Usefulness of a Nonsuture Closure Device in Patients Undergoing Diagnostic Coronary and Peripheral Angiography

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Abstract

Vascular access site complications can follow diagnostic coronary and peripheral angiography. We compared the complication rates of the Catalyst vascular closure device, with the complication rates after manual compression in patients undergoing diagnostic angiographic procedures via femoral access. We studied 1,470 predominantly male patients undergoing diagnostic coronary and peripheral angiography. Catalyst closure devices were used in 436 (29.7%) patients and manual compression was used in 1,034 (70.3%) patients. The former were allowed to ambulate after 2 hours, while the latter were allowed to ambulate after 6 hours. Major complications occurred in 4 (0.9%) patients who had a Catalyst device and in 14 (1.4%) patients who had manual compression (odds ratio [OR]: 0.67, 95% confidence interval [CI]: 0.22–2.1, $p = 0.49$). Any complications occurred in 51 (11.7%) patients who had a Catalyst closure device and in 64 (6.2%) patients who had manual compression (OR: 2, CI: 1.4–3, $p < 0.01$). After adjustment for other variables and for a propensity score reflecting the probability to receive the closure device, the association of major complications with the use of the closure device remained not significant (OR: 0.54, 95% CI: 0.17–1.7, $p = 0.29$), while the association of any complications with the use of the Catalyst device remained significant (OR: 1.9, 95% CI: 1.3–2.9, $p < 0.01$). The Catalyst device was not associated with an increased risk of major groin complications but was associated with an increased risk of any complications compared with manual compression. Patients receiving the closure device ambulated sooner.

Keywords

- closure device
- groin access complications
- hematoma
- bleeding

Coronary angiography requires arterial access, which carries an inherent risk with vascular access and closure. Although the Seldinger's technique provides a less invasive approach to arterial access, closure of the arteriotomy site is most often done blindly, increasing the risk of vascular complications especially when the access site is the femoral artery. Vascular complications that have been reported with arteriotomy of the femoral artery include major bleeding, hematomas, pseudoaneurysm, arteriovenous (AV) fistula, thrombosis,

and vessel dissection.^{1–3} The incidence of major peripheral vascular complications with percutaneous coronary interventions from a femoral approach has been reported on the range of 0.9 to 9%, and complications from diagnostic angiography on the range of 0.52 to 3.6%.^{2,4–6} Peripheral vascular complications following percutaneous coronary intervention were found to nearly double hospitals costs, while being associated with an increase in 1-year mortality from 1.1 to 7.5%.⁷

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Manual compression of the femoral arteriotomy site is still the “gold standard” in management of patients during coronary angiography to prevent femoral vascular access site complications.⁸ However, manual compression is resource intensive, requiring 20 to 30 minutes of personnel time for hemostasis to occur. Manual compression also requires interruption of anticoagulation therapy, along with requiring several hours of bed rest that provides inconveniences to patient care and resource utilization. Vascular closure devices (VCDs) were designed and have been proven to improve efficiency, efficacy, and safety of closure of arteriotomy sites.^{9,10} VCDs have been shown to decrease hemostasis time, shorten time to ambulation, while not significantly increasing risk for complications.^{11–13} However, a meta-analysis by Koreny et al showed that, while the time to achieve hemostasis decreased with VCD, the risk of hematoma and pseudoaneurysm was increased.¹⁴

Conventional VCDs, such as collagen plugs, suture devices, and vascular clips result in retention of hardware that has been shown to increase infections and embolic complications. Cardiva Catalyst II is a newer device that uses a disk that is coated with protamine sulfate that provides temporary intravascular tamponade, facilitating physiologic vessel contraction and thrombosis. The device is removed at the end of a period of 5 minutes and thus nothing is left behind in the body of the patient. As it is a simple device, it is easy to use the deployment technique and the learning curve is very steep. The device is easier to master than other closure devices such as Angio-Seal, Mynx, or Exoseal. The Cardiva Catalyst II device was proven to be safe and effective in patients undergoing diagnostic catheterization, with low rates of vascular complications in a published study.¹¹ This study did find vascular complication rates that were comparable to manual compression. However, the study may have been unpowered to find a statistically significant difference in vascular complications.

We performed a retrospective study that compared the short-term outcomes and the complications rates of the Cardiva Catalyst II VCD to manual compression for a predominantly male veterans' population undergoing diagnostic coronary and peripheral angiography.

Methods

Study Design

Our study was a retrospective observational analysis. This was a single-center study conducted at the McGuire Veterans Affairs Medical Center in Richmond, VA. The study was approved by the McGuire Veterans Affairs Institutional Review Board for consent waiver. Subjects were consecutive patients undergoing coronary or peripheral angiography via femoral access between January 2010 and September 2012. At the time, 95% of the procedures in our cardiac catheterization laboratory were done via the femoral access. Patients undergoing coronary or peripheral interventions, and patients undergoing both left and right or only right heart catheterization were excluded. Patients who had other closure devices used were also excluded. The Computerized Patient Record System

(CPRS) of the Veterans Health Administrations was used to collect data. As the Veterans Health Administration system is a “closed” system, all patients receive their care within the system and episodes of care are recorded in CPRS.

Procedure

All patients underwent diagnostic coronary and peripheral angiography. Arterial sheath size was mainly 6F; however, the size ranged from 5 to 8F.

Intraprocedural anticoagulation was not routinely given for diagnostic procedures. After completion of the procedure, the closure method was chosen at the discretion of the attending cardiologist. All operators had at least 3-year experience in the cath laboratory and had used at least 25 Catalyst devices before the beginning of the study period. For patients receiving Catalyst VCD, it was deployed in the cardiac catheterization with a dwell time of 10 minutes. After 10 minutes, the Catalyst VCD was removed in the recovery room by a nurse, followed by 5 minutes of compression of the femoral arteriotomy site. Manual compression was performed for 20 minutes to allow for adequate hemostasis in patients who did not receive the Catalyst VCD. After successful hemostasis, patients were required to be on bed rest for 2 and 6 hours for Catalyst VCD and manual compression, respectively. Follow-up of groin complications was performed by the attending cardiologist, cardiology fellow, and medicine house staff. Appropriate vascular studies were performed when clinically indicated. The complications occurring within 30 days of the index procedure are included in the analysis. No patient had evidence of arterial occlusion or underwent surgery related to the femoral access site. Major complications were (1) hematoma > 5 cm, (2) bleeding with drop in hemoglobin > 2 g/dL or requiring blood transfusion, (3) AV fistula, and (4) pseudoaneurysm.

Minor complications were (1) device failure, (2) pain at arteriotomy site, (3) minor bleeding (not causing a drop in hemoglobin of 2 g or more and not necessitating transfusion), and (4) hematoma < 5 cm.

Statistical Analysis

Discrete variables were summarized as frequency and continuous distributions were described with mean $\pm$ standard deviation. A propensity score was calculated to determine the likelihood that a patient would receive VCD based on a non-parsimonious model that included variables such as age, gender, hemoglobin, and other comorbid conditions, as well as medications such as heparin and Lovenox. The propensity score was used as a covariate in the multivariate analysis. The propensity score showed adequate discriminatory power (*c* statistic with 95% confidence interval [CI] was 0.68 [0.65, 0.71]). Two-sided tests were used throughout. A *p* < 0.05 was considered statistically significant.

As the incidence of complications may vary with time, we also introduced a continuous variable to account for the period of the study (0 = first procedure; 1 = last).

Multiple logistic regression models were computed with the three different kinds of complications (major, minor, and any) as outcome and the Catalyst/manual compression

dichotomy, period of the study, and covariates as predictors, to test for any associated differences in the probability of a patient experiencing a complication. Separate models were computed that included the interaction of the Catalyst/manual compression dichotomy with period of the study, to assess whether outcomes changed differentially over time between the two procedures.

Results

A total of 1,470 patients were analyzed. The mean age was 63.9 ± 9.68 years. The mean body mass index of patients was 30.5 ± 6.43 kg/m². The Catalyst II VCD was used in 436

(29.7%) patients and manual compression was used in 1,034 (70.3%) patients. ►Table 1 summarizes the clinical and procedural characteristics of the studied patients.

Among patients who received the Catalyst II VCD, significantly more had hypertension (86.2%) compared with those receiving manual compression (79.3%). In contradistinction, significantly more individuals who underwent manual compression had peripheral vascular disease (12.4%) than individuals who underwent closure with the Catalyst II VCD (6.7%). Finally, heparin or Lovenox was used during and after the procedure in 36.2% of cases in patients undergoing manual compression in comparison to 31.9% of patients receiving the Catalyst II VCD.

Table 1 Clinical characteristics of patients

	All (n = 1,470)	Manual compression (n = 1,034)	Catalyst (n = 436)	p-Value
Male gender	96.5%	96.7%	95.9%	0.43
Age (y)	63.9 ± 9.68	63.9 ± 9.88	64.1 ± 9.2	0.68
Caucasian	62.4%	62.9%	61.2%	0.54
BMI (kg/m ²)	30.5 ± 6.43	30.3 ± 6.59	30.8 ± 6.04	0.17
Comorbidities				
Coronary artery disease	774 (52.7%)	540 (52.2%)	234 (53.7%)	0.61
Hypertension	1,196 (81.4%)	820 (79.3%)	376 (86.2%)	<0.01
Congestive heart Failure	255 (17.3%)	192 (18.6%)	63 (14.4%)	0.06
Diabetes mellitus	620 (42.2%)	427 (41.3%)	193 (44.3%)	0.29
Peripheral vascular disease	157 (10.7%)	128 (12.4%)	29 (6.7%)	<0.01
Chronic kidney disease	239 (16.3%)	177 (17.1%)	62 (14.2%)	0.17
Dialysis	40 (2.7%)	26 (2.5%)	14 (3.2%)	0.45
Atrial fibrillation	139 (9.5%)	98 (9.5%)	41 (9.4%)	0.96
COPD	203 (13.8%)	138 (13.3%)	65 (14.9%)	0.43
Medications				
Beta-blocker	1,009 (68.6%)	704 (68.1%)	305 (70%)	0.48
Aspirin	1,229 (83.6%)	861 (83.3%)	368 (84.4%)	0.59
Plavix	347 (23.6%)	233 (22.5%)	114 (26.1%)	0.14
Coumadin	101 (6.9%)	72 (7%)	29 (6.7%)	0.83
Heparin/Lovenox	513 (34.9%)	374 (36.2%)	139 (31.9%)	0.12
Procedural characteristics				
Indication angina ^a	1,110 (75.5%)	761 (73.6%)	349 (80%)	<0.01
Indication dyspnea ^b	91 (6.2%)	71 (6.9%)	20 (4.6%)	0.1
Indication heart transplant ^c	20 (1.4%)	17 (1.6%)	3 (0.7%)	0.16
Outpatients	949 (64.6%)	662 (64%)	287 (65.8%)	0.51
Coronary angiography	1,429 (97.2%)	1,000 (96.7%)	429 (98.4%)	0.08
Bypass graft angiography	294 (20%)	204 (19.7%)	90 (20.6%)	0.69
Sheath size 6F	1,385 (94.2%)	952 (92.1%)	433 (99.3%)	<0.01
Previous cath	153 (10.4%)	127 (12.3%)	26 (6%)	<0.01

Abbreviations: BMI, body mass index; COPD, chronic obstructive pulmonary disease.

^aIncludes chest pain and abnormal stress test.

^bIncludes dyspnea on exertion, shortness of breath, dyspnea, and heart failure.

^cIncludes heart transplant surveillance.

The Catalyst II VCD was used in more patients who underwent angiography for chest pain, angina, or abnormal stress test (80%) than manual compression (73.6%). The majority of angiographic procedures used 6F sheaths (94.2%); however, with the Catalyst II VCD, 6F sheaths (99.3%) were used more often than with manual compression (92.1%).

Major complications (►Table 2) occurred in 4 (0.9%) patients who had a Catalyst closure device and in 14 (1.4%) patients who had manual compression used for hemostasis (odds ratio [OR]: 0.67, 95% CI: 0.22–2.1, $p = 0.49$). Minor complications occurred in 48 (11%) patients who had a Catalyst closure device and in 52 (5%) patients who had manual compression used for hemostasis (OR: 2.3, 95% CI: 1.6–3.5, $p < 0.01$). Any complications occurred in 51 (11.7%) patients who had a Catalyst closure device and in 64 (6.2%) patients who had manual compression used for hemostasis (OR: 2, 95% CI: 1.4–3, $p < 0.01$). Factors associated with major, minor, and any complications in bivariate analysis are presented in ►Table 3. Age was associated with major complications, while the use of the Catalyst device was associated with minor and with any complications. On bivariate analysis, there was an association between all complications and the period of study.

After adjustment for other variables such as age, gender, peripheral vascular disease, chronic kidney disease, and for the propensity score reflecting the probability to receive the closure device, the association of major complications with the use of the Catalyst II VCD remained not significant (OR: 0.54, 95% CI: 0.17–1.7, $p = 0.29$). However, the association of minor complications and all complications with the use of the Catalyst II VCD remained significant (OR: 2.3, 95% CI: 1.5–3.5, $p < 0.01$ and OR: 1.9, 95% CI: 1.3–2.9, $p < 0.01$ respectively, ►Table 4).

The interaction between group dichotomy (Catalyst vs. manual compression) and period of study was not statistically significant ($p > 0.43$ for all types of complications) suggesting that the complication rates decreased with time in both the manual compression as well as in the Catalyst group.

Table 2 Groin access complications

	All (n = 1,470)	Manual compression (n = 1,034)	Catalyst (n = 436)	p-Value
Major	18 (1.2%)	14 (1.4%)	4 (0.9%)	0.49
Hematoma	11 (0.7%)	7 (0.7%)	4 (0.9%)	0.63
Major bleeding	1 (0.1%)	1 (0.1%)	0 (0%)	1
AV fistula	0 (0%)	0 (0%)	0 (0%)	NA
Pseudoaneurysm	11 (0.7%)	9 (0.9%)	2 (0.5%)	0.41
Minor	100 (6.8%)	52 (5%)	48 (11%)	<0.01
Minor bleeding	25 (1.7%)	10 (1%)	15 (3.4%)	<0.01
Device failure	15 (1%)	0 (0%)	15 (3.4%)	NA
Other complication	83 (5.6%)	51 (4.9%)	32 (7.3%)	0.07
Any	115 (7.8%)	64 (6.2%)	51 (11.7%)	<0.01

Abbreviations: AV, arteriovenous; NA, not available.

Table 3 Bivariate associations with major and minor complications

	Odds ratio (95% CI)	p-Value
Major complications		
Age (y)	1.1 (1–1.1)	0.03
Diabetes mellitus	0.39 (0.12–1.2)	0.1
Peripheral vascular disease	1 (0.23–4.7)	0.95
Atrial fibrillation	1.9 (0.54–6.9)	0.3
Heparin/Lovenox	1.9 (0.73–4.9)	0.18
Aspirin	0.98 (0.27–3.5)	0.97
Plavix	2.1 (0.79–5.5)	0.13
Period of study	0.15 (0.024–0.95)	0.04
Catalyst	0.67 (0.22–2.1)	0.49
Minor complications		
Age (y)	1 (0.98–1)	0.87
Diabetes mellitus	1.1 (0.75–1.7)	0.55
Peripheral vascular disease	0.61 (0.27–1.4)	0.22
Atrial fibrillation	1.5 (0.79–2.8)	0.21
Heparin/Lovenox	1.4 (0.91–2.1)	0.12
Aspirin	1.5 (0.78–2.8)	0.22
Plavix	0.75 (0.44–1.3)	0.26
Period of study	0.2 (0.092–0.44)	<0.01
Catalyst	2.3 (1.5–3.5)	<0.01
Any complications		
Age (y)	1 (0.99–1)	0.57
Diabetes mellitus	0.98 (0.66–1.5)	0.92
Peripheral vascular disease	0.69 (0.34–1.4)	0.3
Atrial fibrillation	1.5 (0.83–2.7)	0.17
Heparin/Lovenox	1.4 (0.92–2)	0.11
Aspirin	1.3 (0.75–2.4)	0.31
Plavix	0.89 (0.56–1.4)	0.62
Period of study	0.2 (0.097–0.42)	<0.01
Catalyst	2 (1.4–3)	<0.01

Abbreviation: CI, confidence interval.

Discussion

Our findings show that in a cohort of predominantly male patients, the use of the Catalyst VCD was not associated with a significantly decreased risk of major groin complications and was associated with an increased risk of minor complications compared with manual compression. The rate of major complications in our cohort is similar to previously reported complication rates.^{2,4–6} The increased complication rate for Catalyst VCD use with femoral arteriotomy is higher than previously reported in a published study, but the number of

Table 4 Multiple logistic regression models

Variable	Odds ratio (95% CI)	p-Value
Major complications		
Catalyst	0.54 (0.17–1.7)	0.29
Age (y)	1 (1–1.1)	0.04
Heparin/Lovenox	1.5 (0.56–4)	0.43
Peripheral vascular disease	1.3 (0.27–6.4)	0.74
Chronic kidney disease	0.67 (0.15–3)	0.6
Period of study	0.17 (0.025–1.1)	0.06
Minor complications		
Catalyst	2.3 (1.5–3.5)	<0.01
Age (y)	1 (0.98–1)	0.58
Male gender	0.52 (0.21–1.3)	0.16
Heparin/Lovenox	1.2 (0.79–1.9)	0.36
Peripheral vascular disease	0.6 (0.26–1.4)	0.23
Chronic kidney disease	1.3 (0.79–2.3)	0.28
Period of study	0.23 (0.1–0.51)	<0.01
Any complications		
Catalyst	1.9 (1.3–2.9)	<0.01
Age (y)	1 (0.99–1)	0.37
Male gender	0.6 (0.24–1.5)	0.27
Heparin/Lovenox	1.2 (0.8–1.8)	0.4
Peripheral vascular disease	0.69 (0.33–1.4)	0.33
Chronic kidney disease	1.3 (0.76–2.1)	0.36
Period of study	0.22 (0.1–0.47)	<0.01

Abbreviation: CI, confidence interval.

patients was considerably smaller than in our study and thus the CIs were larger.¹¹

Since our data are from a cohort of patients and not randomized, the cardiologist performing the procedure was the one who chose the method of hemostasis. To try to compensate for the potential bias introduced by this, we calculated a propensity score to determine the probability to receive the Catalyst VCD. We then made an adjustment for other variables such as age, male, peripheral vascular disease, chronic kidney disease and for the propensity score reflecting the probability to receive the closure device. After adjusting for these factors, major complication rates did not differ significantly; however, minor complication rates remained significantly different. The increase in minor complication rates was mainly due to device failure and pain at the arteriotomy site.

Prior studies looking at the Catalyst VCD found different complication rates in a study of 96 patients undergoing diagnostic catheterization.¹¹ A control arm was not included in the study. The authors reported no major complications with the Catalyst VCD and 5% minor complication rates, which was mainly minor (re)bleeding requiring further manual compression. They did not include failure of device

to deploy nor pain at arteriotomy site as a minor complications although the device failed to deploy in one patient.

Furthermore, 5F sheaths were used for diagnostic angiograms, compared with mainly 6F sheaths in our study, while patients with venous sheaths were included in that study. We did not include patients undergoing right heart catheterization necessitating the insertion of venous sheaths to avoid complications resulting from venous sheaths. Our retrospective data in clinical use of the Catalyst VCD shows somewhat different rates of all complications when compared with previously reported safety data, but the populations studied are not comparable and the techniques are different as is the length of bedrest after the procedure.¹¹ Kiesz et al¹⁵ also reported a series of 400 outpatients who underwent closure with the Catalyst VCD (Cardiva Catalyst) after outpatient peripheral procedures. The reported rates of complications are low, but in contradistinction to our study population in which more than 90% of the sheaths used were 6F and one-third of the patients were inpatients, the sheaths used in the study by Kiesz et al were mostly 5F and the study population was low risk.

When comparing complication rates of femoral arteriotomy closure after diagnostic angiography with the Catalyst VCD to other VCD, we found similar results as previous studies. Arora et al found that the use of a VCD (Angio-Seal, VasoSeal, Perclose, and Duett) resulted in major vascular complications in 0.5% of the cases, compared with 0.9% in our study.¹⁶ In that cohort of more than 6,000 patients undergoing diagnostic catheterization, the authors also found that age older than 70 years was a predictor of groin access complications. This is most likely due to the decrease in elasticity of the vascular wall that occurs with advancing age. Ward et al found all complications occurred in 9% of patients with Angio-Seal use after diagnostic catheterization, compared with 11.7% with the Catalyst VCD in our study.¹⁷ Finally, the use of a suture-mediated closure of femoral artery access resulted in major complications in 2.4% of patients undergoing diagnostic catheterization¹⁸ compared with 0.9% in our study population. Moreover, in a recent randomized trial comparing two types of VCDs with manual compression, Schulz-Schüpke et al found that the VCDs reduce time to hemostasis but not complications.¹⁹ The reason why the Catalyst use was not associated with major complications but was associated with minor complications is not clear. One possible explanation is that the device does promote hemostasis (the number of major complications with the device were numerically lower); however, the increased number of minor complications was driven by device failure and by minor bleedings that did not result in a hematomas. This was also seen in a recent trial¹⁹ where the use of VCDs was associated with an increase in repeat manual compression presumably also for minor bleedings.

Our finding that the frequency of groin complications decreased with time in both the Catalyst VCD group as well as in the manual compression group may be related to the cardiac catheterization laboratory ongoing quality improvement program and the general alertness of physicians and nurses to possible groin complications and the need to avoid them. VCD have the benefit of enhancing patient care by decreasing

hemostasis time, reducing bed rest, encouraging early ambulation, and decrease staff utilization for hemostasis. It has been shown that a percutaneous collagen hemostasis device can significantly decrease time to hemostasis, regardless of anticoagulation use, when compared with manual compression.¹³ Ward et al found similar results with decreased time to hemostasis with a collagen hemostasis device, but they also showed that time to outpatient discharge was reduced by approximately 2.5 hours.¹⁷ Similarly, a suture VCD was shown to be safe and effective to decrease time to ambulation.²⁰ According to our protocol, bed rest was decreased from 6 to 2 hours in patients receiving the Catalyst without an increase in major complication rates.

Study Limitations

Our study has several limitations. This study is a retrospective study and even though we used the propensity score analysis to lower the chance of biases, there still could be hidden biases that we did not account for and that can alter our results. The closure method was at the discretion of the attending cardiologist. Also, there was no standardization for follow-up of patients after hospital discharge and complications that were not captured and recorded in the medical record may not have been included in our data if the patients obtained care at outside hospitals without notifying our medical center (however, this is unlikely since the VA hospital pays for the bills from the outside).

Conclusion

VCDs are designed to increase efficiency and efficacy of arteriotomy sites. Our findings show that the Catalyst VCD allowed patients to ambulate after a decreased bed rest time from 6 to 2 hours, without increases in major vascular complications. However, we found increased rates of minor complications, mostly related to pain at the access site with the Catalyst VCD.

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