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INVITED REVIEW

ESR Essentials: arterial vascular access and closure devices—practice recommendations by the Cardiovascular and Interventional Radiological Society of Europe

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Abstract

Vascular access is the initial, very important, step of endovascular procedures. Various access sites include the common femoral artery, brachial artery, radial artery, popliteal artery, and distal tibial vessels (pedal arteries). Successful arterial access requires advanced knowledge of anatomy, as well as proper training and experience. Today, vascular access should be obtained using real-time, ultrasound guidance to reduce access time, patient discomfort, and puncture-related complications including dissection, arteriovenous communication, and bleeding. Nevertheless, high-level evidence to support this recommendation in peripheral procedures is limited and level A data are mainly derived from randomized cardiac trials investigating only radial and femoral access. Vascular closure devices (VCDs) for femoral access can be broadly categorized as active closure devices, compression assist devices, and external/topical hemostasis devices. There is high-level evidence demonstrating that their use is related to less time for ambulation and increased patient satisfaction. However, available data failed to clearly demonstrate a benefit in complications compared to standard manual compression in peripheral endovascular arterial procedures, and thrombotic and infectious complications reported following VCD use remain an issue. Heterogeneity noted in the literature, caused by the vast variety of devices, access sites, sheath sizes, clinical scenarios, and procedures, poses difficulties in data analysis and future study design. As a result, an individualized VCD use is currently suggested for ≥ 5 Fr femoral artery access not only to reduce time to hemostasis and ambulation and to improve patient comfort, but also to reduce bleeding complications in cases of femoral access with increased bleeding risk, deranged coagulation, and large-bore access, though a high level of evidence to support this later recommendation is limited.

Key Points

- *US guidance is strongly recommended for femoral access and is mandatory to obtain more challenging access.*
- *The use of VCDs for femoral hemostasis is generally safe, effective, and currently supported by level I evidence.*
- *Proper training and correct VCD choice, based on the patient's individual characteristics, are imperative to optimize outcomes.*

Keywords Interventional radiology, Percutaneous endovascular treatment (vascular access), Peripheral arterial procedures, Ultrasound guidance, Vascular closure devices

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Key recommendations

- The importance of ultrasound guidance for vascular access procedures (class I, level B): ultrasound-guided arterial access significantly reduces complications and the level of pain and improves first-pass success rates. It should be considered as the standard approach in peripheral arterial procedures.
- Individualized adoption of VCDs for femoral artery closure post-catheterization (class I, level B): VCDs offer a safe and effective method for achieving rapid hemostasis of femoral punctures. The use of specific devices demonstrated reduced time to hemostasis, time to ambulation, and patient discomfort compared to manual compression, although complication rates remain similar. Comparative data between many different types of VCDs are insufficient to support specific recommendations and the level of evidence is different for various VCDs.
- Individualized VCD use is currently suggested for ≥ 5 Fr femoral artery access. In cases of large-bore access (> 8 Fr), and/or coagulation disorders, and/or an uncooperative patient (e.g., dementia), and/or obese patients, VCDs could be considered a more valid hemostatic solution compared to manual compression (class I, level C).

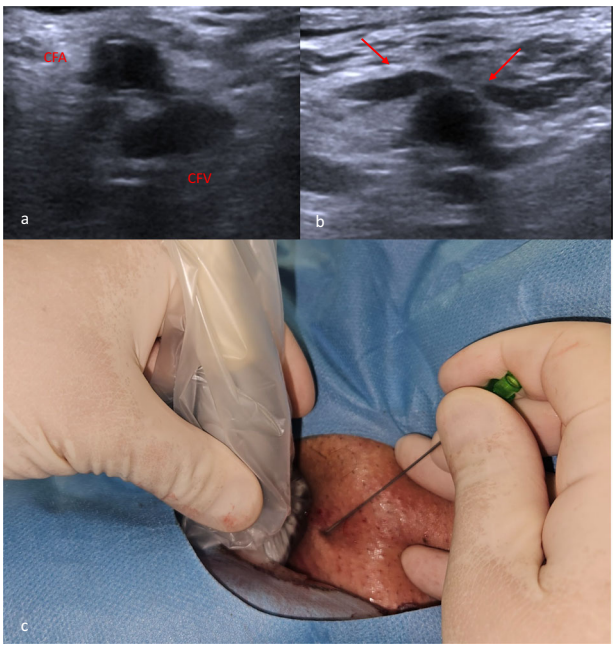

Fig. 1 US-guided local anesthesia and antegrade CFA access. **a** Out-of-plane technique (transverse view) of US-guided lidocaine injection of the CFA. **b** The lidocaine is infused at the anterior wall of the CFA using real-time imaging (arrows). **c** Out-of-plane micropuncture access of the CFA. Note that the in-plane technique (sagittal view) for real-time needle monitoring is not possible in this case due to the large hostile abdomen not permitting the correct needle angle

Introduction

Vascular access is one of the most critical parts of every IR procedure that involves vascular catheterization. Successful access is based on knowledge of anatomy, individual patient characteristics, and basic procedural skills. Access sites during a catheterization procedure usually involve the femoral, brachial, or radial artery. Basic manual compression techniques are most often used to achieve hemostasis on the puncture site. Nowadays, there is a vast variety of vascular closure devices (VCDs) that, if properly used, can greatly assist in securing hemostasis.

Ultrasound guidance for vascular access

Ultrasound-guided vascular access has emerged as a standard practice in recent years, revolutionizing the approach to both arterial and venous catheterizations. Numerous studies [1–6] have demonstrated its superiority over the traditional landmark-based technique, showing higher success rates, fewer complications, and decreased procedure times. The risk of hematoma formation and unintentional puncture of nearby structures is lower thanks to the real-time visualization that ultrasound technology provides. Moreover, studies have consistently shown that ultrasound guidance improves first-pass success rates during vascular access procedures. Furthermore, ultrasound guidance used for local anesthesia infiltration has been demonstrated to significantly reduce the level of pain experienced during vascular access (Fig. 1) [7]. There are two main types of real-time US-guided puncture techniques. The long axis "in-plane" technique (sagittal view in the US) allows real-time visualization of the whole needle trajectory, from the skin to the vessel wall, and the short axis "out-of-plane" technique (transverse view in the US), in which only the tip of the needle is visible during catheterization (Fig. 1). The choice of the technique depends largely on the type of access required and the anatomical details in each individual case. In summary, the routine use of ultrasound-guided vascular access is classified as a class I recommendation with level B evidence for all endovascular procedures and level A evidence for transradial and transfemoral access in cardiac procedures. Healthcare providers should incorporate ultrasound guidance into their practice to optimize vascular access procedures and maximize patient outcomes.

Arterial vascular access

During catheterization procedures, the femoral artery remains the most commonly used arterial access site.

The common femoral artery (CFA) is the most favorable entry point for femoral access. The optimal location lies just below (1–2 cm) the inguinal ligament and roughly correlates to the area of the mid-third of the femoral head, more specifically the part of the CFA that lies inferiorly to the superficial lower epigastric branches and proximally to the bifurcation between the superficial and profound branches [8]. Operators quite often use the inguinal skin crease as an anatomical landmark for skin access, but this may prove misleading as it rarely coincides with the location of the CFA. An image-guided approach is the safest technique prior to a puncture with ultrasound or fluoroscopy guidance, or both (Fig. 2). The FAUST trial results showed that routine use of real-time US guidance improved CFA cannulation only in patients with high CFA bifurcations, but significantly reduced the number of attempts, time to access, risk of venipunctures, and vascular complications in femoral arterial access [9]. The brachial, radial, popliteal, and pedal artery puncture sites may act as alternatives to femoral access (Figs. 3 and 4); each of them offers different benefits and risks, as summed up in Table 1. Access to the above alternative sites should always be attempted using ultrasound guidance, while for radial and pedal access, dedicated low-profile access kits and sheaths are recommended [10]. Finally, in certain cases following iliac artery treatment using a standard CFA retrograde approach, a conversion to an antegrade ipsilateral CFA approach using a sidewinder catheter and advancing a hydrophilic guide wire into the superficial femoral artery (SFA) in order to reposition the sheath in an antegrade manner, may be used to allow the treatment of infrainguinal disease. Nevertheless, the antegrade ipsilateral CFA approach is an advanced technique, that requires experience to avoid access-site-related complications [11].

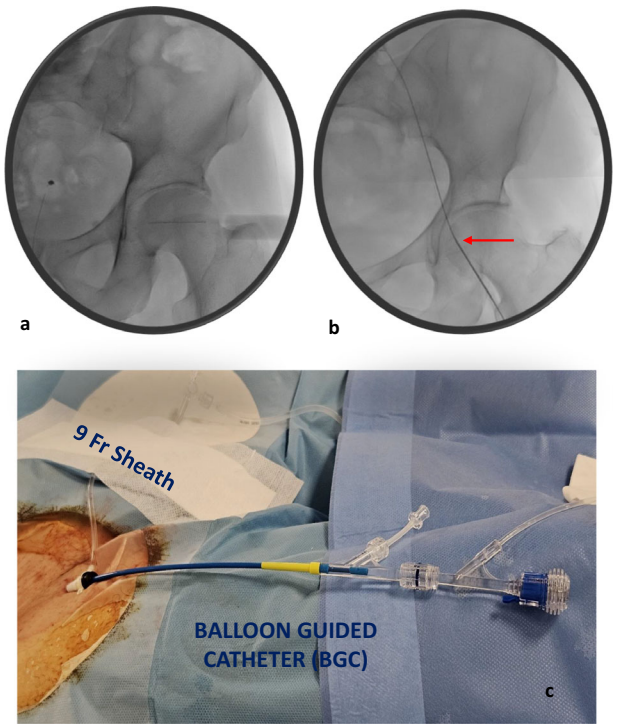

Fig. 2 **a** Local anesthesia needle used for fluoroscopic identification of the mid segment of the CFA, before US-guided puncture for large-9 Fr access during an acute stroke thrombectomy procedure. **b** Accurate needle puncture at the mid-CFA segment access (arrow showing the tip of the needle) and (**c**) 9 Fr sheath and coaxial balloon-guided catheter positioned at the CFA enabling arterial access for cerebral thrombectomy

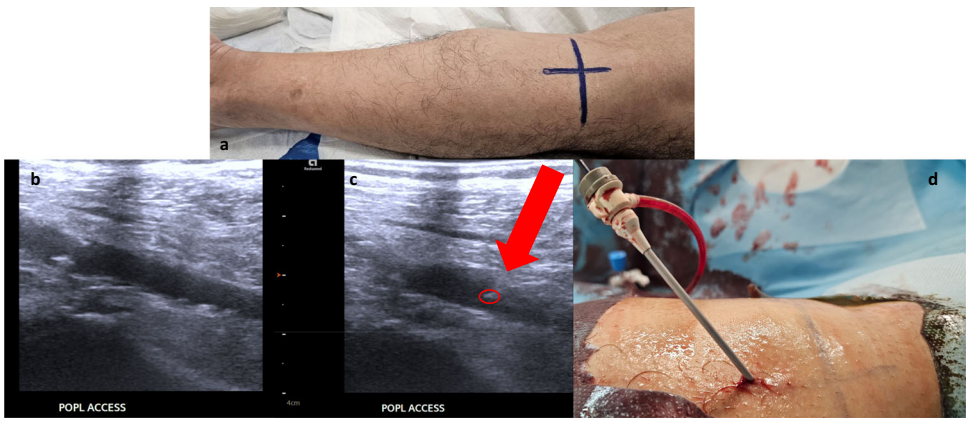

Fig. 3 Ultrasound-guided popliteal access using the in-plane technique. **a** The patient is positioned in the prone position and the exact point of popliteal access is marked. **b** The popliteal artery is identified on a sagittal view and (**c**) in-plane (sagittal view) technique enabling real-time view of the whole needle trajectory from the dermis to the arterial lumen (arrow). Note the tip of the needle within the lumen (circle). **d** 5 Fr sheath positioned below the knee. Note that the puncture is performed a few centimeters below the predetermined arterial access point (cross), to enable the popliteal access using a 45° needle angle as noted in (**c**)

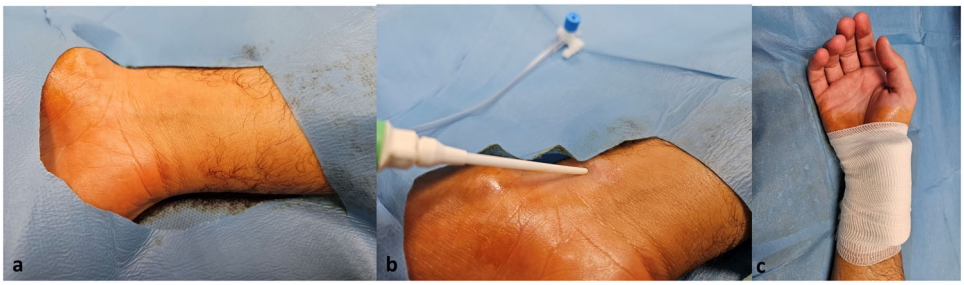

Fig. 4 Radial access using a dedicated 6 Fr access kit. **a** Aseptic technique with the wrist extended to facilitate US-guided radial access. **b** 6 Fr radial sheath positioned within the radial artery. **c** External compression vascular closure device placement made out of gauze for mechanical compression of the puncture site

Table 1 Percutaneous access site selection

Vessel type	Approach	Arteries that can be examined/accessed	
CFA	Retrograde	The aorta and its branches, contralateral femoropopliteal, and tibial vessels	A most common type of access, used to investigate from the cerebral and coronary arteries to the tibials
CFA	Antegrade	Ipsilateral infrainguinal	Best used for distal tibial and pedal intervention, not required for diagnostic angiography.
Brachial/ radial	Retrograde	Aorta and its branches, including cerebral and coronary arteries	Visualization of any vascular bed, but challenging to perform tibial or pedal procedure due to long-distance
Popliteal	Retrograde	Visualization for diagnostic purposes of the femoropopliteal and iliac arteries, as the aorta and its branches	Usually used for the endovascular treatment of SFA, CFA, and iliac artery disease
Pedal	Retrograde	The aorta and its branches, femoropopliteal and iliac arteries	Commonly used for the endovascular treatment of tibial and femoropopliteal arterial disease

CFA common femoral artery, *SFA* superficial femoral artery

There is a vast choice of vascular access needles, but they all serve a common purpose—allowing the introduction of a guidewire through a central canal. There are one or two-piece needles, with the latter having a central sharp style that protrudes slightly beyond the beveled atraumatic needle tip. The style can be solid or hollow. When using hollow-style needles, blood may be visualized once the vessel lumen is entered, and these are most commonly used for US-guided, single-wall, anterior puncture. Two-piece needles are used only for arterial punctures, with the most common being 19- or 18-gauge in diameter. Micropuncture systems use an even smaller 21-gauge diameter needle which employs a sharp, open, bevel-tipped system to enter the vessel, which is consequently converted to a larger, short 4 F or 5 F dilator. They are useful in both arterial and venous punctures. The majority of peripheral endovascular procedures are performed via 5–8 Fr arterial sheaths, while in iliac and femoropopliteal interventions most commonly 6 Fr sheaths are used. However, 4 Fr devices (balloons and stents) can be used for infrapopliteal interventions, and such low-profile devices are also available for the management of iliac and femoropopliteal disease, minimizing the bleeding risk and the need for VCDs. However, disadvantages of placing a 4 Fr sheath include reduced stability, especially when attempting an antegrade approach in patients with a hostile abdomen, and the inability to infuse contrast via the 4 Fr sheath with a 4 Fr diagnostic or balloon catheter inside the sheath, which can cause problems when attempting complex procedures (e.g., subintimal).

Manual compression

Traditionally, the technique of choice for achieving and securing hemostasis for interventional radiology (IR) procedures using percutaneous access has been the application of manual compression over the puncture site for a time period of 15–20 min and a subsequent period of bed rest for 4–6 h. Nevertheless, for various reasons, some cases require prolonged manual compression of over 30 min, and in the presence of bleeding complications bedrest for up to 24 h may be necessary. This technique was introduced by Seldinger in 1953 and little has changed since then, as it is considered safe. Hemostasis is

achieved due to the formation of a fibrin and platelet plug after blood is exposed to collagen at the arterial wall puncture site. Up to 3% of patients who received manual compression for puncture site hemostasis will develop complications that require further attention in the form of treatment, transfusion, or prolonged hospitalization [12].

Patients with musculoskeletal, cardiac, or cognitive diseases are usually the most difficult to comply with bedrest, making the prolonged period of bedrest the most significant drawback of this technique. Risk factors that are linked to the prolongation of bedrest are abnormal clotting, obesity, the use of large sheaths, and the administration of antiplatelet or anticoagulation agents.

Vascular access closure devices

Classification of VCDs

VCDs were introduced in the early 1990s. Designed to close the arteriotomy puncture site and achieve hemostasis, these devices reduce the time needed to stop bleeding at the puncture site and enable early mobilization of the patient. Since their introduction, many companies have gone back to the drawing board creating multiple VCD iterations [13]. Successful deployment, ease of use, and a complication rate less or, at most, equal to that of manual compression should be the goal for every VCD hitting the market. There are different ways to categorize VCDs depending on the method used to achieve hemostasis. A broad categorization of VCDs is the classification of active closure devices, active arteriotomy approximation devices, and invasive compression assist devices. Based on the location of deployment of the device used for hemostasis (suture, plug, anchor, disc, or clip), VCDs can be further categorized as intravascular and extravascular. Table 2 summarizes the level of evidence for the use of each VCD.

I. Active closure devices

Hemostatic plugs are biodegradable devices that are put into the arteriotomy site to aid in the process of hemostasis. These plugs generally include biodegradable components like collagen or synthetic polymers that encourage the aggregation of platelets and the formation of clots, and they provide a mechanical seal at the puncture site (Fig. 5). Over a period of time, the body assimilates the plug, resulting in the formation of a closed arteriotomy site. This category of VCDs includes Angio-Seal (St. Jude Medical), Mynx (Cardinal Health), Femoseal (Terumo Corporation), Vascade (Haemonetics), and ExoSeal (Cordis Corporation). Multiple randomized prospective trials and retrospective studies with a combined sum of 10,000 patients reported a complication rate varying from 5.9% to 0% compared to manual compression 18–0% for major adverse events [13].

II. Active arteriotomy approximation devices

This class of device achieves a type of limited surgical closure, placing one or two sutures or a nitinol clip around the arteriotomy wall defect. Even though the density compared to an open surgical arterial closure is not as high, they can cause complete apposition of the walls of the arteriotomy.

These devices often employ a pre-tied knot or self-anchoring mechanism to secure the sutures in place, providing reliable hemostasis. Suture-based closure devices may be manual or automated, with the latter offering enhanced procedural efficiency. The Perclose (Abbott Vascular) family of devices and the Prostar XL (Abbott Vascular) use a suture-based type of mechanism, while the StarClose (Abbott Vascular) device uses a nitinol-clip-based mechanism. Both types of devices have no limitation concerning repeated vessel punctures at the same site, but they are generally complex devices that require many procedural steps, thereby increasing the complexity of VCD [14]. Several randomized controlled trials (RCTs) and observational studies support the use of Perclose (Abbott Vascular) and Prostar (Abbott Vascular) VCDs, with high rates of achieving hemostasis (ranging from 85.7% to 99%), along with reduced times to post-procedural ambulation, and at the same time with no increase in the complication rate. The infection rate using this type of device was shown to be 0.5% [15–17]. Newer closure techniques involving the Perclose (Abbott Vascular) and Prostar (Abbott Vascular) VCDs are also widely used for hemostasis of larger arteriotomies, enabling percutaneous endovascular aortic aneurysm repair (pEVAR) procedures. In the recent STEP randomized controlled study, the authors randomized 203 patients undergoing lower-limb arterial endovascular revascularization and reported a significantly superior technical success rate for the intravascular polymer-based FemoSeal (Terumo Corporation) vs the suture-mediated ProGlide (Abbott Vascular) (OR: 3.98; 95% CI: 2.22–7.14; $p < 0.0001$) [18].

Clip-based closure systems use metallic or polymeric clips to approximate the edges of the arteriotomy and achieve hemostasis. These clips are deployed either manually or with the assistance of specialized delivery systems. Clip-based closure systems offer rapid closure and are particularly useful in cases where precise alignment of tissue edges is challenging. The Starclose (Abbott Vascular) device has no residual implanted intraluminal material (Fig. 6), but its disadvantage is a permanent metal implant which can cause susceptibility artifacts during MRI examinations [13]. When comparing StarClose (Abbott Vascular) success

Table 2 Evidence for VCDs

VCD type	Clinical data quality	No. of patients	Complication rate (vs manual)	Level of evidence
Active closure devices				
Angio-Seal	Multiple RCTs [12], network meta-analysis [27]	5852, 15,252	Major and minor complications 5.9–0.5% (vs 18–1.8%), the lowest rate of combined adverse vascular events and hematoma	IA
Mynx	One prospective non-randomized study, retrospective studies, and case reports [12]	325	Major complications 0.5%, intravascular sealant 18%, pseudoaneurysm formation 11% (retrospective study)	IIC
Exoseal	Randomized prospective trial and retrospective study [12]	401	Major complications 0% (vs 0%)	IB
Femoseal	Multiple RCTs [27]	4019	Relative risk = 0.75 [0.60, 0.94]	IA
Active arteriotomy approximation devices				
StarClose	RCT and case reports [12]	596	Major complications 1.1% (vs 1.1%)	IC
Perclose	Multiple RCTs [12]	3335	Major and minor complications 7–0% (vs 2.7–0%)	IB
Invasive compression assist devices				
Axera	Retrospective trial [12]	94	Major complications 0%, minor complications 3%	II
Catalysts II and III	Prospective non-randomized trial [12]	96	Major complications 0%	II

VCD vascular closure device, *RCT* randomized controlled trial

to manual compression the CLIP trial concluded that hemostasis was achieved in 94.1% of diagnostic cases and 86.8% of interventional cases of 596 patients that underwent catheterization, while it also resulted in significantly reduced times to hemostasis and ambulation [19]. In the observational study of Das et al [20], hemostasis was achieved in 96% of the patients involved, although an 8% incidence of small hematomas and a 3% incidence of minor bleeding that settled spontaneously was reported [21].

III. Invasive compression assist devices

Passive arteriotomy approximation devices belong to the category of VCDs that help bring together the walls of an arteriotomy without the need for retained sutures or clips. While their theoretical advantages over other techniques include a reduction in the infection risk rate and a negligible embolization or arterial occlusion risk, they require manual compression of the puncture site, albeit for a shorter amount of time Figs. 7 and 8.

The Axera device is used at the initiation of the arterial access and relies on no additional sealant, procoagulant, or suture material. The shallow needle trajectory during arterial access allows for improved apposition of the arteriotomy site, which in turn allows for more rapid hemostasis. Manual compression is still necessary after the sheath is removed, but since there is no material retained in the patient, there is no risk of embolization or infection for this VCD [22]. The Catalyst II and III (Cardiva Medical Inc) type of VCDs use a deployable nitinol mesh disc which provides temporary hemostasis, by allowing the vascular smooth muscle wall to recoil back to the size of an 18-gauge puncture needle while at the same time stimulating the hemostatic cascade. After the removal of the mesh disc, manual compression is performed to achieve final hemostasis [14]. In the observational study of Doyle et al [23] that included 96 patients, successful deployment and hemostasis were achieved in 99% of patients, and there were no major complications; the rate of minor complications was 5%.

FemoStop (Abbott Vascular) represents another type of compression assist devices, which act through external mechanical compression of the puncture site. More specifically, the FemoSTop (Abbott Vascular) places an inflatable bubble over the puncture site and is secured in place by a belt that wraps around the patient, while staying inflated for 1–2 h to achieve hemostasis. However, published data investigating this device are scarce.

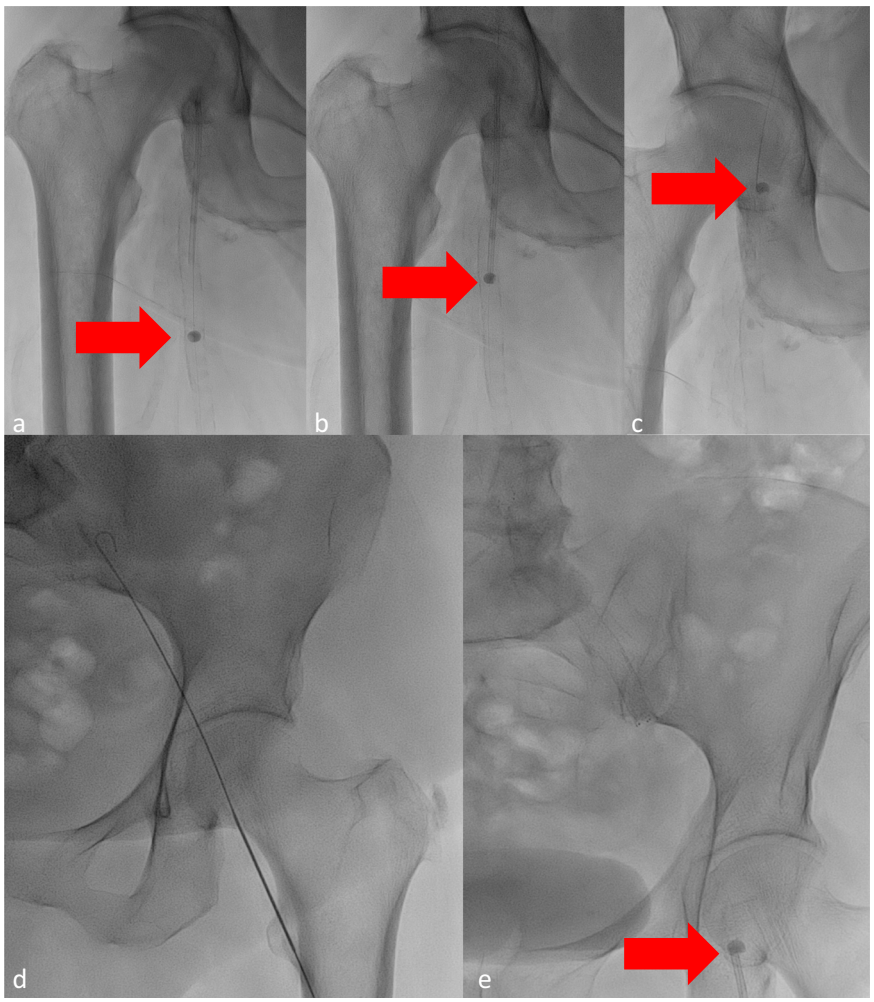

Fig. 5 Examples of CFA hemostasis using the Mynx 6 Fr device. Antegrade (**a**–**c**) and retrograde (**d**, **e**) CFA access and demonstration of the intravascular temporary balloon used for vessel anchoring (arrows) before plug deployment

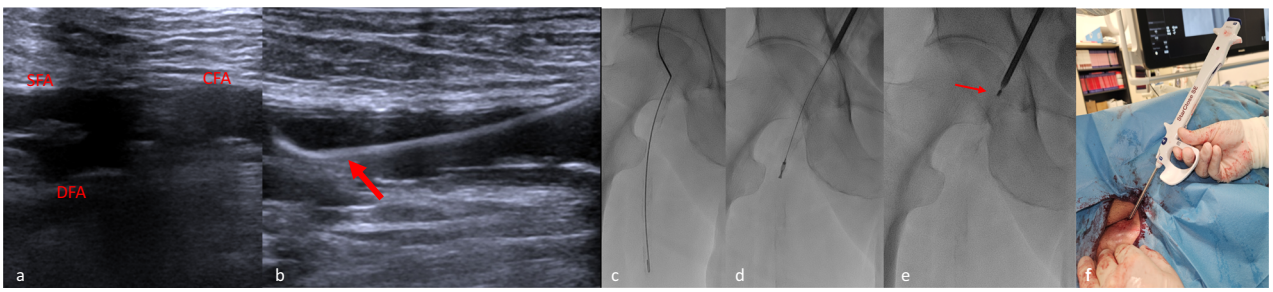

Fig. 6 Example of CFA hemostasis using the Starclose 6 Fr device. **a** In-plane technique for US-guided antegrade CFA access, depicting the CFA bifurcation in SFA and DFA. **b** US-guided positioning of the guidewire at the SFA (arrow) to enable endovascular treatment. **c**–**e** Imaging of the temporary intravascular anchor just prior to clip deployment at the CFA (arrow). **f** Demonstration of the correct device angle for antegrade clip deployment

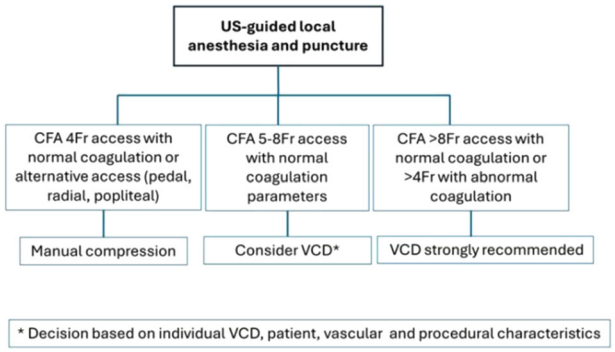

Fig. 7 Flowchart summarizing recommendations regarding percutaneous vascular access and hemostasis

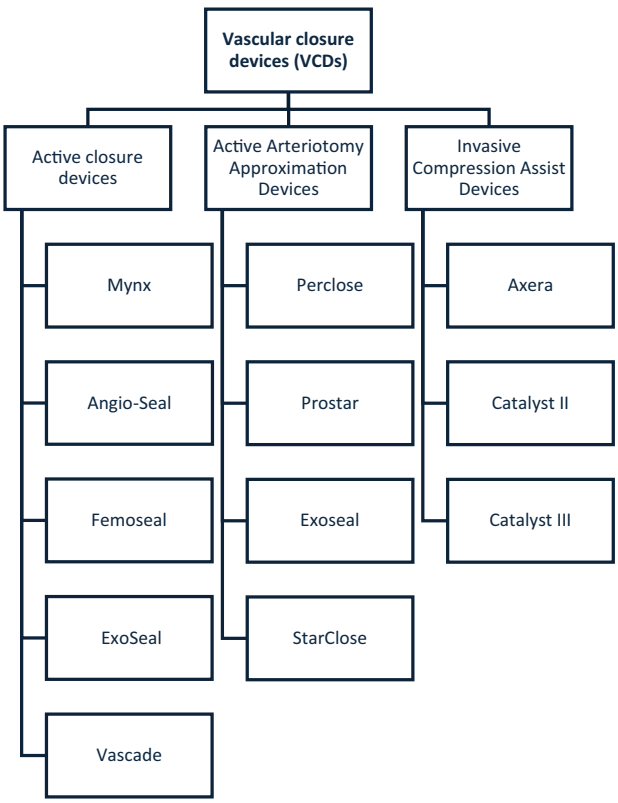

Fig. 8 Classification of VCDs based on the mechanism of action

Drawbacks and limitations

Despite extensive long-standing experience with VCDs, which over the years has allowed endovascular specialists to consider treating patients with the severe arterial disease even as day cases [24], there are several issues regarding their use that require careful consideration. Firstly, a recent 2018 systematic review investigating the use of VCDs in femoral hemostasis following peripheral endovascular procedures (34 studies with procedures ranging from diagnostic angiograms to pEVAR), demonstrated improved time to hemostasis and ambulation, and superior patient comfort and satisfaction, but similar complications, safety, and efficacy rates compared to manual compression [25]. Moreover, infection risk (0.6% VCDs vs 0.2% manual compression) and thrombotic complications (0.3% VCDs vs 0% manual compression) were noted although the rates were extremely low [26]. On the other hand, a 2017 metanalysis of RCTs and cohort studies comparing VCD closure vs surgical cutdown in aortic interventions (endovascular aneurysm repair, thoracic endovascular aneurysm repair, and transcatheter aortic valve repair) demonstrated favorable results for VCDs regarding wound complications, urging the authors to recommend a percutaneous approach for such interventions in select patients [27]. The level of evidence regarding VCD use is significantly compromised by the heterogeneity created by different devices available, different sites of access (femoral, popliteal, pedal, etc) used for peripheral interventions, variety in the size of sheaths used (ranging from 4 Fr to 24 Fr), and the vast variety of interventions performed, creating substantial difficulties in the design of large randomized studies that could address the clinical scenarios of every-day clinical practice. As a result, current data allow the recommendation of VCD use for aortic and peripheral interventions only on an individualized basis [13].

When selecting a VCD, healthcare providers should consider factors such as the operator's experience, the patient's mental and physical state, the size of the arteriotomy, vascular anatomy and pathology (calcifications and stenosis at the access site), procedural intricacy, and resource availability. It is crucial for healthcare providers to carefully select the most appropriate device based on these considerations to guarantee optimal complication-free outcomes for patients undergoing femoral artery catheterization procedures [28]. Notably, for procedures performed via 4 Fr CFA sheaths manual compression will reasonably suffice, and active VCDs are not recommended as their use will upsize the 4 Fr access potentially increasing the bleeding risk. It should also be highlighted that until today there are no reliable data to support the use of VCDs in access sites other than the femoral artery (only small series) and manual compression is still recommended for brachial popliteal, radial, and pedal access [13]. Nevertheless, devices for radial access hemostasis mainly investigated in the ambit of coronary interventions (for example the TR Band) can also be considered following peripheral interventions. Additionally, all operators should be aware of the limitations of these devices and the potential risk of thrombosis and limb loss. Special care should be taken when using active VCDs in small caliber, calcified vessels, or those with atheromatic stenosis (even < 50%), to avoid an abrupt arterial occlusion resulting in acute limb ischemia

necessitating prompt surgical or endovascular treatment. However, US-guided puncture and subsequent US-guided VCD deployment could be used to reduce such complications as vessel wall calcifications and atheromas can be avoided during puncture. During VCD deployment, immediate device failure can be visualized, as well as vessel wall movement, interaction of the device with the atheroma, and acute lumen occlusion, allowing for a safer deployment and prompt action in case of failure/complication [29].

Summary statement

Optimizing vascular access and closure techniques is crucial for minimizing procedural complications and improving patient outcomes. Key suggestions backed by strong evidence include using ultrasound guidance for vascular access and using VCDs for femoral artery access in selected patients. These strategies aim to enhance the safety, efficacy, and patient experience of vascular procedures.

Patient summary

IR provides non-surgical, via the skin and through the arteries, so-called endovascular treatment options, for a variety of arterial diseases. Endovascular procedures often require accessing blood vessels, which can sometimes lead to problems like bleeding or infection. To improve safety and effectiveness, it is recommended to use ultrasound to guide the needle into the blood vessel at the beginning of the procedure. After the procedure, special VCDs can be used to close the small hole in the artery, allowing the person to get up and walk faster. VCDs can also cause problems, such as acute disruption of the blood flow, which is called ischemia, that require further treatment. Current data indicate that these complications occur rarely, and VCD use is considered safe.

Abbreviations

CFA	Common femoral artery
IR	Interventional radiology
pEVAR	Percutaneous endovascular aortic aneurysm repair
RCTs	Randomized controlled trials
SFA	Superficial femoral artery
VCDs	Vascular closure devices

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Compliance with ethical standards

Guarantor

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Conflict of interest

The authors of this manuscript declare no relationships with any companies, whose products or services may be related to the subject matter of the article.

Statistics and biometry

No complex statistical methods were necessary for this paper.

Informed consent

Written informed consent was not required.

Ethical approval

Institutional Review Board approval was not required.

Study subjects or cohorts overlap

Not applicable.

Methodology

- Practice recommendations

Author details

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