considered statistically significant. The study protocol was approved in advance by the local institutional review board.

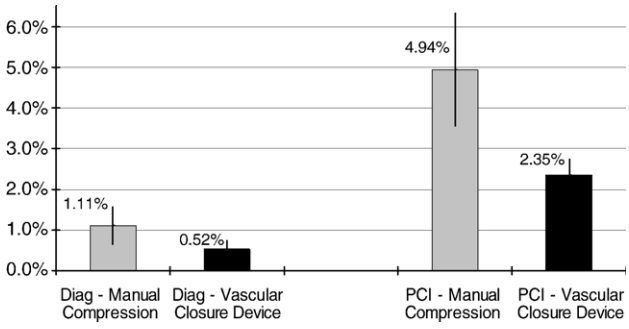
Because VCD use was not randomly assigned in this patient population, adjustment for potential selection bias was

Table II. Vascular complications

	Diagnostic cases (n = 6024)			PCI cases (n = 6913)		
	Manual compression (n = 1990)	VCD (n = 4034)	*P* value	Manual compression (n = 951)	VCD (n = 5962)	*P* value
Groin bleeding	0.3% (6)	0.1% (4)	.07	1.0% (9)	0.5% (31)	.1
Hematoma	0.4% (8)	0.2% (7)	.09	2.5% (24)	1.1% (66)	<.001*
Pseudoaneurysm	0.5% (9)	0.2% (7)	.04*	1.0% (10)	0.1% (7)	<.001*
Arteriovenous fistula	0%	0.02% (1)	.4	0.2% (2)	0.05% (3)	.09
Retroperitoneal hemorrhage	0.1% (2)	0.05% (2)	.5	0.2% (2)	0.6% (33)	.2
Limb ischemia	0.1% (2)	0.05% (2)	.5	0.1% (1)	0.1% (6)	.9
Surgical repair	0.3% (5)	0.1% (5)	.1	0.7% (7)	0.2% (9)	<.001*
Minor vascular complications	0.5% (10)	0.2% (9)	.07	3.0% (29)	1.6% (96)	.002*
Major vascular complications	0.5% (10)	0.2% (7)	.02*	1.1% (10)	0.7% (40)	.2
Any vascular complication	1.1% (22)	0.5% (21)	.01*	4.9% (47)	2.4% (140)	<.001*

Minor vascular complications included groin bleeding, hematoma, pseudoaneurysm, and arteriovenous fistula (without any need for surgical repair). Major vascular complications included retroperitoneal hemorrhage, limb ischemia, and any surgical repair.
*$P < .05$.

Figure 1



Overall vascular complication rates in diagnostic catheterization and PCI patients. Both diagnostic and PCI patients experienced significantly lower vascular complications when receiving VCDs as compared with mechanical compression. *Diag*, Diagnostic catheterization.

Table III. Multivariate prediction model for vascular complications

Predictors of vascular complications	OR	*P* value	95% CI Upper	95% CI Lower
Diagnostic catheterization				
VCD	0.47	.02*	0.25	0.88
Chronic renal insufficiency	2.97	.01*	1.29	6.83
Procedure duration	1.005	.006*	1.002	1.009
Female sex	1.67	.1	0.89	3.12
PCI				
VCD	0.56	.001*	0.40	0.79
Age >70 y	1.65	.001*	1.22	2.23
Female sex	1.84	<.001*	1.36	2.48
Elective case	0.67	.02*	0.49	0.92
GpIIb/IIIa	1.24	.15	0.92	1.67
Chronic renal insufficiency	1.51	.1	0.88	2.59
Venous sheath use	1.22	.19	0.91	1.63

*$P < .05$.

attempted by the regression adjustment method of propensity analysis as described by D'Agostino and Jonas et al.[29,30] The probability of a patient receiving a VCD was calculated with a multivariate logistic regression model for diagnostic catheterization and PCI groups separately. The propensity model covariates for both groups consisted of age, sex, body mass index, peripheral vascular disease, chronic renal insufficiency, acute myocardial infarction, diabetes, hypertension, procedure urgency, procedure duration, arterial sheath size, venous sheath use, GpIIb/IIIa inhibitor use (pre- or intraprocedural), bivalirudin, and individual operators. The predicted propensity scores were subsequently incorporated as continuous variables in the final multivariate logistic regression models for prediction of vascular complications in each group.

Results

Table I describes the baseline characteristics of the 12937 study patients, of which 6024 (47%) underwent diagnostic coronary catheterization and 6913 (53%) underwent PCI. Vascular closure devices were used for hemostasis in 9996 cases (77%). Collagen-based Angio-Seal device was used in 8201 (82%), suture-based Perclose device in 1691 (17%), and other VCDs in 104 (1%) cases, respectively. Sixty-seven percent of the patients in diagnostic catheterization and 86% of those in the PCI group received VCDs. Older individuals, female patients, and those with chronic renal insufficiency and peripheral vascular disease were more likely to receive manual compression. Arterial sheaths with size >6F were used only for 0.93% of diagnostic and 8.7% of PCI cases. In patients undergoing PCI, use of arterial sheath larger than 6F and simultaneous venous access were more frequently followed by manual compression, whereas GpIIb/IIIa inhibitor use was associated with higher rates of VCD deployment. The median procedure duration was significantly greater in patients undergoing manual compression.

Table II summarizes the vascular complications experienced by 230 patients (1.8%), tabulated by closure

Table IV. Stepwise multivariate logistic regression analysis of VCD use and vascular complications (propensity analysis)

	OR (CI)	*P*	ROC	χ^2	H-L (*P*)
Diagnostic catheterizations					
Unadjusted (VCD use)	0.47 (0.26-0.85)	.01*	0.59		
Adjusted for age, sex	0.49 (0.27-0.91)	.03*	0.64	3.2	.9
Adjusted for age, sex, and propensity to use VCDs	0.43 (0.23-0.81)	.02*	0.65	5.2	.72
Adjusted for all significant covariates	0.47 (0.25-0.89)	.001*	0.70	3.8	.87
Adjusted for all significant covariates, propensity to use VCDs	0.42 (0.22-0.81)	<.001*	0.71	9.9	.26
PCIs					
Unadjusted (VCD use)	0.46 (0.33-0.65)	<.001*	0.56		
Adjusted for age, sex	0.56 (0.39-0.78)	<.001*	0.66	3.9	.85
Adjusted for age, sex, and propensity to use VCDs	0.57 (0.40-0.82)	<.001*	0.66	6.7	.56
Adjusted for all significant covariates	0.57 (0.41-0.82)	<.001*	0.68	12.1	.14
Adjusted for all significant covariates, propensity to use VCDs	0.58 (0.41-0.83)	<.001*	0.68	9.3	.31

Significant covariates for diagnostic catheterizations = sex, chronic renal insufficiency, procedure duration. Significant covariates for PCIs = age, sex, chronic renal insufficiency, elective procedure, GpIIb/IIIa use, venous sheath use. *ROC*, Area under the receiver-operator characteristic curve; *H-L (P)*, Hosmer-Lemeshow goodness of fit, *P* value.
*$P < .05$.

type. The overall complication rate was 0.7% in the diagnostic catheterization group and 2.7% in the PCI group ($P < .001$*). Vascular complications were less frequent with closure device use as compared with manual compression in both diagnostic angiography (0.5% vs 1.1%, $P = .01$*) and PCI (2.4% vs 4.9%, $P < .001$*) groups (Figure 1).

There was a significantly greater risk of hematoma and pseudoaneurysm development after manual compression, whereas retroperitoneal hemorrhage occurred more frequently after VCD use in PCI patients; but the difference was not statistically significant (Table II).

Although any hematoma with size ≥5 cm was considered as a vascular complication for the purpose of this study, a secondary analysis was performed restricting hematoma to be considered present if the size was >10 cm. The results were unchanged, showing lower rates of complications with VCD use than manual compression (0% vs 0.15% in diagnostic angiography, $P = .01$*; and 0.13% vs 0.63% in PCI patients, $P = .002$*).

Multivariate logistic regression models for determining predictors of vascular complications are presented in Table III. Vascular closure device use seemed protective and remained an independent predictor of complications in both diagnostic catheterization (odds ratio [OR] 0.47, $P = .02$*) and PCI patients (OR 0.56, $P = .001$*). Presence of chronic renal insufficiency, procedure duration in diagnostic catheterization cases, age >70 years, female sex, and emergency procedures in PCI cases also were independent predictors of complications. The final multivariate models yielded appropriate calibration (P value > .05) and a goodness of fit C statistic of 0.68 for diagnostic catheterization patients and 0.67 for PCI patients (Table III).

As the 2 predominant VCDs used in this study were Angio-Seal and Perclose, further subanalysis was performed for device-specific outcomes. Multivariate analyses showed that the use of Angio-Seal had a protective influence on vascular complications in both diagnostic catheterization and PCI patients (OR 0.37 [0.18-0.75], $P = .006$* and OR 0.56 [0.38-0.82], $P = .003$*, respectively), although the same effect was not preserved for Perclose (OR 0.55 [0.15-2.01], $P = .4$ and OR 0.64 [0.36-1.15], $P = .1$).

Table IV shows the results of propensity analysis of VCD use. The incorporation of propensity score into multivariate logistic regression models adjusted for age, sex, and other significant predictors of vascular complications was statistically insignificant in the final model and had no effect on the discrimination of the final models' ability to predict vascular complications.

Discussion

The present study describes femoral arterial access site complications and impact of VCDs in >12 000 consecutive patients treated during the contemporary era of diagnostic cardiac catheterization and PCI. The risk of vascular complications was 0.7% in the diagnostic group and 2.7% in PCI patients, which is comparable with previously published literature.[1,5-8] In this study, the most powerful predictor of complications in both diagnostic and therapeutic groups is nonuse of VCDs. For diagnostic procedures, the use of VCD was independently associated with a 58% (95% CI 19%-88%) reduction in the occurrence of vascular complications, whereas for PCI procedures, VCD use was independently associated with a 42% reduction in vascular complications (95% CI 17%-59%).

Since the introduction of VCDs for femoral arteriotomy closure, multiple such devices have been approved by the FDA for use in clinical practice. Safety outcomes of these devices in published RCTs and observational registries showed mixed results, with some showing superiority of these devices,[14,16] whereas others reported no difference[11,13,15,18,20] or

worse outcomes.[17,19] Most of the RCTs had small numbers of patients enrolled and very few vascular adverse events.[11,12,14,15] Two recent meta-analyses published by Koreny et al (January 2004; RCTs only) and Nikolsky et al (February 2004; RCTs and observational studies) reported no reduction in overall vascular complications with VCD use.[21,22]

The study by Nikolsky et al included 37 066 patients from 30 studies of various VCDs and showed a trend toward decreased complications using Angio-Seal in a PCI setting.[22] Similarly, a recent observational study by Applegate et al also showed a reduction in the incidence of vascular complications with Angio-Seal use compared with manual compression in both diagnostic catheterization and PCI patients, although it was not statistically significant.[31] The findings from our current study demonstrate statistically significant protection from vascular complications for the use of the Angio-Seal device relative to manual compression for both diagnostic and therapeutic catheterization procedures (OR 0.37 [0.18-0.75], $P = .006$* and OR 0.56 [0.38-0.82], $P = .003$*, respectively). Although the use of Perclose closure device also showed similar protective trend, it was not found to be of statistical significance (OR 0.55 [0.15-2.01], $P = .4$ and OR 0.64 [0.36-1.15], $P = .1$). This could have been due to the smaller number of patients in the Perclose subgroup (1691 patients) as compared with the Angio-Seal subgroup (8201 patients).

Our study population differs from other previously reported studies by virtue of the significantly greater rates of VCD deployment (77% overall, 86% in PCI, and 67% in diagnostic catheterization procedures, respectively) due to an institutional strategy to routinely use VCDs. This study is also one of the largest single-center series of Angio-Seal and Perclose closure device.

To address potential selection bias in the use of VCDs in this prospective registry, we analyzed our data by performing a propensity analysis. Propensity score methods address the issue of biases and confounders by reducing the entire collection of background characteristics to a single composite characteristic that appropriately summarizes the collection of all considered covariates. The major finding of this current study is that the propensity to use VCDs did not affect the protective influence of closure devices on vascular outcomes in both diagnostic catheterization and PCI patients (Table IV).

The generalizability of our study is limited by the source of the data being reported from a single, high-volume center. Despite the institutional policy for deployment of VCDs and the propensity analysis reported, unadjusted biases may still remain in this observational data set. In addition, the lack of propensity adjustment for unfavorable vascular anatomy is a limitation of this analysis.

In conclusion, VCDs seem to offer a safe alternative to manual compression for achieving arterial access site hemostasis in appropriately selected patients undergoing diagnostic and therapeutic cardiac catheterizations. The routine use of such devices was found to be independently associated with a reduction in overall vascular complication rates. This advantage of VCDs is in addition to the previously demonstrated superiority over manual compression with regard to patient comfort, reduced time to hemostasis, and length of hospital stay.

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