Access and Hemostasis: Femoral and Popliteal Approaches and Closure Devices—Why, What, When, and How?

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Abstract

Keywords

- arterial access
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This article reviews the arterial access sites used in the treatment of peripheral arterial disease, including common femoral, superficial femoral, and popliteal arterial puncture. The optimal approach and techniques for arterial puncture will be described and technical tips and tricks will be discussed. An overview of the currently available vascular closure devices will also be presented. Indications, contraindications, and complications will be discussed. Results of the use of vascular closure devices compared with manual compression will be presented.

Objectives: Upon completion of this article, the reader will be able to identify the options for arterial access as well as the role of currently available arterial closure devices.

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Percutaneous endovascular procedures play an increasing role in the management of peripheral arterial disease (PAD). The versatility of endovascular techniques permits treatment from the aorta to the pedal vessels via a small sheath. Compared with conventional vascular surgery, percutaneous procedures have a lower morbidity and mortality, high patient acceptability, more rapid recovery, and shorter hospital stay.

Percutaneous procedures are not free from complications; those related to the access site typically occur at the time of

puncture or during hemostasis, and as much care is needed at these stages as during more technically challenging phases of the procedure. Hemorrhage following sheath removal is the most serious complication. Other complications include false aneurysm, arteriovenous fistula, occlusion, infection, and nerve damage. A complication is considered major when at least one of the following adjunctive treatments is required: blood transfusion, vascular repair by surgical or nonsurgical techniques, antibiotic administration, treatment for ischemia, and surgical repair of nerve injury.¹

Arterial Access

The common femoral artery (CFA) is the most common access site since it is relatively large, superficial, fixed, and courses over the femoral head in 92% of cases;² in addition, in 99% of patients the bifurcation of the CFA is below the level of the mid-femoral head.^{2,3} This relationship to bone allows easy manual arterial compression (MC), thus reducing the risk of prolonged bleeding after removal of the catheter or sheath.^{3,4}

Other less frequently used access sites include the popliteal artery and superficial femoral artery. These can be helpful particularly in cases such as marked obesity where CFA access would be difficult, or in patients where CFA access is contraindicated, such as recent surgery. Pedal artery access is discussed

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elsewhere in this *Seminars* issue (Manzi and Palena), and arm access is very rarely needed in routine management of PAD.

All of the current commercially available vascular closure devices (VCDs) have been designed to be deployed at the level of the CFA after retrograde puncture. Most instructions for use (IFU) report an explicit warning against their deployment in other situations, and this has important implications for patient consent if the device is to be used “off label” (e.g., for an antegrade puncture). Correct femoral puncture is therefore critical in reducing the risk of access site complications and maximizing suitability for VCD deployment.

Choice of Approach

The approach to an individual case should be decided in advance based on imaging, treatment planned, patient body habitus, and personal preference. Treatment of infrainguinal disease is usually performed from contralateral retrograde or ipsilateral antegrade CFA access. Superficial femoral and popliteal artery access are much less frequently used, each of these techniques has advantages and disadvantages (►Table 1), and every operator performing endovascular treatment of PAD should master all of these approaches and techniques for guiding puncture (►Table 2).

Guidance for Arterial Puncture

There are three different techniques that can be used to guide puncture. The ideal approach involves a single needle pass into the target artery at the desired point avoiding branch vessels or diseased segments. In practice, most retrograde CFA punctures are performed based on the point of maximum pulsation. Imaging guidance is mandatory in the SFA and popliteal arteries, and operators should have a low threshold for using imaging guidance in the CFA.

Ultrasound-Guided Puncture

This technique permits direct visualization of the artery and its branches as well as any underlying disease. The optimal point of puncture can be chosen to avoid plaque in the

artery, and as the needle is visualized this ensures single wall puncture. Ultrasound (US)-guided puncture is excellent when the femoral pulse is impalpable. In the presence of obesity, a high femoral bifurcation, heavily diseased CFA, or a hostile groin, direct US-guided SFA puncture has been advocated.⁵

Puncture Using Anatomical Landmarks

The point of maximum pulsation correlates with the midpoint of the CFA in 92.7% of cases.⁶ When the pulse is difficult to palpate, the midpoint between the anterior superior iliac spine and pubic tubercle by palpation can be used⁶. The groin crease is an unreliable marker and is located distal to CFA bifurcation in about three out of four patients.^{7,8}

Fluoroscopy-Guided Puncture

One should aim roughly at the bottom of the upper inner quadrant of the femoral head in an anterior-posterior projection. Vascular calcification can also provide a target.

Evidence for Using Guidance

Four randomized trials have demonstrated a lower risk of complications for fluoroscopic-assisted puncture compared with using the inguinal skin crease for retrograde CFA catheterization.^{9–12} These trials were conducted in the setting of coronary intervention, and lack of a femoral pulse was an exclusion criterion. Absence of an appreciable femoral pulse is frequent in PAD patients (especially when retrograde femoral puncture is performed for iliac disease) and in obese patients. Fluoroscopic guidance increases the likelihood of an ideal access site (87–94%), maximizing the possibility of using VCDs.^{9–12} Furthermore, the use of fluoroscopy reduces the incidence of pseudoaneurysm formation, any arterial injury, and a reduction of the length of hospital stay.¹³

Outcomes of real-time US-guided puncture for retrograde CFA catheterization have been investigated in three randomized trials.^{14–16} Compared with fluoroscopy, US assistance achieves a similar success rate of optimal CFA cannulation (86–100%) but is associated with fewer attempts and with a lower incidence of inadvertent venipunctures and hematomas. Patients with a high femoral bifurcation benefit most from this approach.

Unless US guidance has been used, angiographic assessment of the CFA (20-degree ipsilateral anterior oblique) is recommended following access but before use of a VCD.¹⁷ Ideally, angiography should be performed immediately after puncture as early diagnosis of a suboptimal access site allows re-access before insertion of a large sheath.

Arterial Approach

CFA Access

Retrograde and antegrade CFA punctures are both commonly used, and in each case the optimal technique is a single anterior wall puncture in the mid-CFA well above the femoral bifurcation and below the origin of the inferior epigastric artery. Femoral access beyond the anatomical boundaries of the CFA is strongly correlated with post-procedural bleeding

Table 1 Benefits and drawbacks of femoral arterial access routes

Retrograde	Antegrade
Easy	Technically demanding (spontaneous course into deep femoral artery)
Less control	Improved control (pushability, embolectomy)
Potential crossover problems (iliac tortuosity/stenosis)	Crossover avoided
Possible in obese patients	Difficult in obese patients
Freedom to maneuver ^a	Limited space to maneuver ^a
Difficult catheter exchange (fluoroscopy time) ^b	Easy catheter exchange ^b

^aIn case of treatment of infrainguinal disease without crossover.

^bIn case of treatment of infrainguinal disease with crossover.

Table 2 Access problems in PAD

Local factors	
Calcified CFA	Risk of dissection Higher failure rate of suture-mediated VCDs
Stenosed CFA	Multiple punctures (risk of venipuncture/AV fistula) Risk of CFA thrombosis with intra-arterial VCDs
Antegrade femoral access	Increased access difficulty (need of fluoro/US) Higher VCD failure rate
Popliteal artery access	Prone patient Need for US guidance
Multiple percutaneous procedures	Increased access difficulty (periarterial fibrosis)
Scarred groin	Increased access difficulty Higher VCD failure rate (sheath kinking)
Previous endovascular devices (stents, endograft)	Use of VCD not evaluated Risk of VCD failure/embolization
Previous surgical graft (aorto-femoral, fem-pop, CFA patch)	Use of VCD non tested Risk of VCD failure/graft infection
General factors	
Lumbar spine disease	Intolerance to prolonged bed rest and immobility
Mental confusion/old age	Intolerance to prolonged bed rest and immobility
Obesity	Ineffective MC, hidden bleeding
Intraprocedural heparin/fibrinolysis	Prolonged bleeding

Abbreviations: AV, arteriovenous; CFA, common femoral artery; MC, manual compression; US ultrasound; VCD, vascular closure device.

complications^{4,18–20} due to lack of a posterior support during manual compression.

Antegrade femoral access is commonly used to treat infrainguinal disease; the short working length confers maximal steerability and pushability to wires and catheters, which is particularly helpful when treating long occlusions and managing distal disease. The antegrade approach is harder to learn and perform and has been shown to be associated with more complications than retrograde access.^{21–23} A low threshold to US guidance is recommended for an antegrade approach, particularly when a single puncture is essential (e.g., thrombolysis).

Common mistakes made during CFA puncture include an excessively high puncture into the external iliac artery (EIA) and low puncture into the profunda femoris artery (PFA) or superficial femoral artery (SFA). These increase the risk of hemorrhage, false aneurysm, and arteriovenous fistula formation.^{4,18,24,25}

The EIA cannot be compressed effectively, and puncture above the inguinal ligament is the main cause of iatrogenic retroperitoneal hematoma.^{4,19} Retroperitoneal hematoma may be clinically occult until hypotension develops and, because of delayed diagnosis, becomes a life-threatening complication. More than half of these patients require blood transfusion, and have an in-hospital mortality rate of up to 10%.²⁶ Retroperitoneal hematoma is estimated to complicate 0.1 to 0.7% of CFA access procedures.²⁷

Access with a 21G micro-puncture needle instead of a 19G arterial needle has been advocated.²⁸ The theoretical benefit

of this approach is a smaller puncture hole if guidewire passage is unsuccessful or if accidental venipuncture occurs but there is no evidence that this reduces bleeding complications.

Superficial Femoral Artery Access

This is an alternative in cases where CFA puncture would be difficult or is contraindicated. The SFA is relatively mobile and is not directly compressible against bone. It is readily punctured in antegrade or retrograde fashion using US guidance, and this approach can be much simpler than CFA puncture in obese patients. Two studies comparing the bleeding rate of US-guided CFA versus SFA antegrade access found a similar safety profile for the two techniques.^{29,30}

The use of combined retrograde distal SFA and antegrade CFA access has been used to traverse chronic total SFA occlusions (CTO).³¹ This approach requires a puncture with a 15 cm long 21 G needle from the inner aspect of the thigh with the patient turned onto the ipsilateral side with the contralateral knee flexed. Ultrasound guidance can be challenging as the distal SFA /proximal popliteal artery may be difficult to visualize with the patient supine. Alternatively, either a roadmap using the proximal access or the vessel wall calcifications can be used for fluoroscopic guidance.³¹

Popliteal Artery Access

Direct popliteal artery access was introduced as an alternative treatment strategy in the treatment of CTO in combination with antegrade CFA puncture. The popliteal artery is punctured with the patient prone. Once the occlusion has been

traversed the patient is usually turned supine. Retrograde popliteal and distal SFA approaches are reserved for patients where conventional femoral access has been unsuccessful^{32,33} The combined approach to CTO is sometimes known as the “SAFARI” technique (“Sub-intimal Arterial Flossing with Antegrade-Retrograde Intervention”).³⁴ The occlusion is crossed in a retrograde fashion via a 4F sheath with a larger sheath in the CFA for angioplasty/stenting.

The popliteal artery is notoriously difficult to palpate, particularly in the case of CTO. Ultrasound guidance greatly simplifies popliteal artery puncture and should be considered routine. “Blind” puncture should be strongly discouraged because of the risk of injury to sciatic and tibial nerves, which run in close proximity to the access vessel.

Ye et al described a novel fluoroscopy-guided technique for distal popliteal artery access with the patient supine. The leg is placed in a 60-degree external rotation with the knee in a gentle flexion. The puncture site is 8 to 10 cm below the border of the medial condyle of the femur and parallel with the posterior medial border of the tibia (similar to the standard surgical approach for the popliteal artery).³⁵ Ye et al achieved hemostasis by a combination of manual pressure and balloon inflation from the antegrade femoral puncture.

Hemostasis

Manual compression (MC) was the only means to achieve hemostasis after percutaneous endovascular procedures until the first hemostatic devices became available in the early 1990s.^{36,37} MC compresses the artery, preferably against the underlying bone, reducing arterial pressure and limiting extravasation and hematoma while gradual formation of a thrombus takes place.³⁸ Effective hemostasis takes a minimum of 10 minutes. MC is time consuming and can be uncomfortable for both the operator and the patient, especially when there is difficulty obtaining control or a large hematoma has developed. It is essential to be vigilant while obtaining hemostasis and to be alert to signs of hemodynamic compromise, which may represent occult bleeding. If the patient is deteriorating, one should consider placing an occlusion balloon from an alternative access site to control bleeding and stabilize the patient. When continued bleeding is suspected, vascular surgeons should be notified and one should have a low threshold for further imaging. Ultrasound is usually readily available but can be challenging in a large patient and the presence of hematoma. Contrast-enhanced computed tomography is the gold standard investigation and in patients with CFA puncture, CT should include the pelvis in case of retroperitoneal bleeding.

MC is usually followed by a period of immobilization, typically bed rest for 4 to 8 hours. Patients should be kept under close observation and instructed to avoid limb movement as much as possible to prevent rebleeding. Age > 70 years, female gender, mental confusion, small body surface area (< 1.6 m²), obesity, bleeding disorders (including chronic kidney disease), emergency procedures, large bore sheaths, and use of drugs that prolong coagulation or prevent platelet aggregation are known to reduce the efficacy of MC.^{38,39}

Vascular Closure Devices

The term VCD refers to a heterogeneous group of commercially available tools intended to replace or to reduce the duration of MC. An ideal VCD would have a better safety profile than MC and also be more effective than MC in terms of cost, duration of MC, time to achieve hemostasis, time to mobilization and discharge, and patient comfort.

VCDs are classified as active or passive devices depending on their mechanism of action. Passive VCDs such as hemostatic patches or external compression devices reduce the MC time. They rely on the formation of blood clot; so post-procedural bed rest is still required. Active devices close the arteriotomy and achieve immediate hemostasis when deployment is successful and, hence, have the potential to obviate the need for prolonged bed rest or immobilization; some authors advocate immediate patient ambulation.^{40–42}

VCDs are not normally required when using 4F or 5F sheaths. However, the use of 6 to 10F sheaths for femoropopliteal stenting, stent grafting, and thrombectomy^{43–47} means that VCDs are now increasingly used after an antegrade CFA approach.

It is beyond the scope of this article to describe the handling of all specific devices and discussion is kept to the general principles. A detailed description of individual devices can usually be found on the manufacturers Web sites.

Active VCDs

Active VCDs fall in one of three categories: plug-mediated devices, suture-mediated devices, and clip-mediated devices.^{48,49} It is essential to perform imaging of the CFA before deployment of any of these devices. Disease in the CFA may lead to the device failing to deploy (e.g., suture mediated devices in a calcified artery) or maldeployment (e.g., if the footplate of an Angioseal [St. Jude Medical, St. Paul, MN] device catches on plaque remote from the arteriotomy, the plug may deploy inside the artery).

Plug-Mediated VCDs

With these devices, a hemostatic plug is deployed in the extravascular space in contact with the arteriotomy; this mechanism limits maximum puncture size to around 8F. Plugs are made of variety of materials that swell on contact with arterial blood causing mechanical sealing of the vessel wall and tissue tract (Angio-seal collagen [St. Jude Medical]; FISH small intestinal submucosa [Morris Innovative, Bloomington, IN]; Mynx polyethylene glycol [TD Medical B.V., Eindhoven, the Netherlands]; Exoseal polyglycol acid [Cordis Johnson and Johnson, Miami, FL]). In addition, the plug material in some devices may enhance the process of clot formation.^{17,38} Angioseal utilizes an endoluminal bioabsorbable anchor, Mynx an endoluminal balloon; Exoseal and FISH do not require any endoluminal tool.

Suture-mediated VCDs

Perclose Proglide and Prostar XL (Abbott Vascular; Temacula, CA) work by driving two (Proglide) to four (Prostar) needles through the anterior wall of the femoral artery, creating a nonbiodegradable polypropylene suture without the need of

surgical exposure. The arteriotomy is closed by advancing a pre-made (Perclose) or hand-made (Prostar XL) slipknot.^{17,38} Suture-mediated devices are the most complicated to deploy but, if the sutures are deployed at the start of the procedure, they have the greatest scope for use with devices up to 18F and have allowed the development of successful completely percutaneous endovascular aneurysm repair.

Clip-Mediated VCDs

The Starclose SE (Abbott Vascular) acts by applying a disc-shaped nitinol clip to the adventitial and medial layers of the arterial wall at the level of the arteriotomy.

Novel devices designed to achieve arterial closure without the use of any foreign material are under development: local application of thermal energy to the arterial wall at the arteriotomy site (Epiclose, CardioDex, Ltd., Israel),⁵⁰ and creation of a preprocedural controlled arteriotomy with a different angle to produce a “self-sealing” arterial tissue overlap after sheath removal (Axera, Arstasis, Fremont, CA)⁵¹ are two strategies under evaluation.

Vascular Closure Device Versus Manual Closure: Evidence Update

VCDs have been introduced with the aim of enhancing the performance of endovascular procedures in terms of safety, time, and cost-effectiveness.

VCD and Patient Safety

Many studies have compared MC and VCDs, and most report a similar safety profile^{1,52,53} or a decreased rate of complications with the use of VCDs.^{54–58} Unfortunately, the findings may not be directly relevant to the management of patients with PAD in particular when the CFA itself is diseased. Vidi et al found VCD failure in 781 of 28,183 procedures (3.3%), and peripheral vascular disease was a documented risk factor for failure.⁵⁹

In a meta-analysis of 31 clinical randomized trials comparing MC with VCDs in 7,528 patients, there was a similar overall risk of adverse events. Only three of these trials included patients treated for PAD; most of the other trials excluded patients with PAD. Complications after the use of VCDs were more severe, including infection and ischemia, and their treatment was more complex and resource demanding than complications following MC.⁶⁰ It is worthwhile speculating why this might be the case. One explanation would be if VCD are being used in the highest risk cases, for example, larger sheaths, more anticoagulation and antiplatelet agents, less cooperative patients. An alternative hypothesis is that the patients are not observed as closely due to false reassurance following VCD use; hence, complications are detected at a more advanced stage. Conversely, it may simply be that VCDs cause a different spectrum of complications possibly unique to the individual devices.

Tavris et al reviewed access site complications in more than 1,800,000 percutaneous coronary intervention (PCI) procedures.⁶¹ The relative risk of access site complications was significantly reduced with the use of Angioseal (OR 0.68), Perclose (OR 0.54), Starclose (OR 0.77), and MC plus hemo-

static patches (OR 0.70). Complication rates were similar for Mynx (OR 0.91) and higher with mechanical compression devices (OR 1.15).⁶¹ Angioseal was associated with a slightly increased risk of retroperitoneal hematoma (0.4 vs. 0.2%), confirming findings from previously published series.^{26,62,63}

Kara et al⁶⁴ published results of Angioseal use in a prospectively enrolled population of 121 consecutive patients with severe PAD treated via 6F and 8F sheaths. There were two major ischemic complications (1.7%) related to the device. In one, the plug was deployed in the arterial lumen, and in the other the footplate caused a focal CFA dissection. Six (5%) patients had minor complications, mostly only requiring observation. A single false aneurysm resolved with MC only.

Data on VCDs use for closure of antegrade access are limited.^{65–73} A moderate rate of device failure with a higher rate of conversion to MC (8–12%) than in retrograde access (2.7–3.3%) has been reported.^{59,65,74} This is probably due to the steeper angle of the needle that is necessary when performing an antegrade puncture. Obese patients have a higher risk of deployment failure because of the long distance from skin to vessel, causing kinking of the device sheath.⁶⁹ In one series, unsuccessful deployment did not translate into a higher rate of major or minor vascular complications.⁷⁵

Periarterial and intra-arterial fibrosis has been described as a late complication after use of the Angioseal device. This may lead to stenosis and/or occlusion of the artery at the level of the puncture site.⁷⁶ This extensive extravascular scarring (periarterial inflammation) leading to vascular narrowing has also been observed in animal studies and can seriously complicate surgical exposure of the CFA.⁷⁷

Successful VCD Deployment

Each VCD device has its own deployment sequence, learning curve, and failure rate, and may cause device-specific complications. Tavris et al showed that complication rates with each device tend to decrease with time. Plug-mediated VCDs have the highest success rate (97.9%) compared with suture-mediated (93.1%) and clip-mediated (90.5%) devices.⁵⁹ This may in part be related to the short learning curve of plug-mediated devices.

The Cardiovascular and Interventional Radiology Society of Europe (CIRSE) multicenter prospective registry reported outcomes with Angioseal on 1,107 diagnostic or therapeutic peripheral procedures via retrograde and antegrade CFA access. Deployment success was 97.2%, with a 1.2% rate of major vascular complications.⁶⁵ Given the fact that no uniform inclusion–exclusion criteria were given to the participating centers, this probably represents results that can be extrapolated to a real-world scenario.

Savings Associated with VCDs

There is a cost associated with the use of a VCD, which needs to be offset by benefits in safety or savings in staff time or duration of patient stay. This issue has not been thoroughly investigated, and in an increasingly cost-conscious healthcare environment should be the target for future research designed to demonstrate genuine savings.

VCD Special Considerations

VCDs have not been evaluated in patients with previous surgical or endovascular procedures (hostile groins). These may result in scarring of the groin that may affect the ability to use VCDs. In addition, the presence of prosthetic aorto-femoral bypass, prosthetic femoro-popliteal bypass, prosthetic femoral patch, covered stent grafts of the external iliac arteries, or stenting of the origin of the SFA extending into the CFA may limit the use of VCDs.

If a closure device is being considered in close proximity to a stent, an extravascular VCD (Mynx, Exoseal, and Starclose) is probably safest to use to minimize the risk of a vessel locator getting entangled in the stent struts.^{78–80}

Outside the CFA

Use of VCD outside of the CFA is “off label,” and should be discussed with the patient. The use of active VCDs for closure of popliteal or brachial access has been anecdotally reported, although only with entirely extravascular devices because of the small size (< 5 mm) of these arteries.^{81,82} Two papers comparing closure devices for SFA and CFA antegrade access reported a similarly high rate of technical success with no major complications.^{72,75} Good results were achieved with both intra-luminal and entirely extra-luminal devices.

Conclusion

Although percutaneous endovascular treatment is an ideal treatment option for patients with PAD, acute periprocedural complications may occur, mainly related to access and closure of the arterial bed. Being familiar with different access options, their specific indications, and knowing how to perform US-guided or fluoroscopic-guided puncture is particularly important to increase access accuracy and prevent post-procedural complications. In-depth knowledge of the mechanism of action, deployment sequence, failure rate, and specific complications of the adopted VCD are basic requisites for their correct use.

Several potential problems contribute to a higher risk of access site complications in PAD patients. Radiologists, surgeons, and cardiologists providing endovascular treatment for PAD should be familiar with each of these issues to define the best strategy for access and closure as part of procedural planning.

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