European Heart Journal Supplements (2021) **23** (Supplement A), A10–A14
The Heart of the Matter
doi:10.1093/eurheartj/suab002

Managing vascular access and closure for percutaneous mechanical circulatory support

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KEYWORDS
Cardiogenic shock;
Mechanical circulatory support;
Vascular access;
Percutaneous;
Haemostasis

Even with current generation mechanical circulatory support (MCS) devices, vascular complications are still considerable risks in MCS that influence patients' recovery and survival. Hence, efforts are made to reduce vascular trauma and obtaining safe and adequate arterial access using state-of-the-art techniques is one of the most critical aspects for optimizing the outcomes and efficiency of percutaneous MCS. Femoral arterial access remains necessary for numerous large-bore access procedures and is most commonly used for MCS, whereas percutaneous axillary artery access is typically considered an alternative for the delivery of MCS, especially in patients with severe peripheral artery disease. This article will address the access, maintenance, closure and complication management of large-bore femoral access and concisely describe alternative access routes.

Introduction

Vascular access is an essential step for complex percutaneous interventional cardiology procedures. Obtaining safe and adequate arterial access using state-of-art techniques is one of the most critical aspects for optimizing outcomes and efficiency of percutaneous mechanical circulatory support (MCS). Bleeding and vascular complications continue to increase mortality in large-bore access procedures.[1,2] Femoral arterial access is most commonly used for MCS, whereas percutaneous axillary artery access is typically considered as an alternative for delivery of MCS, especially in patients with severe peripheral artery disease.[3,4] This article will address access, maintenance, closure and complication management of large-bore femoral access and concisely describe alternative access routes.

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Femoral access

In patients planned for procedures requiring large-bore access (e.g. elective high-risk percutaneous coronary intervention, transcatheter aortic valve replacement), preoperative assessment of the anatomy of the ilio-femoral axis using computed tomography (CT) angiography is routinely employed and enables proper selection of the arteriotomy site. On the other hand, patients who present to the catheterization laboratory with cardiogenic shock may require immediate large-bore access for MCS without prior knowledge of the anatomy, extent of atherosclerosis or tortuosity of the ilio-femoral arteries, and most clinics do not perform CT angiography if the indication for Impella devices is a high-risk coronary intervention.

Puncture technique and safe access

For safe femoral access, contemporary access techniques include a combination of fluoroscopy, femoral angiography, and ultrasound.[5-7] Successful and safe large-bore femoral

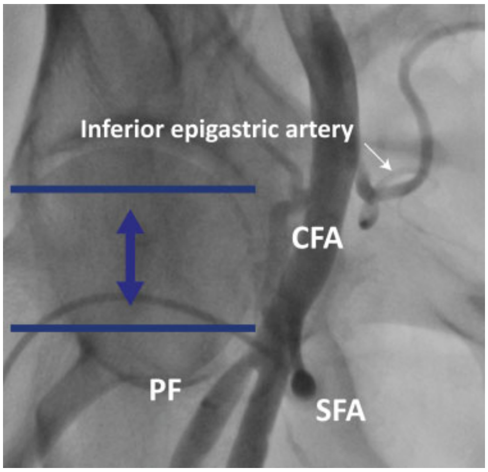

Figure 1 Angiographic course and anatomy of the femoral region. CFA, common femoral artery; PF, profunda femoris artery; SFA, superficial femoral artery.

access is ensured by a single anterior puncture of the common femoral artery (CFA), avoiding areas of calcification and high (above the level of the inferior epigastric artery) and low (superficial or profunda femoral artery) sticks. Fluoroscopy-guided femoral access requires the identification of anatomic landmarks using fluoroscopy and palpation of the femoral pulse (*Figure 1*). A haemostat may be placed on the body surface as a reference to identify the puncture zone of the femoral head. Familiarity with the anatomy of the femoral artery is important for safe vascular access as well as the anticipation and management of complications. For patients with difficult access or who are at high risk for vascular complications, ultrasound-guided access may help to obtain optimal access with fewer complications.[6] Ultrasound readily identifies the CFA bifurcation, the presence of severe atherosclerosis and the vessel diameter (*Figure 2A and B*).[8] Furthermore, ultrasound-guided access enables central cannulation of the artery and therefore provides good preparation for the later application of vascular closure devices.

Surgical axillary artery access

The placement of Impella 5.0 or 5.5 requires surgical access and the use of an 8 or 10 mm graft to place the 21-Fr devices. In stable INTERMACS II or III patients, an angio CT scan is recommended to exclude subclavian stenosis (*Figure 3A*). Intraoperatively, the axillary artery is exposed via an incision below and parallel to the clavicle, and surgical loops are placed around the vessel. After heparinization, a tangential vascular clamp is applied, and the graft is anastomosed preferentially at a 45° angle to facilitate easier introduction of the Impella device (*Figure 3B*). After placement of Impella, the graft is shortened, and the repositioning sheet is introduced in the graft and fixated by ligation. During this period, the axillary artery is occluded by proximal and distal vessel loops to prevent bleeding. To prevent infections during longer support, the graft should be shortened below the skin level. The blue wings of the sheet are therefore fixed to the fascia with non-resorbable

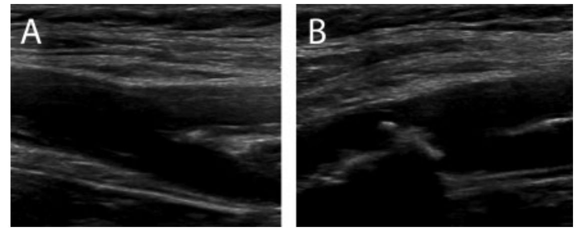

Figure 2 (*A*) Longitudinal ultrasound image at the level of the common femoral artery bifurcation. The longitudinal view enables continuous visualization of the needle during advancement towards the artery and ensures needle entry superior to the femoral bifurcation. (*B*) Longitudinal ultrasound image at the level of the common femoral artery bifurcation with severe stenosis. Large-bore access at this site carries a high risk of failure, dissection, and limb ischaemia.

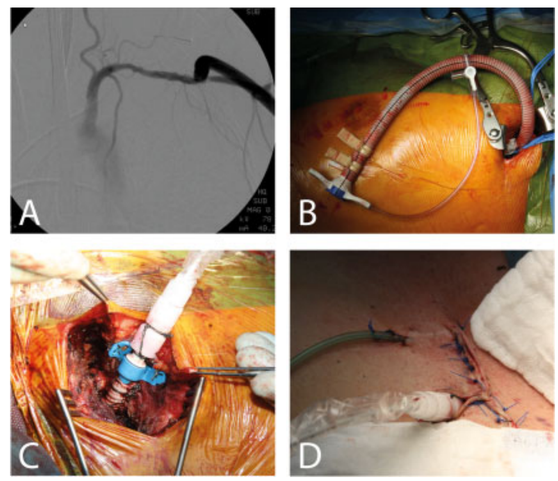

Figure 3 Surgical axillary access (*A*) an angio computed tomography scan is recommended to exclude subclavian stenosis. (*B*) Graft positioning after anastomosis. (*C*) Graft shortened and sutured after insertion of the Impella. (*D*) Fixation and wound closure.

sutures (*Figure 3C*). The Thouy-Borst connector is secured with additional ligation to prevent disconnection. A T-shaped incision facilitates the optimal position of the sheet in relation to the graft (*Figure 3D*). Furthermore, fixation at the skin should be conducted compared to driveline fixation in left ventricular assist device patients.

Equipment removal and haemostasis

Removal of the MCS devices and large-bore arterial sheets requires meticulous techniques to prevent vascular complications and to preserve vessel patency. Removal of equipment and haemostasis may be achieved with manual compression. However, for large-bore arterial access, manual compression is time-consuming, strenuous and challenging in the control of access-site bleeding. In these cases, compression devices such as the FemoStop^{TM} (St. Jude Medical) may be used (*Figure 4*). The transparent pneumatic dome is placed slightly proximal to the arteriotomy site before removal of the large-bore sheath. The compression device is held in place with a belt wrapped and tightened around the supine patient. For equipment removal, according to our institutional protocol, the

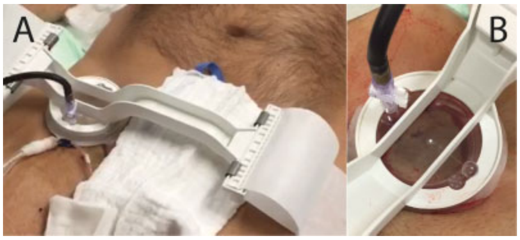

Figure 4 FemoStop™ (St. Jude Medical). (*A*) The transparent pneumatic dome is placed slightly proximal to the arteriotomy site before removal of the mechanical circulatory support device. A belt is wrapped and tightened around the supine patient, holding the rigid frame and pneumatic dome in place. (*B*) During compression, the arteriotomy site can be monitored for bleeding through the transparent dome.

pneumatic dome is inflated to approximately 60–80 mmHg. Then, the sheath is removed while keeping the rigid frame of the compression device in place to avoid any shifting away from the pneumatic dome. The pneumatic dome is then inflated to approximately 20 mmHg higher than the systolic blood pressure of the patient for 20 min for initial haemostasis. Afterwards, the pneumatic dome is deflated to the mean arterial blood pressure of the patient for another 20 min. Then, the pneumatic dome is deflated to 30–40 mmHg for another 20 min. During the compression period, the patient is monitored for bleeding, distal limb perfusion, and excess pain at the compression site.

In patients with a high bleeding risk (extensive vessel calcification or tortuosity), the dry closure technique with a crossover balloon may be used to achieve haemostasis.[9] In brief, from the contralateral CFA, a wire is advanced distal to the large bore arteriotomy site in the superficial femoral artery. Then, after exchanging a 45 for a 55 cm 7-Fr sheath, a balloon is advanced to the contralateral external iliac artery (*Figure 5*). The size of the balloon depends on the diameter of the iliac artery (usually 8–9 mm × 40 mm as estimated by the iliac angiogram). The large-bore sheath is then retracted distal to the distal iliac artery/CFA. The balloon is inflated to temporally occlude the iliac artery (usually 4–6 atm pressure), and the sheath is extracted while simultaneously applying manual pressure on the arteriotomy site. Prolonged balloon inflation (up to 30 min) may be necessary to achieve full haemostasis. If bleeding persists, implantation of a covered stent or surgical repair should be considered.

For patients supported with MCS for cardiogenic shock who require delayed haemostasis, deployment of suture-based vascular (pre)closure devices is, in our view, not ideal since sterility of the closure system is difficult to ensure over days and the duration of support and time for recovery are difficult to predict. On the other hand, dedicated large-bore closure devices are gaining popularity and may offer solutions when delayed haemostasis is required. The available devices are the collagen-based Manta®, patch-based PerQseal® and membrane-based InSeal® devices.[10–12] The current generation of sheets for femoral Impella implantation provides a side arm, which allows the introduction of a 0.0035 wire. This can guide vascular closure devices such as the Manta system after Impella and sheet removal. In this situation, depth measurement is not possible; therefore, the implantation

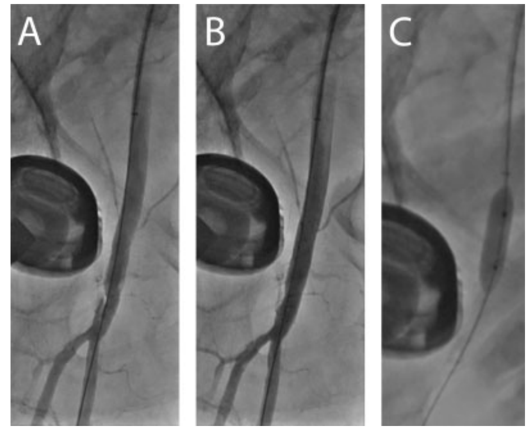

Figure 5 Dry closure technique for large-bore access with a crossover balloon.

depth will rely on the user's experience. In most cases, an implantation depth of 5.5 cm is sufficient.

Complications and management

Access-site bleeding

Minor bleeding from the access site or small haematomas is often observed in patients supported with MCS for cardiogenic shock. During MCS support, patients receive therapeutic anticoagulation with heparin and, commonly, dual antiplatelet therapy, increasing the risk of bleeding. These minor complications are usually stabilized and resolved by avoiding 'over-anticoagulation' and maintaining the coagulation parameters in the appropriate range. On the other hand, major bleeding and large haematomas require immediate management with endovascular crossover balloon tamponade to prevent further extravasation. Bleeding is controlled with balloon inflation to cover the perforation placement of a covered stent or if vascular surgery is indicated (*Figure 6*).

Limb ischaemia

In the setting of large-bore access, close and careful monitoring for acute limb ischaemia is essential. Limb ischaemia is typically multifactorial: large vessel atherosclerosis with a variable combination of local arterial plaque breakup or localized intima flaps due to Impella implantation, profound vasoconstriction due to endogenous and exogenous catecholamines, low arterial to venous perfusion pressure gradients, and, potentially, although not well studied in the context of device therapy, concomitant drugs that interfere with the physiologic regulation of micro-perfusion, such as adrenergic vasoconstrictors and prostaglandin synthesis inhibitors. Often, the trigger of acute limb ischaemia is complete vessel occlusion by the large-bore sheath, dissection or peripheral embolism. Ischaemia typically manifests as pain, changes in skin appearance ('mottling', paleness), loss of pulse and prolongation of the recapillarization time upon manual compression of a toe. Clinical evaluation of limb perfusion includes palpation of pedal pulses and Doppler studies. Moreover, laboratory tests should include creatinine kinase, myoglobulin, and

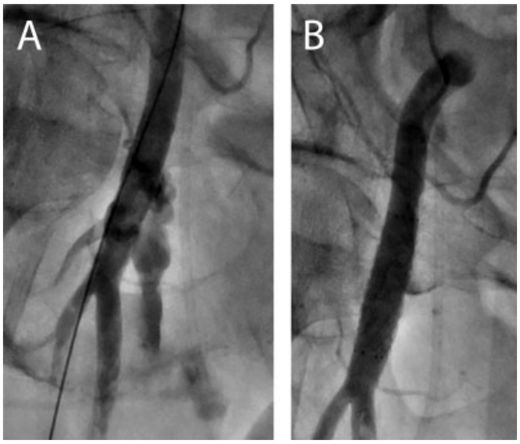

Figure 6 Bleeding from the common femoral artery after large-bore access (*A*). Percutaneous repair with contralateral access and implantation of a covered stent (*B*).

lactate for monitoring limb ischaemia. Precipitating and cofactors should be eliminated if possible. Acute limb ischaemia is commonly due to complete vessel occlusion by the large-bore sheath, dissection or peripheral embolism. In the settings of occlusive large-bore sheath or dissection, femoral to femoral bypass circuits may improve distal limb perfusion.[13] However, if limb ischaemia persists despite the circuit, complete angiography of the arteriotomy site from contralateral access should be performed. If the large-bore sheath is occluded or the vessel is dissected, extraction of the large-bore sheath with simultaneous percutaneous or surgical repair should be considered.

Pseudoaneurysms

Pseudoaneurysms after large-bore access are detected clinically as a pulsatile mass with a bruit on auscultation. The diagnosis is then confirmed by ultrasonography. Small pseudoaneurysms are best managed with ultrasound-guided percutaneous thrombin injection or prolonged compression (up to 30 min) with an ultrasound head that allows compression and imaging at the same time, using local (e.g. lidocaine) and systemic (e.g. an opiate) analgesia prior to compression to optimize patient experience and outcome. Large pseudoaneurysms and those with a wide neck are often an indication for surgery due to the risk of distal embolization of the injected thrombin.

Alternative access routes

Patients with severe systemic atherosclerosis, particularly aorto-ilio-femoral atherosclerosis, are a challenge for all mechanical support devices. Preferred haemodynamic support management depends on several factors: the need for a device to maintain life, the urgency of the presentation, the experience of the operator, the availability of vascular and/or cardiothoracic surgeons, and the range of support devices available in-house. If the indication to implant an Impella device is difficult, the following options have been reported by experienced Impella users:

- Femoral implantation through a calcified femoro-iliac axis using a long sheath: Depending on the Impella model, the introducer sheath may not extend beyond the narrowest vessel location. Crossing the stenosis by a long Abiomed or Cook 14F sheath may enable crossing of the stenosis with the Impella pump head, and the small diameter of the Impella shaft may leave the arterial axis unobstructed and leg perfusion maintained after sheath removal (in the case of the Abiomed sheath).
- Femoral implantation after preparation of the iliac artery using balloon angioplasty with optional stenting. This option may guarantee access and minimize the risk of leg ischaemia, but it requires experience in iliac artery angioplasty by the interventional cardiologist or an interventional radiology colleague. Using a long introducer sheath may facilitate advancing the Impella device through the freshly implanted stent.
- Axillary percutaneous implantation using ultrasound-guided access is possible and requires experience, the availability of suitable material, and a plan for removing the Impella device after successful therapy.
- Surgical axillary or subclavian implantation is an option, particularly if a large Impella device is to be used or if a prolonged support duration is envisaged.
- The supraclavicular approach is a last-resort access option if the aortoiliac axis is not feasible, e.g. due to abdominal aortic occlusion, and the haemodynamic condition of the patient does not allow the time for axillary percutaneous or surgical access. The artery can be easily located by palpation or ultrasound. Damage to the brachial plexus is a theoretical concern, so the indication should be well considered, the non-dominant arm of the patient chosen, and the scalpel only used for a superficial skin incision.

Conclusions

With recent advancements in interventional cardiology techniques, more complex procedures, including MCS, are being performed percutaneously. Hence, large bore vascular access has become increasingly prevalent with the emergence of such interventions with femoral access being the most commonly employed access site, whereas the axillary artery is typically considered an alternative, especially in patients with severe peripheral artery disease. Obtaining safe vascular access and closure is critical and essential to optimize outcomes and efficiency of percutaneous MCS, since bleeding and vascular complications continue to increase mortality in large-bore access procedures.[1] The combination of utilization of ultrasound and fluoroscopy guidance, along with advanced imaging (typically CT angiography) leads to safer large bore access in most patients. Removal of the MCS devices and large-bore arterial sheets requires also meticulous techniques to prevent vascular complications and to preserve vessel patency.[9,13] Complications attributed to large-bore access include access-site bleeding, retroperitoneal haemorrhage, vascular perforation, limb ischaemia, and pseudoaneurysms. Operators who perform procedures requiring large-bore vascular access should be familiar with access-related complications, their diagnosis, and management.

Acknowledgements

This manuscript is one of eight manuscripts published as a Supplement to address patient management and mechanical circulatory support in the ICU.

Funding

This work has been supported by the Abiomed Europe GmbH to cover publication costs as well as professional language editing of each manuscript. No individual fees were paid to the authors in the generation of this publication. This paper was published as part of a supplement financially supported by Abiomed GmbH.

Conflict of interest: K.K. and P.H. report personal fees from ABIOMED, outside the submitted work. D.S. served as a consultant for Abiomed, Abbott, and LivaNova.

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