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# Vascular Closure Device Failure in Contemporary Practice

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**Objectives** The goal of this study was to assess the frequency and predictors of vascular closure device (VCD) deployment failure, and its association with vascular complications of 3 commonly used VCDs.

**Background** VCDs are commonly used following percutaneous coronary intervention on the basis of studies demonstrating reduced time to ambulation, increased patient comfort, and possible reduction in vascular complications as compared with manual compression. However, limited data are available on the frequency and predictors of VCD failure, and the association of deployment failure with vascular complications.

**Methods** From a de-identified dataset provided by Massachusetts Department of Health, 23,813 consecutive interventional coronary procedures that used either a collagen plug–based (n = 18,533), a nitinol clip–based (n = 2,284), or a suture-based (n = 2,996) VCD between June 2005 and December 2007 were identified. The authors defined VCD failure as unsuccessful deployment or failure to achieve immediate access site hemostasis.

**Results** Among 23,813 procedures, the VCD failed in 781 (3.3%) procedures (2.1% of collagen plug–based, 6.1% of suture-based, 9.5% of nitinol clip–based VCDs). Patients with VCD failure had an excess risk of "any" (7.7% vs. 2.8%; $p < 0.001$), major (3.3% vs. 0.8%; $p < 0.001$), or minor (5.8% vs. 2.1%; $p < 0.001$) vascular complications compared with successful VCD deployment. In a propensity score–adjusted analysis, when compared with collagen plug–based VCD (reference odds ratio [OR] = 1.0), nitinol clip–based VCD had 2-fold increased risk (OR: 2.0, 95% confidence interval [CI]: 1.8 to 2.3, $p < 0.001$) and suture-based VCD had 1.25-fold increased risk (OR: 1.25, 95% CI: 1.2 to 1.3, $p < 0.001$) for VCD failure. VCD failure was a significant predictor of subsequent vascular complications for both collagen plug–based VCD and nitinol clip–based VCD, but not for suture-based VCD.

**Conclusions** VCD failure rates vary depending upon the type of VCD used and are associated with significantly higher vascular complications as compared with deployment successes. (J Am Coll Cardiol Intv 2012;5:837–44) © 2012 by the American College of Cardiology Foundation

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Vascular closure devices (VCD) have been used with increasing frequency in the management of femoral arterial access following cardiac catheterization and coronary interventional procedures on the basis of demonstrated improvement in patient comfort and reduced time to ambulation (1–3). Although randomized clinical trial data are lacking to show a clear advantage in reducing vascular complications relative to manual or mechanical compression, recent registry studies indicate that VCDs may be an effective bleeding avoidance strategy compared with manual compression (4–8). Importantly, the rate of vascular complications following VCD deployment varies substantially depending upon the type of VCD used, success of deployment of the VCD, and other factors (7,9–11). Although successful deployment of VCD has been shown in several series to reduce the vascular complication rate, consequences of VCD failure are not well defined (4,9,12–14).

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The objective of this study was 2-fold. First, we sought to evaluate the frequency of VCD failure in routine practice settings and its association with vascular complications following the deployment of the most commonly used VCDs (collagen plug–based [Angio-Seal, St. Jude Medical, St. Paul, Minnesota], nitinol clip–based [StarClose, Abbott Vascular, Redwood City, California], and suture-based [Perclose, Abbott Vascular, Santa Clara, California] VCDs). Second, we wished to identify factors that might predict VCD failure.

**Abbreviations and Acronyms**

CI = confidence interval
OR = odds ratio
PCI = percutaneous coronary intervention
VCD = vascular closure device

## Methods

**Study population and data collection.** The Massachusetts Department of Public Health angioplasty registry collects detailed clinical data and inpatient outcome information for all adults (18 years of age or older) who undergo coronary intervention at all nonfederal acute care Massachusetts inpatient facilities. Using a de-identified dataset from 22 hospitals in Massachusetts provided by the Massachusetts Department of Public Health, we evaluated consecutive interventional coronary procedures by femoral access between June 2005 and December 2007. Patients who received either a collagen plug–based (Angio-Seal), a nitinol clip–based (StarClose), or a suture-based (Perclose) VCD, representing the 3 most commonly used VCDs, were selected for the study. Patients who received other VCDs (n = 130) and those who required an intra-aortic balloon pump (n = 189) during the cardiac catheterization procedure were excluded from the study. The state-wide dataset is based on the American College of Cardiology–National Cardiovascular Data Registry definitions and contained clinical and procedural elements for each patient and follow-up information for the occurrence of all in-hospital complications (15–18).

**Cardiac catheterization and VCD protocol.** Percutaneous coronary intervention (PCI) was performed according to standard clinical practice. The registry provided information on routine clinical care as delivered to all consecutive patients treated with PCI. Periprocedural glycoprotein IIb/IIIa inhibitors and bivalirudin were used at the discretion of the treating physician. The decision to use a VCD, as well as the type of VCD used, was also left to the operator's discretion. VCD failure was defined as unsuccessful deployment or failure to achieve hemostasis in the laboratory and was captured prospectively in the registry.

**Outcome measures.** Patients were followed for the occurrence of in-hospital vascular complications as part of state-mandated clinical outcomes reporting. Vascular complications included groin bleeding (defined as blood loss at the access site resulting in blood transfusion, increased length of stay, or a drop in hemoglobin of >3 g/dl), large hematoma (size >10 cm), pseudoaneurysm (confirmed by arteriography or ultrasonography), arteriovenous fistula (confirmed by arteriography or ultrasonography), retroperitoneal hemorrhage, limb ischemia (loss of peripheral pulse requiring vascular or surgical evaluation), or any case requiring vascular access–related surgical intervention. Major vascular complication was defined as any retroperitoneal hemorrhage, limb ischemia, or any vascular access–related surgical intervention. Minor vascular complication was defined as any groin bleeding, hematoma (>10 cm), pseudoaneurysm, or arteriovenous fistula. "Any" vascular complication was defined as the occurrence of either a major or a minor vascular complication.

**Statistical analysis.** Continuous variables are reported as median (with interquartile range) and categorical variables as total number (percentage in the group). The baseline clinical and procedural characteristics of the patient groups were compared using the chi-square test or Fisher exact test for categorical variables. Normally distributed continuous variables were compared using the Student *t* test. Non-normally distributed continuous variables were compared with either the Wilcoxon rank sum test (for 2 patient groups) or the Kruskal-Wallis test (for 3 patient groups), for which post hoc comparisons were performed using the Wilcoxon rank sum test with Bonferroni correction. We employed an overall significance level of 0.05 except where correction was used. Statistical analysis was performed using SAS version 9.2 (SAS Institute, Cary, North Carolina).

Univariate analysis was performed to determine the clinical and procedural characteristics associated with VCD failure and vascular complications. A multivariate model was built to evaluate the determinants of VCD failure using

a generalized estimating equation (PROC GENMOD)—for logistic regression with binomial family and logit link, and an independent working correlation structure that accounted for within-hospital clustering of patients. In addition, we performed a sensitivity analysis of the determinants of VCD failure by using an exchangeable correlation structure in logistic regression. The model was built using risk factors identified from published research or considered by domain experts to potentially influence VCD failure. This approach has been shown to achieve better performance when compared with automated stepwise variable selection methods (4,9,12,19). The following variables were used in the multivariate model: age, body mass index, female sex, hypertension, diabetes mellitus, peripheral vascular disease, estimated glomerular filtration rate <60 ml/min, left ventricular ejection fraction ≤30%, glycoprotein inhibitor use, bivalirudin use, right heart catheterization, fluoroscopic time, emergent status of PCI, and clinical site.

Because of the significant difference in the key baseline characteristics among the 3 VCD patient groups, we performed a propensity score–adjusted sensitivity analysis to evaluate the relationship between VCD choice and subsequent VCD failure and vascular complications. Propensity score for VCD failure was estimated by using a nonparsimonious multivariable multinominal logistic regression model, with variables selected based on literature review for predictors of vascular complications as well as on domain expert opinion. The following variables were used to calculate the propensity score: age, body mass index, female sex, hypertension, diabetes mellitus, tobacco smoking, dyslipidemia, peripheral vascular disease, estimated glomerular filtration rate, history of congestive heart failure, acute myocardial infarction, left ventricular ejection fraction ≤30%, glycoprotein inhibitor use, bivalirudin use, right heart catheterization, fluoroscopic time, emergent status of PCI, and clinical site. The propensity score–adjusted risk of VCD failure and vascular complications was subsequently calculated using a generalized estimating equation for logistic regression (PROC GENMOD).

There were 10 (0.04%) missing values for body mass index and 972 (4%) missing values for estimated glomerular filtration rate in the dataset. Missing values of these 2 variables were managed by simple imputation of their median values.

## Results

Among 23,813 procedures in the study cohort using 1 of the studied VCD following PCI, 18,533 procedures (78%) used a collagen plug–based VCD, 2,284 procedures (10%) used a nitinol clip–based VCD, and 2,996 procedures (12%) used a suture-based VCD deployment. VCD deployment was successful in 23,032 procedures (96.7%), and VCD failure occurred in 781 procedures (3.3%). The baseline character-

**Table 1. Baseline Characteristics of Patients Who Received Different VCDs**

| Variable | Collagen Plug–Based VCD (n = 18,533) | Nitinol Clip–Based VCD (n = 2,284) | Suture-Based VCD (n = 2,996) | p Value |
|---|---|---|---|---|
| Age, yrs | 63 (54–73) | 62 (53–72) | 61 (53–71) | <0.001 |
| Female | 5,225 (28.2%) | 650 (28.5%) | 833 (27.8%) | 0.86 |
| BMI, kg/m$^2$ | 28.7 (26–33) | 28.4 (26–32) | 28.5 (26–32) | <0.001 |
| Diabetes mellitus | 5,422 (29.3%) | 627 (27.4%) | 843 (28.1%) | 0.12 |
| Diabetes on insulin | 1,652 (8.2%) | 178 (7.8%) | 258 (8.6%) | 0.19 |
| History of renal insufficiency | 833 (4.5%) | 70 (3.1%) | 111 (3.7%) | <0.001 |
| Estimated GFR (MDRD), ml/min/1.73 m$^2$ | 75.5 (61–89) | 77.8 (64–91) | 76.6 (62–89) | 0.02 |
| Prior MI | 4,753 (25.6%) | 613 (26.8%) | 843 (28.1%) | 0.01 |
| Congestive HF | 1,597 (8.6%) | 177 (7.8%) | 263 (8.8%) | 0.34 |
| Hypertension | 13,918 (75.1%) | 1,683 (73.7%) | 2,214 (73.9%) | 0.16 |
| Hyperlipidemia | 14,832 (80.1%) | 1,830 (80.1%) | 2,410 (80.4%) | 0.88 |
| PVD history | 1,769 (9.5%) | 174 (7.6%) | 260 (8.7%) | 0.01 |
| STEMI | 3,257 (17.6%) | 351 (15.4%) | 524 (17.5%) | 0.03 |
| LV ejection fraction ≤30% | 8,210 (44.3%) | 788 (34.5%) | 1,242 (41.5%) | <0.001 |
| GPI use | 8,738 (47.2%) | 923 (40.4%) | 1,228 (41%) | <0.001 |
| Right heart catheterization | 1,881 (10.2%) | 105 (4.6%) | 189 (6.3%) | <0.001 |
| Emergent PCI | 3,563 (19.2%) | 447 (19.6%) | 641 (21.4%) | 0.02 |
| Fluoro time (min) | 14.3 (9–23) | 15.1 (10–23) | 14.5 (10–23) | <0.001 |

Values are median (interquartile range) or n (%). The p values for continuous variables were calculated by the Kruskal-Wallis test and for categorical variables were calculated by the Fisher exact test.

BMI = body mass index; CABG = coronary artery bypass grafting; GFR = glomerular filtration rate; GPI = glycoprotein inhibitor; HF = heart failure; IQR = interquartile range; LV = left ventricle; MDRD = Modified Diet and Renal Disease; MI = myocardial infarction; PCI = percutaneous coronary intervention; PVD = peripheral vascular disease; STEMI = ST-segment elevation myocardial infarction; VCD = vascular closure device.

**Table 2. Vascular Outcomes Stratified by the Type of VCD and Deployment Success**

| Variable | Collagen Plug–Based VCD (n = 18,533) | | | Nitinol Clip–Based VCD (n = 2,284) | | | Suture-Based VCD (n = 2,996) | | |
|---|---|---|---|---|---|---|---|---|---|
| | VCD Success (n = 18,153) | VCD Failure (n = 380) (2.1%) | p Value | VCD Success (n = 2,067) | VCD Failure (n = 217) (9.5%) | p Value | VCD Success (n = 2,814) | VCD Failure (n = 185) 6.1% | p Value |
| Any vascular complication | 529 (2.9) | 41 (10.8) | <0.001 | 45 (2.2) | 13 (6.0) | 0.01 | 61 (2.2) | 6 (3.3) | 0.30 |
| Major vascular complication | 170 (0.9) | 21 (5.5) | <0.001 | 8 (0.4) | 4 (1.8) | 0.02 | 10 (0.4) | 1 (0.5) | 0.50 |
| Minor vascular complication | 395 (2.2) | 28 (7.4) | <0.001 | 41 (2) | 11 (5.1) | 0.01 | 52 (1.9) | 6 (3.3) | 0.17 |

Values are n (%). The p values were calculated by the Fisher exact test.
VCD = vascular closure device.

istics of the patients receiving the 3 different VCDs are provided in Table 1. After correction for multiple comparisons, patients who received a collagen plug–based VCD were more likely to be older, to have higher body mass index, to have lower estimated glomerular filtration rate, and required lesser fluoroscopic time compared with patients who received a nitinol clip–based VCD. Baseline characteristics of patients who had successful versus unsuccessful VCD deployment are provided in the Online Appendix (Online Table 1) Patients who had VCD failure were more likely to be female, to have presented with ST-segment elevation myocardial infarction, to have received glycoprotein inhibitor, and to undergo emergent PCI. VCD failure was less common in patients who were hypertensive, had impaired left ventricular ejection fraction ≤30%, and who received drug-eluting stents.

**VCD deployment failure.** Overall, VCDs failed in 781 procedures (3.3%). Collagen plug–based VCD had the lowest VCD failure rate of 2.1%, sutured-based VCD had a VCD failure rate of 6.1%, and nitinol clip–based VCD had the highest VCD failure rate of 9.5% (Table 2, Fig. 1). Multivariable predictors of VCD failure included body mass index, female sex, use of a glycoprotein inhibitor, use of bivalirudin, hypertension, peripheral vascular disease, a high estimated glomerular filtration rate, and those with left ventricular ejection <30% (Fig. 2). Sensitivity analysis performed by using an exchangeable correlation structure in logistic regression showed similar results. Propensity score–adjusted analysis of the impact of VCD choice on VCD failure demonstrated that compared with patients who received a collagen plug–based VCD, patients who received a nitinol clip–based VCD had a 2-fold higher incidence of VCD failure (odds ratio [OR]: 2.0, 95% confidence interval [CI]: 1.8 to 2.1, $p < 0.001$), and patients who received a suture-based VCD had a 25% higher incidence of VCD failure (OR: 1.25, 95% CI: 1.2 to 1.3, $p < 0.001$) (Table 3).

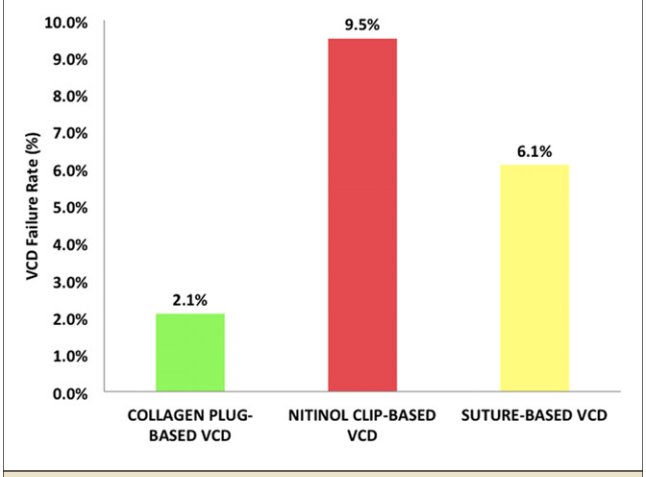


**Figure 1. Deployment Failure Rates of Different VCDs**

A vertical bar graph showing deployment failure rates of the 3 vascular closure devices (VCDs).

**Vascular complications.** Those patients in whom VCDs failed had significantly higher "any" (7.7% vs. 2.8%, $p < 0.001$), major (3.3% vs. 0.8%, $p < 0.001$), and minor (5.8% vs. 2.1%, $p < 0.001$) vascular complications compared with the group with successful deployment of VCD (Online Table 2). VCD failure and subsequent vascular complications were dependent upon the type of VCD used (Table 4, Fig. 3). In the unadjusted analysis, although the collagen plug–based VCD had the lowest VCD failure rate, it had the highest vascular complication rate in those patients who had VCD failure, compared with other VCDs. Although the vascular complication rates were dependent upon the success of deployment for the collagen plug–based VCD and nitinol clip–based VCD, the vascular complication rates in the suture-based VCD were independent of the success of that VCD.

Propensity analysis confirmed that VCD failure was a significant predictor for vascular complications. Compared with patients who had successful deployment of a VCD, propensity analysis demonstrated that patients with VCD failure had, on average, a 3-fold higher incidence of any vascular complication. Similarly, compared with patients who had successful deployment of VCDs, patients with VCD failure had a 5-fold higher incidence of a major vascular complication and a 3-fold higher incidence of a minor vascular complication. Vascular complications were not significantly different between nitinol clip–based VCD

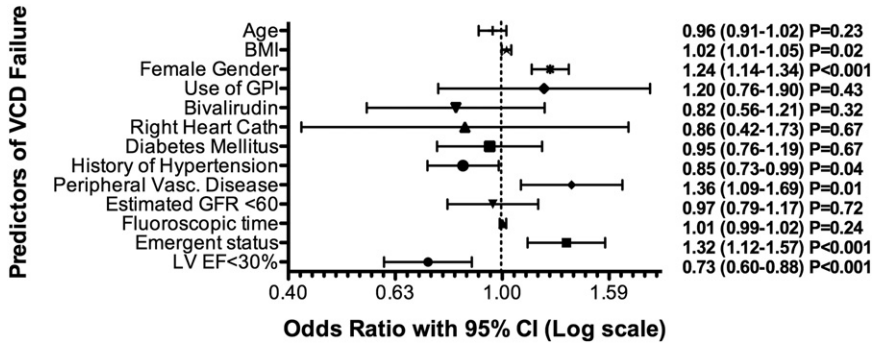


**Figure 2. Multivariable Predictors of VCD Failure**

Multivariable predictors of vascular closure device failure with their associated odds ratios with 95% confidence intervals and p values were calculated using a generalized estimating equation (GENMOD) procedure for logistic regression using an independent working correlation structure in SAS statistical software. Odds ratios (ORs) with 95% confidence intervals (CIs) are plotted on a logarithmic axis. The nonlogarithmic values for odds ratios with 95% confidence intervals are provided on the **right side** of the plot. BMI = body mass index; GFR = glomerular filtration rate; GPI = glycoprotein inhibitor; LV EF = left ventricular ejection fraction; PCI = percutaneous coronary intervention; VCD = vascular closure device.

and collagen plug–based VCD. However, suture-based VCD was noted to have a lower incidence of any (OR: 0.85, 95% CI: 0.77 to 0.95, p = 0.003) and major (OR: 0.62, 95% CI: 0.48 to 0.80, p < 0.001) vascular complications (Table 3) after propensity score adjustment.

## Discussion

Using a high-quality, mandatory state-level clinical outcomes database, this study assessed the frequency and predictors of VCD failure and subsequent vascular complications of 3 commonly used VCDs. This analysis demonstrated that the rates of VCD failure and vascular complications vary among different types of VCDs. Multiple patient characteristics determine the success of VCD deployment and subsequent vascular complications.

**Table 3. Propensity Score–Adjusted Analysis of VCD Failure and Vascular Complications**

| Variable | OR (95% CI) | p Value |
|---|---|---|
| VCD failure | | |
| Nitinol clip–based VCD vs. collagen plug–based VCD | 2.00 (1.88–2.13) | <0.001 |
| Suture-based VCD vs. collagen plug–based VCD | 1.25 (1.16–1.33) | <0.001 |
| Any vascular complication | | |
| Nitinol clip–based VCD vs. collagen plug–based VCD | 0.91 (0.82–1.02) | 0.11 |
| Suture-based VCD vs. collagen plug–based VCD | 0.85 (0.77–0.95) | <0.001 |
| VCD failure | 3.27 (2.78–3.84) | <0.001 |
| Major vascular complication | | |
| Nitinol clip–based VCD vs. collagen plug–based VCD | 0.79 (0.62–1.02) | 0.07 |
| Suture-based VCD vs. collagen plug–based VCD | 0.62 (0.48–0.80) | <0.001 |
| VCD failure | 5.44 (4.25–6.96) | <0.001 |
| Minor vascular complication | | |
| Nitinol clip–based VCD vs. collagen plug–based VCD | 0.99 (0.88–1.12) | 0.91 |
| Suture-based VCD vs. collagen plug–based VCD | 0.89 (0.79–0.99) | 0.05 |
| VCD failure | 2.97 (2.47–3.58) | <0.001 |

A propensity score–adjusted multivariable odds ratio (OR), 95% confidence intervals (CI), and p values were calculated using a generalized estimating equation (GENMOD) procedure for logistic regression in SAS statistical software.
VCD = vascular closure device.

**VCD failure.** VCDs have been established as an effective strategy following PCI to enable early patient ambulation and improve patient satisfaction and comfort related to the avoidance of prolonged sheath insertion and manual compression (4,8,20,21). However, a small proportion of VCD deployments fail. The reported failure rates for these devices vary widely, from 1.5% to 20% in contemporary studies (9–11,22–28). Moreover, reported failure rates of VCDs depend upon the type of VCD used. In our statewide PCI cohort, the VCD failure rate was 3.3%, and the device-specific failure rate ranged from 2.1% to 9.5%. The relatively higher failure rate of the nitinol clip–based VCD as compared with other VCDs may be partly explained by the learning curve effect associated with the adoption of the device since its introduction in early 2006, whereas the other VCDs studied had been in use in routine practice for many years (29,30). Our findings regarding the failure rate for the nitinol clip–based VCD are similar to reported failure rates with nitinol clip–based VCDs (10,11). However, that some of the independent predictors of VCD failure, such as a history of hypertension and low left ventricular ejection fraction (<30%), were identified to be protective against VCD failure seems counterintuitive. It is also possible that case selection bias (due to the physician's decision to choose a VCD or not) might be an important factor affecting VCD failure.

The results of this study show that VCD failure is associated with significantly higher any, major, and minor vascular complications compared with the group with suc-

**Table 4. Vascular Complications and Other Outcomes of Different VCDs**

| Variable | Collagen Plug–Based VCD (n = 18,533) | Nitinol Clip–Based VCD (n = 2,284) | Suture-Based VCD (n = 2,996) | p Value |
|---|---|---|---|---|
| Complications | | | | |
| Vascular bleeding | 387 (2.1) | 20 (0.9) | 33 (1.1) | <0.001 |
| Bleeding at PCI site | 178 (1.0) | 16 (0.7) | 11 (0.4) | <0.001 |
| Retroperitoneal bleeding | 157 (0.85) | 8 (0.35) | 5 (0.17) | <0.001 |
| Vascular occlusion | 11 (0.06) | 1 (0.04) | 3 (0.1) | 0.64 |
| Peripheral embolization | 10 (0.05) | 0 | 2 (0.07) | 0.67 |
| Vascular dissection | 8 (0.04) | 2 (0.1) | 2 (0.07) | 0.43 |
| Pseudoaneurysm | 28 (0.15) | 4 (0.2) | 1 (0.03) | 0.22 |
| AV fistula | 9 (0.05) | 0 | 0 | 0.58 |
| Treated pseudoaneurysm | 16 (0.1) | 3 (0.1) | 1 (0.03) | 0.44 |
| Any vascular complication | 570 (3.1) | 58 (2.5) | 67 (2.2) | 0.02 |
| Major vascular complication | 191 (1.0) | 12 (0.5) | 11 (0.4) | <0.001 |
| Minor vascular complication | 423 (2.3) | 52 (2.3) | 58 (1.9) | 0.49 |
| Other outcomes | | | | |
| Periprocedural MI | 471 (2.5) | 52 (2.8) | 81 (2.7) | 0.62 |
| Stroke | 43 (0.2) | 3 (0.1) | 7 (0.2) | 0.71 |
| Renal failure | 52 (0.3) | 11 (0.5) | 14 (0.5) | 0.10 |
| Death | 122 (0.7) | 15 (0.7) | 21 (0.7) | 0.90 |
| MACE | 689 (3.7) | 77 (3.4) | 117 (3.9) | 0.59 |
| MACCE | 719 (3.9) | 78 (3.4) | 123 (4.1) | 0.42 |

Values are n (%). The p values were calculated by the Fisher exact test.

AV = arteriovenous; MACE = major adverse cardiovascular events; MACCE = major adverse cardiac and cerebrovascular events; other abbreviations as in Table 1.

cessful VCD deployment. Even after adjustment for clinical variables, the VCD failure group had a 3- to 5-fold increase in the odds of having any, major, and minor vascular complications compared with the group with successful VCD deployment. Our findings support the results of the single-center observational study that analyzed failure rates of collagen plug–based and suture-based VCDs (9).

**Influence of the type of VCD.** We found varying failure rates among different VCDs. Although the collagen plug–based VCD showed the lowest failure rate (2.1%), when deployment was unsuccessful, it was associated with the highest vascular complication rate as compared with unsuccessful deployment of the suture-based or nitinol clip–based VCD. Deployment failure of the suture-based VCD did not impact the vascular complication rate as compared with its successful deployment. This may be due, in part, to the availability of a "bailout" mechanism with suture-based VCDs in the event of deployment failure that permits control of the arteriotomy site with sheath replacement or a second attempt at closure with a VCD. However, we can only hypothesize that the availability of a bailout mechanism with suture-based VCDs in the event of failure of suture capture could have contributed to the lack of impact of deployment failure of the suture-based VCD on the vascular complication rate. No bailout mechanism is readily available for either the collagen plug–based or the nitinol clip–based VCD.

We compared the VCD failure rates of different VCDs after propensity score adjustment for baseline risks of vascular complications. Although the nitinol clip–based VCD had a 2-fold increased risk of VCD failure compared with the collagen plug–based VCD, there was no significant difference in the risk of vascular complications between nitinol clip–based and collagen plug–based VCDs, after adjustment for propensity to use the device. In addition, although there was no significant difference in the risk of minor vascular complication rate among different VCDs after propensity score adjustment for baseline risk factors and VCD failure, there was a significantly decreased risk of major vascular complication rates of suture-based VCDs compared with collagen plug–based VCDs.

**Study limitations.** This study has the inherent limitations of all retrospective observational studies. Despite multivariate adjustment for clustering of patients within the clinical site to address the issue of institutional policy regarding VCD use, and use of propensity score adjustment for the risk of VCD failure and vascular complications, unmeasured confounding may still exist. Specifically, detailed angiographic information regarding the location of the access site and presence of atherosclerosis was not available, although these variables are known to be powerful predictors of vascular access site complications (31,32). Operator-level information and the operator's experience in the use of VCD were not available. It is possible that this might play an important role in successful

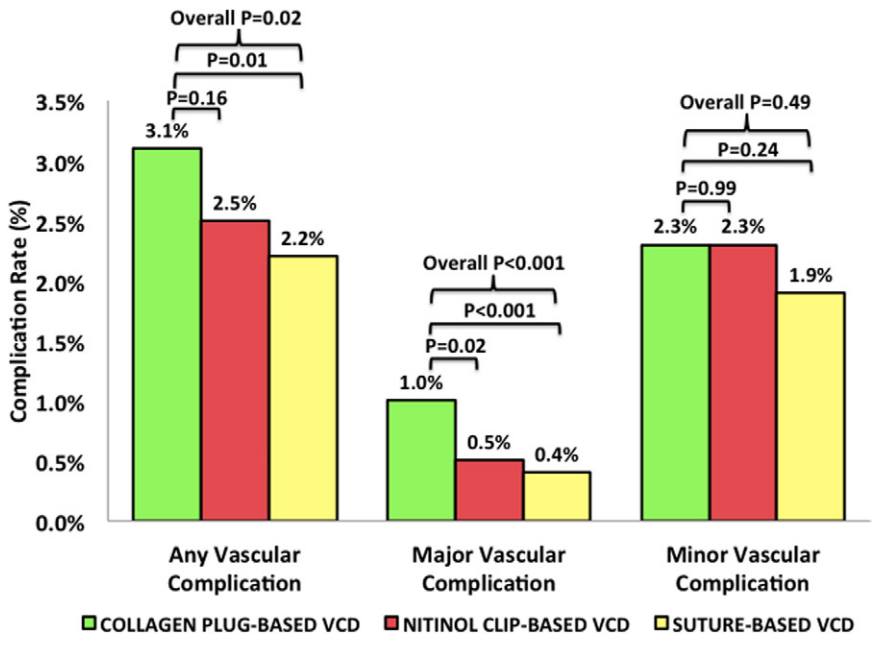


**Figure 3. Vascular Complication Rates of Different VCDs**

A bar graph comparing vascular complication rates of different vascular closure devices (VCDs) (includes instances of successes as well as failures). p values were obtained from the chi-square test.

deployment of VCDs, and such information might be useful to address potential learning curve effects with the adoption of new VCDs. In addition, we evaluated in-hospital outcomes only, and hence, any differences in late complications between devices were not available.

## Conclusions

In contemporary practice, VCD failure is rare but is dependent on specific device choice and patient characteristics. In general, VCD deployment failure significantly increases the subsequent risk of vascular complication rates. Optimizing operator technique and experience with a single type of VCD may help minimize VCD failure rates and thereby improve vascular outcomes especially for collagen plug–based and nitinol clip–based VCDs. In this analysis, the suture-based VCD demonstrated a lower risk of vascular complications when compared with other VCDs, irrespective of the success of VCD deployment. Given the limitations of this retrospective analysis, this finding must be interpreted cautiously and should be confirmed in future prospective studies.

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**Key Words:** Angio-Seal ■ complications ■ Perclose ■ StarClose ■ vascular closure device.

## APPENDIX

**For supplementary tables, please see the online version of this paper.**