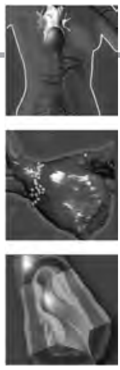

Preventing vascular access site complications during interventional procedures

The common femoral artery is the most widely used route of access to the arterial system for coronary and peripheral percutaneous vascular interventions. This article addresses anatomical aspects relating to common femoral artery puncture, the choice of optimal puncture site and methods to increase the efficacy and safety of the common femoral artery puncture. Complications of vascular access relating to either manual compression or closure devices will be described. Tips and tricks to reduce the occurrence of vascular complications related to vascular access are discussed.

KEYWORDS: complication ▪ femoral artery ▪ puncture

Almarosa Lombardo[1] & Jos C van den Berg[†]

[1]Department of Vascular Surgery, II Operative unit, Policlinico san Donato, San Donato Milanese, Milano, Italy
[†]Author for correspondence: Service of Interventional Radiology, Ospedale regionale di Lugano, Sede Civico, Via Tesserete 46, 6900 Lugano, Switzerland
Tel.: +41 918 116 072
Fax: +41 918 116 090
jos.vandenberg@eoc.ch

After its first introduction by Seldinger, percutaneous vascular access through the common femoral artery (CFA) has become the most commonly used route for the majority of percutaneous revascularization procedures (coronary and peripheral). By accessing the CFA, as opposed to access through other inguinal arteries, the risk of vascular complications can be reduced, owing to the relatively large size of the CFA and its course over a bony structure, that allows for compression [1,2].

Hemostasis has traditionally been achieved by manual compression followed by 4–8 h of bed rest. Digital compression of the CFA against the bony support of the femoral head after removal of the indwelling catheter allows for confinement of the local hematoma and with normal coagulation parameters, will form a thrombus within minutes. Blood contact with the exposed collagen in the arterial wall leads to platelet adhesion and trapping of red blood cells. This is followed by platelet aggregation and activation. The latter results in the release of humoral factors that enhance proliferation and migration of smooth muscle cells into the thrombus. In the mean time, inflammatory cells, which remove erythrocytes, thrombocytes and fibrin, infiltrate the thrombus. Finally, the arterial wall is reconstituted by an extracellular matrix produced by smooth muscle cells [3].

Peripheral vascular complications after femoral artery puncture occur with an overall incidence of 1.5–17% [4]. The risk of local complications is low for diagnostic catheterization (0–1.1%), while in patients undergoing therapeutic procedures with larger (up to 8 Fr) access sheaths and/or anticoagulation this rate increases to 1.3–3.4%. The highest rate of complications (5.9–17%) is seen after coronary recanalizations with patients receiving a combination of heparin and multiple antiplatelet agents [3,5]. Carefully scrutinizing patients by physical examination and duplex ultrasound can yield a minor and major femoral artery access complication rate after manual compression that is even higher, and can be as high as 64% [6].

Complications include hematomas (both inguinal and retroperitoneal), pseudoaneurysms, arteriovenous fistulae, acute arterial occlusions due to dissection, cholesterol emboli or subacute thrombosis (especially in patients after successfully treated ipsilateral downstream stenoses), and infections, thickening of perivascular tissues, neural damage and venous thrombosis [3,5,7]. Many of these complications are potentially lethal. Access-site hematomas that require transfusion are associated with a ninefold increase in hospital death, and a 4.5-fold increase in 1-year mortality in patients undergoing percutaneous coronary interventions (PCIs) [8].

Approximately 20–40% of patients who experience such complications require additional surgery [9]. The incidence of complications is significantly higher in patients of advanced age, after repeat percutaneous transluminal procedures with previous arteriotomy at the same site, in females and in extremely thin or morbidly obese patients [10]. Additional risk factors for vascular complications include uncontrolled hypertension, type and level of anticoagulation (concurrent anticoagulation with a high international normalized ratio [INR]), arterial sheath size, renal failure, concomitant venous sheath, peripheral vascular disease, prolonged sheath duration and location of the arteriotomy [11]. Most of these factors cannot be influenced or changed, but care should be taken to keep sheath size as small as possible, aim for a fast procedure and interrupt antiaggregational and anticoagulant therapy temporarily (the latter is usually possible with most of the peripheral interventions).

With the advancement of technology, reduction in size of the endovascular material (miniaturization of balloon catheters, guidewires and stents) could be achieved, and bleeding complications that occurred relatively frequently with large size introducer sheaths, became less of an issue. This effect was, however, counteracted by the increasing use of anticoagulant and platelet antiaggregational therapy, that was associated with a higher incidence of hemorrhagic complications. Furthermore, new endovascular devices requiring larger introducer sheaths were developed (covered stents and stent-grafts) [12]. This led to the development of devices assisting manual compression that aim for two benefits: increasing patient (and doctor) comfort (by allowing earlier ambulation and discharge) and decreasing complication rate. It is estimated that at present, approximately half of patients undergoing a percutaneous vascular therapeutic intervention are treated with arterial puncture closure devices [9].

This article discusses the relevant anatomy, choice of puncture site and technical aspects, and will describe complications related to vascular access, manual compression and closure devices. The tips and tricks to reduce femoral vascular access complications and alternative approaches (e.g., transradial access) are discussed.

Puncture site & puncture techniques

■ Relevant anatomy

The main access site to the vascular system for all endovascular interventions is the CFA, and it is known that the optimal choice of puncture site is a determinant factor for outcome. The CFA is the continuation of the external iliac artery after the take-off of the inferior epigastric artery, and after crossing the inguinal ligament (that forms an anatomical landmark, and runs from the antero-superior iliac crest to the pubic bone; an imaginary line drawn between these bony structures indicates the location of the inguinal ligament; Figure 1A) [1,2,13]. Here, the artery lies midway between the anterior superior iliac spine and the pubic bone and is running parallel with the medial aspect of the femoral head. It descends almost vertically down towards the adductor tubercle of the femur and ends at the opening of the adductor magnus muscle, in the so-called femoral triangle. At its origin, the femoral artery is accompanied by the anterior crural nerve laterally and femoral vein medially, and is covered anteriorly by the inferior extension of the fascia of the transverse abdominal and iliac muscles (the so-called femoral sheath). The femoral sheath is funnel shaped, and fuses with the adventitia of the vessels at the site where the greater saphenous vein joins the femoral vein [14]. The presence of the femoral sheath that encloses the CFA, assists in the prevention of pseudoaneurysm formation after puncture. The deep femoral artery branches at 2.5–5 cm distal from the origin of the CFA. The most superficial part of the CFA lies at the level where the artery passes in front of the femoral head [14]. The center of the CFA is lying anterior to the common femoral vein. A portion of the CFA overlaps the corresponding vein in the antero-posterior plane in 65% of cases. This relationship is of importance in the prevention of the development of arteriovenous fistula [15]. Many variations in the above anatomy have been cited in the literature, but extensive discussion is beyond the scope of this paper.

Relative to palpable bony structures, the course of the femoral artery is indicated by the upper two-thirds of the line drawn between the midpoint of anterior superior iliac spine and symphysis pubis to the prominent tuberosity on the inner condyle of the femur with the thigh abducted and rotated outward [16].

The CFA in normal subjects has a mean diameter of 6.4 mm. Women and patients with diabetes have a significantly smaller diameter of the CFA of 6.1 and 6.3 mm, respectively [17].

The association between low puncture site and both pseudoaneurysms and arteriovenous fistula is well known, as well as the high risk of retroperitoneal bleeding in case of a high puncture site (the bleeding may be massive because of the presence of only loose connective tissue in the retroperitoneal space) [18].

■ Choice of puncture site & technical aspects

The inguinal crease is frequently used as a landmark, based on the belief that the level of the inguinal crease is closely related to the inguinal ligament [19,20]. This technique is considered to offer the advantage of avoidance of unintended abdominal puncture of the artery, even if the needle was angulated. However, the distance between the inguinal crease and the inguinal ligament is highly variable, ranging from 0 to 11 cm (mean: 6.5 cm) [20]. The same study demonstrated that the bifurcation of the CFA was above the inguinal crease in 75.6% of patients.

In a study that performed a survey of the superficial landmarks used to select the site of retrograde puncture of the femoral artery for angiography [21], the inguinal skin crease was found to be the most popular, preferred by 39.2% of operators. The maximal femoral pulse irrespective of the position of the skin crease was the next most popular landmark (24.7%). Bone landmarks were least popular (13.0%). The majority (73.7%) of those using the skin crease punctured at the same level or distal to it. The same study also investigated the relationship of these superficial landmarks to the CFA and its bifurcation. The inguinal skin crease was distal to the bifurcation of the CFA in 71.9% of limbs (mean: 0.61 cm). The maximal femoral pulse was over the CFA in 92.7% of limbs, and the CFA was projected over the medial aspect of the femoral head in 77.9% of limbs. This indicates that the level of the strongest femoral pulse is a more reliable means of localizing the CFA, than the level of the inguinal crease. Therefore, although popular, the use of the inguinal skin crease should be considered an unreliable guide for puncture of the CFA. Similar results were observed in another study, which demonstrated that the inguinal crease was lying inferior to the femoral bifurcation in 78% of cases, while the mid-femoral head was positioned inferior to the femoral bifurcation in only 1% of cases [22]. In the obese patient, puncture above the inguinal crease lengthens the tissue tract (through the abdominal pannus), which can greatly encumber movement of large caliber devices through tortuous or severely atherosclerotic vessels. The tract can be shortened by the operator placing a flat hand on the inguinal crease and follow the femoral artery cephalad by pushing the crease along the anterior thigh and underneath the pannus. With this maneuver, the femoral artery can usually be palpated to its disappearance under the inguinal ligament, even in morbidly obese patients. The artery can then be punctured near the inguinal crease in its new location under the pannus and over the femoral head. It may help to loosely tape the pannus to the upper abdomen, or have an assistant manually retract the pannus during the puncture.

The use of palpable landmarks as the iliac crest and the pubic bone has been recommended as a reliable guide to achieve CFA access: either the midpoint of a line drawn between the anterior superior iliac spine and vertical midpoint of pubic symphysis or a point 2.5 cm distally along a line perpendicular to the line drawn between the anterior superior iliac spine and the pubic bone can be used [16]. The presence of clearly identifiable landmarks can be obscured by obesity, presence of (residual) hematoma or scar tissue after previous percutaneous or surgical interventions. Low blood pressure or the absence of pulse distal of a stenosis or occlusion of the iliac arteries can also be a problem when identifying a proper site for puncture.

In the case of an absence of a femoral pulse, the following technique has been described [23]: placement of a finger immediately lateral to the pubic tubercle and inferior to the inguinal ligament, and subsequent palpation of the point that allows the most posterior depression that anatomically lies between the iliopsoas muscle laterally and pectineus medially. The femoral vein can be found in this depression and the CFA will be found 1.5 cm lateral to this point.

Besides palpation, fluoroscopy was already used in early interventional experience as a landmark [24,25], with the CFA bifurcation occurring at, or below the center of the femoral head in 98.5% of cases [13].

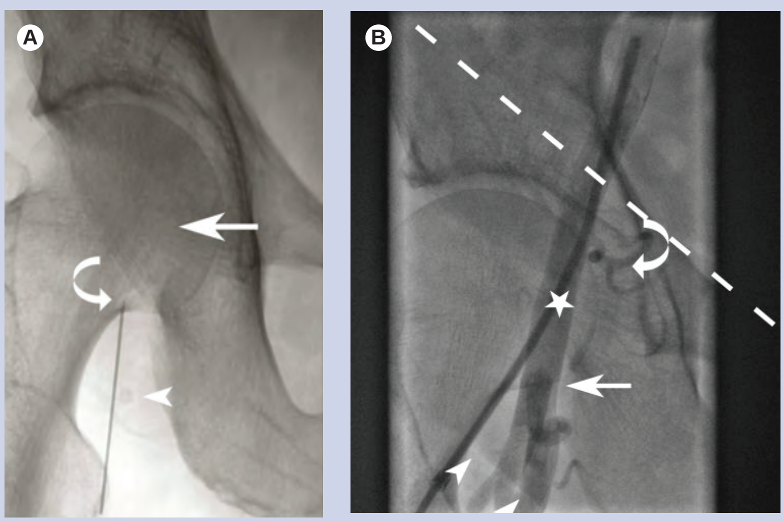

Figure 1. Fluoroscopic puncture site determination. (A) Fluoroscopic image of right inguinal area; note presence of Starclose clip (after previous vascular access for percutaneous coronary intervention) well beyond the inferior margin of the femoral head (arrowhead), needle tip overlying skin entry site (curved arrow); the projected arterial entry site is at the level of the middle segment of the femoral head (arrow). **(B)** Cinefluoroscopic image (anteroposterior projection) depicting the level of the femoral bifurcation (arrow), the inferior epigastric artery (curved arrow), arterial entry site (star), inguinal crease (arrowheads) and course of the inguinal ligament (dashed line).

The puncture entry site at the level of the skin should be made 1–2 cm caudal (in case of retrograde puncture) to the planned arterial entry (in case of antegrade puncture cranial of the arterial entry site). The site of skin entry should vary, according to the amount of subcutaneous fat. After skin penetration of the needle, and with the needle lying directly over the artery, fluoroscopy should be performed again. At this point, the needle should be left lying. By doing so, one can avoid radiation exposure to the hands of the operator. The main disadvantage of the fluoroscopic method is the increase in radiation exposure to the patient (and to a lesser extent, the operator) [16].

The use of fluoroscopy aiming at the level of the middle femoral head will lead to a puncture of the CFA (above the bifurcation) in 99% of cases, and by using this technique no intraperitoneal punctures will occur. Needle entry in the artery should be roughly at the bottom of the upper inner quadrant of the femoral head (in an anterioposterior projection; Figure 1B) [22].

When the use of a closure device is anticipated a femoral angiography through the needle can be performed at this point (or immediately after placement of the sheath placement). It is advisable to perform an ipsilateral anterior oblique projection (20°), this will both allow visualization of the level of the femoral bifurcation, as well as depiction of wall irregularities that are located in a more anterior and posterior position. This does not necessarily have to be a classic digital subtraction angiography; a roadmap or cinefluoroscopic image may also suffice. In case the puncture site is inadvertently too high or low, adopting this action will also avoid the placement of a large introduction sheath (manual compression can be performed or a 4 Fr dilator can be left in place and be removed at the end of the procedure). Inadvertent too low puncture will lead to significantly more pseudoaneurysms and formation of arteriovenous fistulae and increases the risk of thrombosis [1,21]. If the puncture is too proximal, the external iliac artery may be entered, increasing the risk of retroperitoneal hemorrhage and in these cases bleeding can be life-threatening owing to the presence of loose connective tissue. Furthermore, manual compression is more likely to be inadequate after the procedure, because of the tense inguinal ligament and deep location of the external iliac artery [26].

One randomized trial comparing arterial puncture, using palpation only with puncture using palpation and fluoroscopy, could not demonstrate an increase in the probability of arterial puncture over the femoral head, or the rate of successful CFA cannulation (85% in palpation group, 90% in palpation and fluoroscopy group; $p = 0.49$). Access was obtained faster in the palpation group (4.5 vs 5.6 min; $p < 0.001$) [11]. However, in this study (morbidly) obese patients and patients with a lack of palpable femoral pulses were excluded. There are probably two categories of patients that in fact might benefit most from fluoroscopically guided puncture; another study found that especially in obese patients, routine femoral fluoroscopy increases the likelihood of ideal needle placement [27].

With the use of fluoroscopy, the incidence of pseudoaneurysms or any other arterial injury can be reduced, while no difference in the occurrence of bleeding complications or an influence on the length of hospital stay can be observed [28].

An arterial entry site that is above the level of the most inferior border of the inferior epigastric artery in patients undergoing PCI was associated with 100% of all peritoneal bleeds ($p < 0.001$). By performing a femoral angiogram before the end of the procedure, patients can be risk-stratified, in order to avoid this (life-threatening) complication [1].

The third technique that can be adopted is ultrasound-guided puncture. With the use of ultrasound, the location of the CFA, femoral artery bifurcation and inferior epigastric arteries can be readily identified, and thus inadvertent high or low puncture can be avoided. In addition to this, ultrasound is able to identify arterial wall disease (atherosclerotic plaque, with or without calcification, and mural thrombus) that cannot be easily identified with angiography (especially when performed in an anterioposterior position). In this way, puncture of diseased areas or the side wall can be avoided, and this will reduce the risk of puncture site complications, especially when arterial closure devices are being used. Real-time monitoring of needle advancement in the subcutaneous tract, and intraluminal position of the needle tip can be confirmed, thus avoiding posterior wall puncture. It has been demonstrated that the incidence of pseudoaneurysm formation can be reduced significantly from 4.5% (in patients undergoing traditional palpation-guided vessel cannulation) to 2.6% when ultrasound guidance is used, mainly by avoiding inadvertent puncture of the external iliac artery, and superficial and deep femoral artery [29]. In a prospective evaluation of ultrasound-guided CFA puncture it was found that the ultrasound-guided technique reduces the time to puncture and the number of attempts in obese patients and patients with weak or absent pulses [30]. No significant change in local vascular complication rate was observed.

In cases of a so-called hostile groin, direct access of the superficial femoral artery can be considered, using ultrasound guidance. With the use of ultrasound the number of complications, fluoroscopy times and resulting radiation exposure can be reduced [31].

Finally, the use of a micropuncture set is recommended in difficult cases, offering the advantage of having a very small puncture hole in cases where the needle needs to be withdrawn, and a second puncture is made.

When using vascular closure devices, verifying that the puncture site is in the anterior wall at the level of the CFA is recommended, as well as excluding significant vascular disease at the site of access before deployment (Figure 2) [32]. This can be performed by fluoroscopy, angiography and/or road-map or by ultrasound evaluation. The primary determinant of the success of an arterial closure device remains the quality of the initial arterial puncture.

In determining whether an artery is suitable for a percutaneous arterial closure device, several factors are important. Patient-related risk factors (high-age, obesity, cachexia, diabetes, hypertension, female sex, steroid therapy and noncompliance with bed rest) and procedure-related factors (large sheath sizes, prolonged procedure time, high level of anticoagulation and puncture below the level of the CFA) are important to consider [3]. Regardless of the anticoagulation status of the patient the sealing of the arteriotomy must be carried out without compromising the arterial lumen.

■ Alternatives to femoral access

As an alternative to femoral access, approaches from either the radial or brachial artery have been proposed.

There is an increasing amount of data suggesting that the transradial approach is associated with less bleeding at the access site and other vascular complications when compared with procedures carried out through the femoral artery. The safety and efficacy of the transradial approach is demonstrated in the European registry of PCI in ST-elevation myocardial infarction (STEMI) [33].

The brachial artery is often used for coronary angiography. However, data on brachial access for aortic and peripheral intervention are limited. Brachial artery access is necessary for complex endovascular procedures and can be achieved in most patients safely. Postprocedural vigilance is warranted because most patients with complications will require operative correction [34,35].

However, in octogenarians, the radial approach for PCI is technically challenging for the operator and exposes patients to a greater volume of nephrotoxic contrast media. However, it results in early ambulation and significantly reduces vascular complications in this high-risk population [36,37].

Manual compression

Following percutaneous interventions with sheath size smaller than 8 Fr arterial puncture site hemostasis was traditionally achieved with manual compression directly over the arterial puncture site. With digital compression after removal of the indwelling catheter, the local hematoma remains confined and with normal coagulation parameters, will form a thrombus within minutes. The procedure requires 10–20 min of vigorous groin compression, which most patients considered the worst part of their procedure, since the most painful aspect is related to the manual adjustments of the compression. Patients are prescribed bed rest from 4 to 8 h to avoid complications. Noncompliance by the patient with lengthy immobilization may result in significant bleeding. Whilst effective in obtaining hemostasis, the extended immobilization (together with the reduction of venous flow by the presence of a compressive bandage) increases the risk for deep venous thrombosis. Overforceful compression may lead to acute arterial thrombosis, especially in patients with a (venous or synthetic) femoropopliteal bypass. This risk is probably elevated in patients who underwent percutaneous revascularization of infrainguinal arteries through an ipsilateral, antegrade approach. A pulse-oxymeter placed on the great toe during manual compression can be used to find the optimal compression force; the pressure applied should be enough to achieve hemostasis, and should not lead to complete disappearance of the distal pulses during compression (as can easily be monitored by using the pulse–oxymeter).

Manual compression remains an unappealing and unpopular part of the procedure for the operator and is also time consuming. Therefore, alternative ways of obtaining hemostasis have been developed.

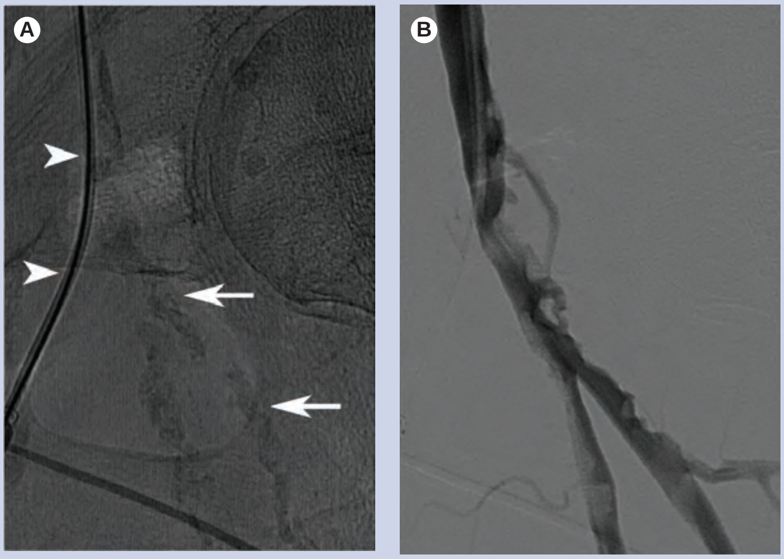

Figure 2. Severe calcification of the common femoral artery. (A) Fluoroscopic image showing 6 Fr introduction sheath (arrowheads) and extensive calcification of the common femoral artery, deep and superficial femoral arteries (arrows).
(B) Digital subtraction angiograph showing stenosis of the common femoral artery; in this case the use of a vascular closure device was considered inappropriate and manual compression was performed.

Vascular closure devices

Arterial closure devices can be classified into the following categories: external compression devices, external hemostatic patches, plug-mediated devices, suture-mediated devices and staple-mediated devices [3,38]. It is beyond the scope of this paper to discuss the characteristics of closure devices extensively.

Hands-free systems for compression are placed at the best site for compression with a fixed position. The system is less time consuming, at least for the operator, compared with manual compression. External hemostatic patches, which merely assist manual compression and speed up the time to clot, are not intended for use over 5–6 Fr.

Plug-mediated devices are based upon a collagen plug that initiates the coagulation cascade over the ateriotomy from within the percutaneous tract. Percutaneous suture- and staple-mediated closure devices use a mechanical delivery system to deploy vascular sutures/staples to appose the arterial walls. The use of plug-mediated, suture-mediated and staple-like devices is formally restricted to single-wall retrograde CFA punctures (closure devices will not address posterior wall puncture). Successful deployment has been reported after antegrade femoral procedures as well.

It has to be kept in mind that the instructions for use for all vascular closure devices require routine predeployment angiography, and some authors even extend this recommendation when hemostasis is to be obtained by manual compression [39]. Failure to document puncture site and the presence of arterial wall disease of the CFA predisposes to many of the complications reported for vascular closure devices [40].

Patient tolerance and pain experience are reportedly higher in subjects undergoing mechanical compression using external-compression devices [3]. The use of external-compression devices also results in an increased frequency of vagal reactions [41]. However, the use of external mechanical compression has been demonstrated to reduce the incidence of ultrasound-defined vascular complications (femoral artery thrombosis, echogenic hematoma, pseudoaneurysm and formation of arteriovenous fistulae) by approximately two-thirds [6], and allows for safe, immediate sheath removal after PCIs [42–44]. In one study, more bruising (as visible during physical examination) of the puncture site area was reported when using external compression devices, compared with manual compression [44].

Hemostatic external patches also allow for earlier ambulation, and can achieve hemostasis at a faster rate compared with manual compression, without an increase in complications. A high rate of technical failures (up to almost 20%) has to be anticipated though [45].

Differences between several systems have been reported [46], but no superiority of one device over another has been demonstrated [3,47]. With all devices (regardless of type), a significant reduction of time to hemostasis and time to ambulation and hospital discharge can be obtained [12,46,48–57]. The time to achieve hemostasis can be reduced to 17 min, while reduction of time to ambulation is 10.8 h [9,58]. Shorter time to ambulation, together with proper patient selection facilitates performing outpatient vascular interventions, even in cases where a larger size sheath was used [12,58,59].

However, with the use of arterial closure devices occurrence rates of false aneurysms (Figure 3) and arteriovenous fistulae are similar compared with manual compression [52,60], but the rate of hematoma formation and need for surgical repair are statistically significantly higher [60]. A shift from pseudoaneurysms to ischemic complications has been described [61].

Briefly, femoral closure devices have a higher overall risk profile than manual compression [37,62], although certain rare complications, such as retroperitoneal hemorrhage and severe access-site infection, may be more common with the use of these devices [63,64]. One study describes an increase in formation of hematoma, significant rebleeding or bleeding delaying hospital discharge compared with manual compression when using closure devices [65].

Three specific conditions described by Teh *et al.* remain problematic for suture-mediated device use and therefore preoperative radiological assessment of the ilio-femoral vessels and careful patient selection is required [66]. The presence of either significant arterial tortuousity or scarring from previous punctures tends to deflect the device's needles upon deployment causing closure failure. In addition, obese patients have a high incidence of failed hemostasis due to the technical difficulty in advancing the device's slipknots through the extended subcutaneous access canal. Cases involving any of these conditions had a higher frequency of femoral artery cutdown conversion (in case of large bore devices, e.g., stent graft and percutaneous valve repair) and device failures [66].

Complications

One study reported a higher success rate of obtaining hemostasis with manual compression compared with two types of arterial closure devices (AngioSeal™ and Perclose®) [67]. Mechanical failure of the arterial closure device contributes to this [68]. Device failure has been identified as an independent predictor of vascular complications [69]. The technical success rate for deployment of closure devices varies from 88 to 98% [50,70–72].

Women show a significantly increased risk of developing severe complications secondary to the application of a collagen-based arterial closure device and arterial clip closure, which is most probably related to the smaller arterial dimensions [73–75]. The incidence of the formation of a retroperitoneal hematoma is higher in patients with a low body surface area and in cases where the femoral puncture site has been relatively high (i.e., close to the inguinal ligament) [76]. This emphasizes the importance of choosing the right puncture site, even when using closure devices. It is therefore advised by some authors to perform femoral angiography prior to the deployment of arterial closure devices, and to deploy the device only in the CFA, preferably having an arterial diameter over 5 mm [12,73]. Severe circumferential calcification, greater than 50% stenosis of the CFA and elective surgical intervention at the ipsilateral femoral artery are considered additional contraindications for the use of closure devices [77]. Some devices, such as QuickSeal, require a minimum length of subcutaneous tissue tract (3–7.5 cm) [58]. In patients undergoing suture-mediated closure of the femoral arterial puncture, diabetes appears to be an independent predictor of the occurrence of

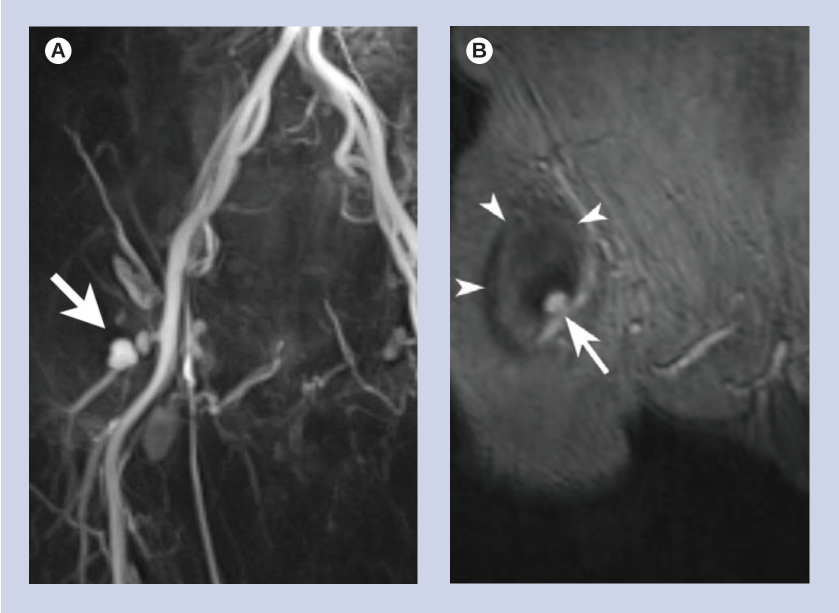

Figure 3. Pseudoaneurysm formation after puncture of the deep femoral artery. (A) Maximum intensity projection reconstruction of magnetic resonance angiography in a patient with swelling in the right groin after percutaneous coronary intervention; note the extravasation of contrast at the level of the right deep femoral artery (arrow). **(B)** Coronal image demonstrating extension of (partially thrombosed) pseudoaneurysm (arrowheads) to advantage, as well as origin of pseudoaneurysm from deep femoral artery (arrow); puncture site-related complication.

Figure 4. Occlusion of venous bypass after closure device. (A) Fluoroscopic image demonstrating presence of three clips after multiple percutaneous coronary interventions (Starclose; arrowheads) in a patient after femoropopliteal autologous venous bypass. **(B)** Digital subtraction angiograph at the same level indicating position of the clips in the deep femoral artery (arrow), femoral bifurcation (curved arrow) and proximal bypass (arrowhead), respectively; the latter has caused occlusion of the bypass; complication/failure due to puncture site error (location and diameter not compatible with use of closure device).

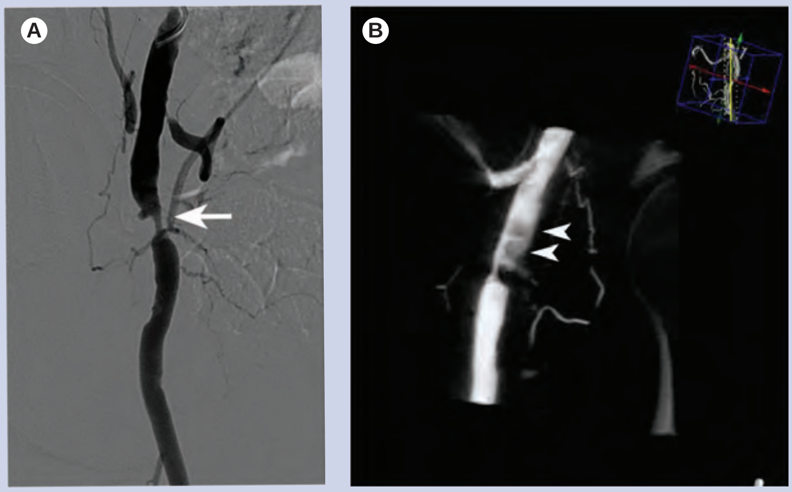

Figure 5. Stenosis of the common femoral artery after use of closure device. (A) Digital subtraction angiograph of a patient with pre-existing occlusion of the deep femoral arery; stenosis of the common femoral artery (arrow) after closure with AngioSeal device after percutaneous coronary intervention. **(B)** XperCT image in the same patient, demonstrating stenosis to advantage; note the presence of two protruding plaques just proximal of the stenosis (arrowheads); the anchor of the closure device has dissected the arterial wall during insertion; puncture site-related failure.

vascular complications, while age is a predictive factor for vascular complications when using the AngioSeal system [78].

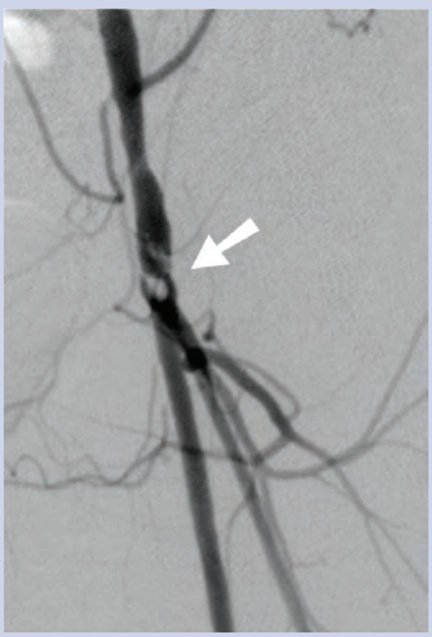

Figure 6. Stenosis of common femoral artery after use of closure device. Stenosis (arrow) at level of bifurcation of the left common femoral artery after suture-mediated closure device after percutaneous coronary intervention; puncture site-related complication.

Complications of vascular closure devices should be divided into those relating to the arterial puncture itself (most frequently to puncture site), and complications that are specifically related to the use of arterial closure devices. An overview of these complications is listed below, with guidelines to prevent.

A unique complication of closure devices that is hardly ever observed with manual compression is infection of the puncture site and closure device. The incidence has been reported to be as high as 9% [64,79,80]. Local infection, which can be fatal, has been described with the use of plug-mediated devices and with suture-mediated systems [81–84]. The most effective management strategy to deal with infectious complications is prevention [85]. In order to reduce the incidence of infection several measures can be taken: administration of prophylactic antibiotics, changing of gloves, repreparation of the puncture site and irrigation of the soft tissue tract with antibiotics [3]. One series with of over 1000 patients treated with a suture-mediated closure device reported absence of infection, when using a meticulous technique, comprising of resterilization of the access site, use of new draping and gloves [86].

Stenosis or occlusion occurring at the level of the puncture site has been described with the use of staple- and suture-mediated closure devices (Perclose) [87,88] and the AngioSeal-device (Figures 4–6) [68,84,88]. This complication appears to be more frequent after procedures where the superficial femoral artery was punctured (the superficial femoral artery being smaller in diameter, and thus more prone to device failure) [89]. Successful treatment with balloon angioplasty has been reported [87], but in case of intimal flap dissection that interacts with the posterior wall of the vessel owing to early deployment (operator error) of the device following suture-mediated closure devices, surgical repair may be warranted [88]. Occlusive problems after use of the AngioSeal device are usually caused by posterior wall dissection that is created during withdrawal of the anchor intraluminally, lifting up atherosclerotic plaques [90]. It is therefore advised by some authors to insert the device no more than 0.5 cm (instead of the 1–2 cm as described in the instructions for use) [77], or to refrain from closure device use in case of the presence of significant arterial wall disease. Another cause of occlusion, is puncture at the level of the CFA bifurcation [77].

Care should be taken when attempting percutaneous revascularization of a stenosis of the CFA after percutaneous closure using the AngioSeal devices, since embolization of the anchor of the AngioSeal device has been described [71]. Complete intraluminal placement of an AngioSeal closure device and Vasoseal has been described (to be considered operator error), and should be treated surgically by arteriotomy and embolectomy [85,88,90].

The presence of severely diseased femoral arteries seems to predispose to vessel occlusion [91]. When evaluating the CFA ultrasonographically after insertion of the AngioSeal device, it should be taken into consideration that the collagen plug and the polymer anchor can create an acoustic shadow, that might be mistakenly interpreted as a vascular occlusion [92].

Late femoral artery thrombosis has been reported with the use of the AngioSeal device [93], the thrombus occurring at the site of the anchor. Early thrombosis has been described using the Duett (caused by intravascular deposition of the thrombin component) and AngioSeal devices [80,94]. This condition can be successfully treated by catheter-directed local thrombolysis [95].

A femoral neuralgic syndrome caused by irritation of the anterior femoral cutaneous nerves is a rare condition that is related to the use of suture-mediated closure devices. Complaints can be relieved with nonsteroidal anti-inflammatory therapy [96].

Embolization (of part) of the closure device has been reported. Collagen plug embolization has been described using the (first generation) VasoSeal device, while using the AngioSeal device, the polymer anchor (that remains at the inner side of the vessel wall) has also been observed to embolize spontaneously [3,68,74]. Recently popliteal artery embolization with the Mynx closure device (an extravascular soluble plug-mediated closure device) has been reported [97]. However, a less frequent complication that always requires surgical intervention is retainment of (part of) the arterial closure device [79,85].

Arterial wall laceration (caused by pulling the anchor of the device through the attenuated wall of the CFA) leading to massive blood loss has been described with the use of the AngioSeal device [77]. In addition, incidental occurence of femoral endarteritis and lymphatic fistula has been reported [12,82,98].

A late complication after use of the AngioSeal device, which may lead to stenosis and or occlusion of the artery at the level of the puncture site is peri-arterial and intra-arterial fibrosis [77]. This extravascular scarring (periarterial inflammation) leading to vascular narrowing has also been observed in animal studies [99], and cannot be prevented.

Conclusion

The incidence of vascular access site complications can be reduced significantly by applying anatomical knowledge (using bony landmarks) during arterial puncture. In addition to this, image-guided determination of the puncture site can further reduce the occurrence of complications. A final means to reduce complications is strict adherence to the indications and contraindications of closure devices, confirmation of proper puncture site, ruling out vessel pathology by means of femoral angiography and/or ultrasound, and keeping in mind alternative approaches such as transradial access.

Future perspective

Femoral access-related problems will be reduced by applying anatomical knowledge, further development of closure devices and use of alternative arterial approaches such as radial access. New arterial closure devices should provide a better safety profile, high ease of use and cost–effectiveness.

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Executive summary

- Complications related to femoral arterial access are still a major concern in percutaneous peripheral and coronary interventions.
- The use of arterial closure devices has not reduced the incidence of access-related complications.
- Thorough knowledge of anatomy and use of image-assisted puncture (fluoroscopy and ultrasound), as well as use of alternative access sites (e.g., radial artery) can significantly reduce access-site complications.

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