JACC: CARDIOVASCULAR INTERVENTIONS
VOL. 5, NO. 8, 2012

ISSN 1936-8798/$36.00
PUBLISHED BY ELSEVIER INC.
http://dx.doi.org/10.1016/j.jcin.2012.06.006

EDITORIAL COMMENT

Vascular Closure Device Failure

We Are Getting Better But Not There Yet*

Robert J. Applegate, MD

Winston-Salem, North Carolina

Manual compression for femoral artery access site hemostasis had been the standard of care until the early 1990s. At that time, 2 significant changes in clinical practice challenged the effectiveness of manual compression as the optimal hemostasis method: the use of large-bore catheters to perform coronary atherectomy, and intensive anticoagulant regimens needed for the first clinical introduction of intracoronary stents. At that time, large hematomas and other vascular bleeding complications after coronary intervention in these patients were commonplace and frustrating to most interventionalists. In parallel, several devices underwent development and final clinical approval to achieve hemostasis more directly as an alternative to manual compression. These vascular closure devices (VCDs) ushered in a new error of vascular access management that has undergone extensive clinical evaluation and scrutiny.

See page 837

A suture-based device (Perclose, Abbott Vascular, Redwood City, California) and an extravascular collagen plug (VasoSeal, Datascope, Mahwah, New Jersey) were introduced for clinical application in 1994, whereas an intravascular anchor and extravascular collagen sandwich, or collagen plug (Angio-Seal, St Jude Medical, St Paul, Minnesota), was approved for clinical use in 1996. The first versions of these closure devices achieved hemostasis and shortened time to ambulation in most patients in whom they were used. However, device failure requiring immediate or delayed manual compression still occurred in up to 10% to 20% of these patients. Since the initial versions of the closure devices were made available for clinical use, both the Perclose and the Angioseal devices have undergone extensive modifications to address issues of device failure. For example, in the 1,000-patient Angio-Seal Evolution registry, using the most recent collagen plug device in an all-comers 10-center prospective registry, device-mediated immediate hemostasis was achieved in 99% of uses (1). In this issue of *JACC: Cardiovascular Interventions*, Vidi et al. (2) report a 93.9% success rate with the suture-based device as reported in a Massachusetts Department of Health registry. Interestingly, although modifications were made to the extravascular collagen plug device to enhance its effectiveness, observations from 2 meta-analyses of clinical outcomes with VCDs in 2004 indicated an increased risk of vascular complications with the device compared with manual compression and ultimately led to the withdrawal of this product from the marketplace (3,4).

The consequences of closure device failure would seem self-evident, particularly in the percutaneous coronary intervention (PCI) patient. However, the extent and severity of associated bleeding or other vascular complications is potentially affected by many variables, including the size of the arteriotomy as well as the presence and extent of anticoagulation. In a patient who has undergone simple diagnostic cardiac catheterization with a small caliber sheath, failure to achieve immediate hemostasis with a VCD is treated with manual compression, often leading to successful hemostasis and minimal bleeding or other vascular complications. However, in the setting of PCI where a VCD is placed at the end of the procedure in a patient still effectively anticoagulated, the potential extent and severity of bleeding and/or other vascular complications are expected to be much higher. Despite these presumptions, there are only limited data that evaluate issues relevant to VCD failure.

Vidi et al. also evaluated the frequency and predictors of VCD deployment failure as well as bleeding and vascular complications observed in these patients from 23,813 consecutive interventional coronary procedures as identified from a dataset from the Massachusetts Department of Health (2). Between June 2005 and December 2007, there were 18,533 collagen plug VCDs, 2,996 suture-based VCDs, and 2,284 nitinol clip-based VCDs used for femoral artery hemostasis after PCI. Overall, VCD failure occurred in 3.3% of procedures with failure rates of 2.1% with collagen-based VCD, 6.1% with suture-based VCD, and 9.5% with nitinol clip-based VCD. As expected, VCD failures were associated with an increased risk of vascular complications compared with those in whom the VCD was successfully deployed for all types of vascular complications assessed. In a subsequent subgroup analysis using a propensity score–adjusted evaluation, the authors evaluated the relative likelihood of VCD failure and observed a 2-fold increased risk with the nitinol clip-based VCD and 1.25-fold increased risk with a suture-based VCD compared with the collagen plug-based device. Interestingly VCD failure was a significant predictor of vascular complications for the collagen plug-based VCD as well as the nitinol clip-based VCD but not for the suture-based VCD.

*Editorials published in *JACC: Cardiovascular Interventions* reflect the views of the authors and do not necessarily represent the views of *JACC: Cardiovascular Interventions* or the American College of Cardiology.

From the Wake Forest School of Medicine, Winston-Salem, North Carolina. Dr. Applegate has received research grants from Abbott Vascular, St. Jude Medical, Terumo Corporation and honoraria from Abbott Vascular; has served on the consultant/advisory board for Abbott Vascular; and served as consultant for St. Jude Medical and Terumo Corporation.

JACC: CARDIOVASCULAR INTERVENTIONS, VOL. 5, NO. 8, 2012
AUGUST 2012:845–7

There are a few aspects of this study that merit further discussion. The observations from this analysis provide a contemporary standard for the frequency of VCD failure and its association with vascular complications. As acknowledged by the authors, VCD failure is uncommon but is associated with a significant increase in the incidence of a vascular complication. There also seems to be variability in the likelihood that a vascular complication will occur after VCD failure, depending on the type of VCD used. Despite a significantly lower rate of VCD failure, the collagen plug-based VCD was associated with a statistically higher rate of any vascular complication than either the nitinol clip-based or suture-based VCD (2.1% vs. 6.1% and 9.5% respectively, $p < 0.001$), due primarily to a statistically higher rate of major vascular complications.

This apparent dissociation between a very low rate of device failure and a higher rate of overall vascular complication is unexpected. The reason(s) for this apparent dichotomy are not readily apparent. There are clear differences in the number of patients treated with the different devices (80% collagen plug-based VCD) as well as baseline clinical characteristics. Although the authors appropriately applied propensity score matching methodology to adjust for these differences, the ultimate impact of these potential biases remains unclear. Another source of difference might have occurred with the study definition of complications. The authors hypothesized that vascular complications might have been lower with the suture-based VCD, because a bailout strategy exists for this device—where an additional device could be deployed or a sheath reinserted—but not for the other 2 devices. Although this is plausible, we would need to know how often this occurred and whether this strategy "counted" as a vascular complication. Finally, there is an association between a "high femoral artery stick" and use of a VCD after PCI, resulting in an increased incidence of vascular complications (5). The extent to which this occurred and with which device might have also influenced the study outcomes. However, there are no data available to address this issue.

The observation of the authors naturally leads one to compare the "superiority" of 1 VCD with another. There has been long-standing interest in the efficacy and safety of VCDs compared with manual compression as well as whether 1 particular VCD is safer and associated with lower vascular complications than another. With respect to the issue of the safety of VCDS compared with manual compression, a number of small randomized trials have been performed, and multiple large registries have been published showing a consistent decrease in the association of vascular complications with VCDs compared with manual compression. Biancari et al. (6) incorporated some of these more recent randomized clinical trials in a meta-analysis and were not able to demonstrate increased safety with VCDs compared with manual compression, despite modifications in the closure devices leading to decreased rates of device failure at the time of implantation. These data and the absence of the definitive large randomized clinical trial led to a Class III indication for VCD use to decrease bleeding after a coronary intervention, no benefit, in the most recent 2011 American Heart Association/American College of Cardiology/Society for Cardiovascular Angiography and Interventions PCI guidelines update (7). In these same guidelines, no recommendation was made as to device-specific safety, and it has been the type of study by Vidi et al. in this issue that have shaped interventionalist perception of device-specific safety.

What should we take away from this study? First, VCD failure rates are lower than for the original version of each of the devices. However, failure rates of almost 10%, as observed with the nitinol clip-based device, would be unacceptable for any other device used during a PCI procedure. Clearly, opportunities for improvement in the safety and performance of these closure devices still remain. Second, comparison of the relative safety of these devices is problematic. The dissociation between the incidence of device failure in fully anticoagulated patients and the incidence of overall vascular complication remains unexplained and weakens the conclusions that can be drawn about the relative safety of these devices. Third, from a clinical perspective, it would have been useful to provide information on the timing of the vascular complication (i.e., at deployment or after leaving the laboratory), because this might have provided insights into the mechanism of failure. Understanding the reason for VCD failure is paramount to developing better and more effective devices. Finally, that these data are coming from an observational registry and not a randomized clinical trial underscores the strong need of appropriately powered and designed clinical trials to address the efficacy and safety of closure devices.

Reprint requests and correspondence: Dr. Robert J. Applegate, Section of Cardiology, Wake Forest School of Medicine, Medical Center Boulevard, Winston-Salem, North Carolina 27157-1045. E-mail: bapplega@wakehealth.edu.

REFERENCES

1. Applegate RJ, Turi ZG, Sachdev N, et al. The Angio-Seal evolution registry: outcomes of a novel automated Angio-Seal vascular closure device. J Invasiv Cardiol 2010;22:420–6.
2. Vidi VD, Matheny ME, Govindarajulu US, et al. Vascular closure device failure in contemporary practice. J Am Coll Cardiol Intv 2012;5:837–44.
3. Koreny M, Riedmüller E, Nikfardjam M, Siostrzonek P, Müllner M. Arterial puncture closing devices compared with standard manual compression after cardiac catheterization: systematic review and meta-analysis. JAMA 2004;291:350–7.

4. Nikolsky E, Mehran R, Halkin A, et al. Vascular complications associated with arteriotomy closure devices in patients undergoing percutaneous coronary procedures: a meta-analysis. J Am Coll Cardiol 2004;44:1200–9.
5. Tiroch KA, Arora N, Matheny ME, Liu C, Lee TC, Resnic FS. Risk predictors of reroperitoneal hemorrhage following percutaneous coronary intervention. Am J Cardiol 2008;102:1473–6.
6. Biancari F, D'Andrea V, Di Mario C, Savino G, Tiozzo V, Catania A. Meta-analysis of randomized trials on the efficacy of vascular closure devices after diagnostic angiography and angioplasty. Am Heart J 2010;159:518–31.
7. Wright RS, Anderson JL, Adams CD, et al. ACCF/AHA focused update of the guidelines for the management of patients with unstable angina/non-ST-elevation myocardial infarction (updating the 2007 guideline): a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol 2011;57:1920–59.

Key Words: PCI ■ vascular access ■ vascular complications.