Extravascular Closure Devices: Are They Advantageous?

Comparing the available data on different closure devices and pinpointing the questions yet to be answered.

BY M. NICHOLAS BURKE, MD

The Achilles' heel of femoral arterial access is, and always has been, hemostasis. Numerous technical, anatomic, and procedural aspects have been introduced (or discarded) over the years in an effort to decrease patient discomfort, time to ambulation, resource utilization, and most importantly, morbidity and mortality associated with femoral access site complications. Vascular closure devices (VCDs) have been developed in an attempt to further improve upon the "gold standard" of manual compression for achieving hemostasis. For the purpose of this article, VCDs will be defined as devices that directly interact with the arteriotomy to facilitate closure of the site, rather than devices that provide pressure or indirectly attempt to effect closure of the puncture site.

DEVICE DESIGN

The ideal VCD is one that is safe, effective, easy to use, inexpensive, and appropriate for all patients. No current device fulfills all of these criteria, and several of the very early VCDs failed to fulfill most or all of them. Most devices have utilized some form of procoagulant placed at the arteriotomy to accelerate the body's natural hemostatic mechanisms. Examples of this type of VCD that are currently available in the United States include Angio-Seal (St. Jude Medical, Inc.), Mynx (AccessClosure, Inc.), Exoseal (Cordis Corporation), and Catalyst (Cardiva Medical, Inc.). Other devices have utilized a more mechanical approach to hemostasis, including Perclose ProGlide (Abbott Vascular), which closes the arteriotomy with a suture, and StarClose SE (Abbott Vascular), in which a clip is deployed directly on the exterior surface of the artery to close the access site. VCD devices have used various mechanisms to locate the arteriotomy site for appropriate device/procoagulant deployment, including visual markers, distance measuring, and anchors deployed on the luminal side of the arteriotomy (both retractable and left in place/resorbable).

A concern of VCD design is whether there is a significant effect upon the vessel's luminal surface. Do VCDs that disrupt or change the endothelial surface, so-called intravascular closure devices (IVCDs), with sutures such as Perclose ProGlide or with a resorbable anchor (as with Angio-Seal) lead to an increase in complications? Is it better to leave nothing permanent on the luminal surface, as with extravascular closure devices (EVCDs)? This question is perhaps even more germane for patients in whom the vessel size is smaller than average, such as women, smaller patients, and patients with lower extremity peripheral vascular disease. An additional question is whether the use of procoagulants on the exterior of the artery could potentially result in inflammatory changes severe enough to cause long-term problems.

DATA REVIEW

Many studies have documented the clinical variables associated with an increased risk for vascular complications, including bleeding. Factors known to be predictive of complications include age, female sex, smaller body size, history of congestive heart failure, chronic obstructive pulmonary disease, emergent procedure, shock, severity of coronary artery disease, renal insufficiency, use of anticoagulants or antiplatelet agents, and lower extremity peripheral vascular disease.[1] No VCDs have

TABLE 1. INCIDENCE OF BLEEDING AND VASCULAR COMPLICATIONS ACCORDING TO METHOD OF HEMOSTASIS COMPARED TO MANUAL COMPRESSION*

Hemostasis Strategy	Bleeding Complications	Vascular Complications	Either Type of Complication
Mechanical compression	Increased	Increased	Increased
AngioSeal	Decreased	Decreased	Decreased
Perclose ProGlide	Decreased	Decreased	Decreased
StarClose SE	No effect	Decreased	Decreased
Boomerang	No effect	Decreased	Decreased
Mynx	Increased	Decreased	No effect
Patches	No effect	Decreased	Decreased

**Modified from Tavris et al.*[2]

been studied specifically in these particular patient populations, except those who are anticoagulated or treated with platelet inhibition.

One of the major issues surrounding the use of VCDs has been the paucity of high-quality studies assessing their safety, efficacy, and comparability. Most studies have been relatively small, have inconsistent endpoints, and are often compared to historical controls. Very few studies are available that compare any devices in a head-to-head fashion, and new devices or new iterations are approved without demonstrable improved outcomes compared to their predecessors or other devices. Tavris et al reviewed the CathPCI registry data from 2005 to 2009 and reported outcomes of several types of closure devices compared to a manual compression control (Table 1).[2] Also included in the analysis was the use of mechanical compression devices, as well as superficial patches designed to accelerate coagulation and thus hemostasis. There were sufficient data to evaluate the use of Angio-Seal, Perclose ProGlide, StarClose SE, Boomerang closure wire (Cardiva Medical), and Mynx, and their effects upon bleeding rates and vascular complications were reported. Angio-Seal and Perclose ProGlide were associated with a decreased risk of both bleeding and vascular complications. StarClose SE and Boomerang had no effect on bleeding but were associated with a decreased risk of vascular complications. Mynx was associated with a decrease in vascular complications but an increase in bleeding risk. This study was published in 2012 and did not include newer VCDs, such as Exoseal and Catalyst. Furthermore, Cardiva Medical is no longer selling the Boomerang closure wire.

One trial did compare two different VCDs.[3] Shammas et al randomized patients undergoing angiography alone or with PCI to either treatment with Angio-Seal or with VasoSeal (Datascope Corporation). In this small study, there were no differences in effectiveness (as measured by time to hemostasis and ambulation) or in the incidence of significant vascular complications. Interestingly, Datascope eventually withdrew VasoSeal from the market because of an increase in reported complications.

There are very limited data available on the long-term effects of VCDs. There is some concern that IVCDs might alter the anatomy and physiology of the vessel enough to result in luminal impingement over time. The study by Shammas et al did compare an IVCD (Angio-Seal) with an EVCD (VasoSeal), but the follow-up was only 1 month, so no long-term conclusions could be drawn. Furthermore, despite being an EVCD, the ultimate problem with VasoSeal was in its design. VasoSeal employed a removable balloon to tamponade the arteriotomy internally, and purified bovine collagen was then advanced onto the arteriotomy. Unfortunately, over time, it was found that the procoagulant could inadvertently enter the arterial lumen causing intra-arterial thrombus formation.

Lee et al prospectively studied 265 patients receiving either Perclose ProGlide or Angio-Seal and reported long-term results with a mean follow-up of 3,320 ± 628 days.[4] Clinical evaluation, ankle-brachial indexes, and duplex ultrasound of the femoral arteries (using the nonaccessed side as control) were performed. Follow-up was incomplete (145 patients). Two patients (0.8%) developed symptoms of claudication, neither of which were determined to be related to access site issues. Ankle-brachial indexes and ultrasound measurements in the accessed artery were not worse than those obtained in the nonaccessed control artery. In fact, arterial diameters on the accessed side (right) were larger than on the nonaccessed side (left), consistent with the fact that the right common femoral artery is known to be larger than the left. It was noted that the arterial diameters of the accessed side were significantly larger in the group who received Perclose ProGlide compared to the group

receiving Angio-Seal. Doppler velocities, however, tended to be slightly higher in the Perclose ProGlide group.

The most recent VCD study reported is the ISAR-Closure trial, which was presented at TCT in September 2014. This trial randomized patients undergoing transfemoral coronary angiography to manual compression or one of two VSDs in a 1:1:1 fashion. The devices used were FemoSeal (St. Jude Medical, Inc.), an IVCD utilizing a biodegradable polymer disc for direct mechanical hemostasis (not available in the United States), versus the ExoSeal. The study found that these two VCDs were noninferior to manual compression in terms of complication rates. However, FemoSeal appeared to have a lower rate of complications in comparison to ExoSeal.

SUMMARY

It is tempting to speculate that perhaps patients with small or significantly diseased arteries might have improved outcomes with EVCDs as opposed to IVCDs; however, there are no solid data to support or refute this. Virtually all studies of VCDs specifically exclude patients with small or diseased vessels. For this reason, most interventionists tend to avoid using VCDs in these patients.

The question as to whether, in general, EVCDs might have some advantage over IVCDs is unresolved. The analysis by Tavris et al is now dated, but it is still the best available data. In it, both IVCDs and EVCDs decreased the incidence of vascular complications when compared with manual compression. The IVDCs (Perclose ProGlide and Angio-Seal) actually outperformed the EVCDs in terms of bleeding. Further, the FemoSeal IVCD preliminarily appears to have a lower complication rate than the ExoSeal EVCD. It does appear that VCDs for appropriately chosen patients may actually decrease the risk of vascular complications compared with manual compression. As always, larger studies with longer follow-up are needed before any conclusions can be made. ■

M. Nicholas Burke, MD, is Director, CV Emergency Programs; and Director, CTO Program, Minneapolis Heart Institute in Minneapolis, Minnesota. He stated that he has no financial interests related to this article. Dr. Burke may be reached at (612) 863-3900; mnicholas.burke@allina.com.

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