Vascular closure devices (VCDs) status post femoral artery puncture are underutilized in the most benefitting population. The advantages of VCDs go beyond improved satisfaction and convenience for patients and staff, which are not insignificant benefits themselves.\(^1\) However, for the right patients the benefits include reduction in significant complications. The key to realizing these net benefits is using them in the highest risk patients.

It is true that the overall complication rate of percutaneous coronary intervention (PCI) has decreased in recent years with the advent of newer techniques and technology. Bleeding rate improvements have come in part from use of smaller catheters, less intense anticoagulation, avoidance of GPIIb/IIIa inhibitors, and transradial approach. Major femoral bleeding decreased from 8.4% (1994-1995) to 5.3% (1996-1999) to 3.5% (2000-2005).\(^2\) However, despite these improvements, bleeding complications remain a significant issue in the transfemoral approach. Adverse outcomes of major femoral bleeding include prolonged hospital stay (4.5 days vs 2.7 days), increased need for transfusion (39% vs 4.7%), and a statistically significant decrease in 30-day and long-term survival.\(^2\) Still taking into consideration the increased complication rate with failure of deployment of a VCD, the incidence of failure is low and the net impact remains positive. Moreover, when citing bleeding rates across different studies, it is extremely important to be familiar with the commonly used definitions, which are varied, and the shortcomings of each. One bleeding risk model used in the CathPCI registry was developed by Mehta et al and is described in Table 1 and Figure 1.\(^3\)

Previous data did not show benefit or as robust a benefit as is likely present because VCDs were not used in the highest risk population often enough. In another study from the CathPCI registry, Marso et al showed

---

**Table 1**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Points Assigned</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACS type</td>
<td>10</td>
</tr>
<tr>
<td>ST-elevation MI</td>
<td>8</td>
</tr>
<tr>
<td>Non-ST-elevation MI/unstable arthralgia</td>
<td>6</td>
</tr>
<tr>
<td>Cardiogenic shock</td>
<td>5</td>
</tr>
<tr>
<td>Female gender</td>
<td>4</td>
</tr>
<tr>
<td>Age, y</td>
<td>2</td>
</tr>
<tr>
<td>Diabetes</td>
<td>2</td>
</tr>
<tr>
<td>NYHA class IV CHF</td>
<td>2</td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td>1</td>
</tr>
<tr>
<td>Estimated glomerular filtration rate (per 10 unit decrease if &lt;90)</td>
<td>1</td>
</tr>
</tbody>
</table>

CHF indicates congestive heart failure; NYHA, New York Heart Association.
bleeding reduction was statistically significant with the use of VCDs in high-risk patients (Table 2).4

This registry includes approximately 1.5 million patients from 955 centers. Bleeding in manual compression of high bleeding risk patients was 6.1% as compared to 4.6% with VCDs, 3.8% when bivalirudin was used, and 2.3% when both bivalirudin and VCDs were used.4 Paradoxically in the high-risk bleeding patients, combined bivalirudin and VCDs were used least often (14.4%) and manual compression was used most often (40.3%).3 Mechanical circulatory support device use has a higher rate of bleeding: in one recent study, aortic balloon pump use had an incidence of severe bleeding at 11.4%.5 This is at least due in part to the larger size catheter necessary for insertion. The intra-aortic balloon pump uses an 8 Fr catheter and the Impella 2.5 uses a 13 Fr catheter.6,7 A large prospective study showed vascular complication rate was significantly lower with closure device use compared with manual compression. Benefit was seen in both diagnostic angiography (0.5% vs 1.1%, P=.01) and PCI (2.4% vs 4.9%, P<.001) groups.8 In this study VCD use was associated with a 58% (95% CI 19%-88%) reduction in the risk of vascular complications in diagnostic procedures catheterization and a 42% (95% CI 17%-59%) reduction in PCI patients.8

A large single-center study evaluating 7,718 consecutive patients who underwent PCI via femoral access from 2003 to 2009 for whom 1-year follow-up was available showed multiple findings supporting the use of VCDs in PCI patients. The main findings were that post-procedure vascular complications without severe blood loss did not increase 1 year mortality.5 However,
regardless of the magnitude of hematocrit decrease, transfusion was associated with an increase in 1-year mortality. Therefore, efforts to reduce significant bleeding with VCDs will yield benefits in the right patient. Vascular closure devices had a statistically significant lower incidence of transfusions in a large observational cohort study including 32 hospitals in Michigan with 85,048 PCI patients. Bleeding, vascular perforation, or laceration requiring surgical repair did reduce 1-year survival. Age, female gender, higher levels of intraprocedural anticoagulation, and the use of glycoprotein IIb/IIIa inhibitors were strongly associated with increased risk for postprocedural severe hematocrit decrease. Confirming previous findings the use of bivalirudin rather than heparin and the use of closure devices were independently associated with reduced risk for severe bleeding.

Larger dedicated randomized control trials are under way, including the ISAR–CLOSURE trial randomizing approximately 4,500 femoral artery puncture patients to 3 arms: manual compression and two separate types of closure devices. This study is expected to give further insight into the use of VCDs in the contemporary practice of interventional cardiology. Like most decisions in medicine patient selection is paramount for ensuring the best patient outcomes, and in these appropriate high-risk patients, vascular closure devices should be used.

Editor’s Note: Disclosure: The authors have completed and returned the ICMJE Form for Disclosure of Potential Conflicts of Interest. The authors report no financial relationships or conflicts of interest regarding the content herein.

REFERENCES
Minimizing Femoral Access Complications: Vascular Closure Devices Are Not Routinely Needed

Ehrin J. Armstrong, MD, MSc
From University of Colorado School of Medicine and Denver VA Medical Center, Denver, Colorado.

Vascular closure devices (VCD) are frequently used to achieve hemostasis in patients undergoing percutaneous coronary or peripheral arterial intervention. Potential benefits of VCDs include a shorter time to ambulation and fewer staffing requirements to manage hemostasis after femoral arterial sheath removal. However, no definitive data support the use of VCDs specifically to decrease vascular access complications. Consistent with this, current society guidelines provide a class IIa recommendation for use of VCD to decrease the duration of bed rest, but a class III recommendation for use of VCD to reduce vascular access complications.1

WHAT DO THE DATA SAY?

The data are mixed on the outcomes of VCD use among patients undergoing PCI. Initial observational studies suggested an increased risk of bleeding complications with VCD, including an increased risk of retroperitoneal hematoma.2,3 In contrast, more recent observational studies have suggested decreased rates of bleeding among patients treated with VCDs compared to manual compression. In one of the largest analyses, the NCDR registry reported a decreased rate of vascular complications among patients treated with VCDs after PCI, with the greatest benefit apparent among patients treated with both bivalirudin and a VCD.4 While these data are encouraging, they are limited by the inclusion of multiple devices, the inherent biases of observational studies, and a lack of rigorously adjudicated endpoints. In addition, VCD failure is associated with an almost 5-fold risk of bleeding complications.5 For these reasons, meticulous attention should be paid to the initial arterial access, which is likely a larger determinant of outcomes than the use of a VCD vs manual compression at the conclusion of the procedure.

TECHNIQUES TO MINIMIZE COMPICATIONS OF FEMORAL ARTERIAL ACCESS

With current techniques, the major determinants of an access site complication are related to the technical aspects of obtaining femoral arterial access. Three major techniques can be used to reduce femoral arterial access complications: fluoroscopic landmarks, ultrasound guidance, and micropuncture needle access.

Fluoroscopic landmarks provide a reference for the location of the femoral head, thereby identifying a compressible site for hemostasis. Multiple studies have shown that the inguinal crease does not reliably identify the femoral head; this is especially true in obese patients.6 By using fluoroscopic landmarks, the needle access site can be reliably directed to the mid-femoral head, thereby also increasing the chances of common femoral artery cannulation. Use of fluoroscopic guidance has been associated with a decreased incidence of pseudoaneurysm and any arterial injury, but not overall
bleeding, in a cohort of unselected patients. Fluoroscopic guidance may have an additional benefit among women, where use of fluoroscopy was associated with significantly lower rates of vascular complications.

Ultrasound-guided access can provide direct visualization of the common femoral artery and location of the profunda femoris/superficial femoral artery bifurcation. It also has the advantage of localizing calcium or other atherosclerotic disease, so that the access site can be optimized for a given vessel. The FAUST study was a multicenter randomized trial that compared fluoroscopic vs. ultrasound guided femoral access. The overall study found no significant difference in rates of common femoral artery cannulation, although patients with a high bifurcation were more likely to have successful common femoral artery cannulation with ultrasound guidance (83% vs 70%). Vascular complications were also significantly lower in the ultrasound-guided group (1.4% vs 3.4%, P=.04). These results suggest that ultrasound-guided access has significant advantages in optimizing the results of femoral arterial access, even when compared to standard fluoroscopic guidance.

Micropuncture access with a 21-gauge needle and an .018" wire is also frequently used to minimize vascular complications. An advantage of this technique includes minimal trauma to the vessel in the case of multiple arteriotomies. When using a micropuncture technique, it is imperative to visualize the wire under fluoroscopy prior to sheath insertion, because inadvertent cannulation of the circumflex branch of the femoral artery can lead to vessel perforation. The data supporting micropuncture use are based on observational studies that showed no benefit and a possible increased risk of retroperitoneal bleeding. Despite the lack of definitive data in support of micropuncture access, a combined technique using ultrasound and micropuncture may provide optimal outcomes of femoral arterial access. Further clinical trials are necessary to evaluate the advantages of this combined technique.

WHEN TO USE A VASCULAR CLOSURE DEVICE

Although meticulous attention to femoral access is the best determinant of outcomes regardless of closure technique, a number of situations may warrant specific use of a closure device. The increasing development of percutaneous large sheath procedures including transcatheter aortic valve replacement and endovascular aortic aneurysm repair has necessitated novel approaches to vascular closure, as manual closure typically is not feasible for larger sheath sizes. Suture-mediated devices including the preclose technique may offer significant advantages for these applications. Even in these cases, however, fluoroscopic and ultrasound-guided access offer additional advantages of optimizing the access site.

Editor’s Note: Disclosure: The author has completed and returned the ICMJE Form for Disclosure of Potential Conflicts of Interest. The author reports no financial relationships or conflicts of interest regarding the content herein.

REFERENCES


