Should vascular closure devices be the method of choice for closing percutaneous coronary intervention patients?

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Keywords: hemostasis • percutaneous coronary intervention • vascular closure devices

Vascular access site complications are an infrequent but persistent complication following cardiac catheterization and percutaneous coronary intervention (PCI). These complications can lead to significant morbidity and mortality with an associated increase in healthcare costs. The use of radial artery access is effective in decreasing vascular site complications. However, a transfemoral approach is still utilized in the majority of patients undergoing cardiac catheterization and coronary intervention. Rates of vascular access site complications and bleeding rates have improved temporally, with the current rate of access site-related bleeding complications following PCI at approximately 2% [1–3]. While more contemporary anticoagulation strategies may account for some of this improvement, the increased use of vascular closure devices (VCDs) likely also plays a role.

Since introduction in the early 1990s VCDs have become an increasingly common alternative to manual compression as a means of achieving access site hemostasis. While digital compression remains the 'gold standard', other manual compression strategies include devices with both clamp-based and pneumatic compression systems. Distinct from these compression-based strategies, multiple different VCDs have been developed with significant heterogeneity among devices with rapid technological evolution and advancement. These devices typically employ sutures, clips or plugs to achieve arterial hemostasis. Currently available and frequently used devices include the PercloseProGlide (Abbott Vascular, CA, USA) suture-mediated closure system, the StarClose (Abbott Vascular) extravascular nitinol-clip closure system, the Angio-Seal (St Jude Medical, MN, USA) bioabsorbable collagen-plug closure system and the Mynx (AccessClosure) polyethylene glycol-based sealant system. The exact details and specifications of these individual platforms are discussed elsewhere [4,5].

VCDs are typically utilized to provide the benefit of reduced duration of bed rest and arterial compression. Other benefits include improved patient comfort, satisfaction and convenience while affording increased staff availability. VCD use is also expanding as larger caliber arterial access for structural interventions becomes more common, with suture-based preclosure playing an integral role in access management for transcatheter aortic valve replacement [6].

Current guidelines, however, continue to emphasize the use of VCDs primarily for patient comfort and convenience. A 2010 AHA Scientific Statement on the use of arteriotomy closure devices, as well as a 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention, both recommend the use of VCDs to achieve more rapid hemostasis and ambulation following transfemoral arterial access after accounting for patient body habitus, arteriotomy location, sheath size and presence of systemic disease (Class IIa, level of evidence [LOE]: B), but not for the purposes of decreasing vascular complications, including bleeding (Class III, LOE: B) [7,8].

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The data regarding the efficacy of these devices are extensive, but also widely varied, and concerns remain concerning their safety and ability to decrease complications. Some earlier reports, including meta-analyses, have suggested increased rates of vascular complications with the use of certain VCDs in some subsets of patients, including increased rates of hematoma and pseudoaneurysm formation, infection and limb ischemia [9–12]. However, other authors have shown reduced rates of vascular access site complications through the use of VCDs [13–15], even in higher risk settings, such as acute coronary syndromes [16]. Previous reports demonstrating worse outcomes with VCDs were weighted by use of devices that are no longer in use and there are limited randomized data on the safety and efficacy of contemporary VCDs. A recently published report from over 85,000 patients undergoing emergent and nonemergent PCIs from the Blue Cross Blue Shield of Michigan Cardiovascular Consortium highlights the importance of patient selection on the use of VCDs, showing a significant reduction in vascular complications and transfusion requirements with VCD use in obese and overweight patients that was not seen in patients with a BMI <25 kg/m^2 or those treated with GP IIb/IIIa inhibitors [17].

As a means of reducing bleeding complications in high-risk patients, other strategies, such as preferentially utilizing smaller French sheath sizes, transradial arterial access or bivalirudin for periprocedure anticoagulation, may all be beneficial [18,19]. When transfemoral access is used during PCI, combining a lower risk anticoagulation strategy with a VCD may further incrementally decrease the risk of bleeding complications [16].

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From a practical perspective, we would advocate for VCD usage following transfemoral PCI in settings where there is concern regarding patient comfort or when manual compression may not provide adequate hemostasis. These situations include, but are not limited to certain populations of obese patients or when larger caliber sheaths are used. This should be weighed against the operator's comfort level with the available VCD, as well as favorable iliofemoral anatomy. Prior to deployment of a VCD, eligible patients should undergo femoral angiography (ACCF/AHA/SCAI Class I recommendation, LOE: C) to identify the arteriotomy location relative to the inguinal ligament and femoral bifurcation, as well as to exclude significant femoral arterial disease, which may increase the risk of VCD-related complications [8,20].

At our institution, manual compression remains the closure method of choice, but is often operator dependent. However, closure devices are used frequently in situations of suitable femoral anatomy in patients perceived to be at increased risk of femoral access site bleeding complications. Individual device utilization varies among providers depending on personal preferences and experience levels. For those with ongoing coagulopathy or significant bleeding risk, we preferentially utilize the radial artery for access during PCI, with the femoral artery reserved for anatomic restrictions or when technical considerations (e.g., larger sheath sizes or the need for mechanical support) require. When large caliber femoral arterial access is utilized for structural interventions such as transcatheter aortic valve replacement, we preferentially utilize preclosure of the arteriotomy with a suture-based closure device.

In conclusion, VCDs have become increasingly common as a means for closing transfemoral arterial access after diagnostic cardiac catheterization and PCI, both for patient comfort and convenience, as well as for decreased complication rates in some patient populations. We recommend the use of VCDs in those with favorable femoral anatomy and risk profile who may be at increased risk of access site complication following PCI, although further efforts towards better delineating which patient subsets are most likely to benefit from the use of VCDs are warranted. As always, knowledge of the various types of complications associated with each strategy should play a key role in determining the appropriate closure method for each patient.

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