PART 6

PERCUTANEOUS CIRCULATORY SUPPORT: VASCULAR SITE ACCESS

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Key messages

- The anatomical features of the vessels and the vascular status play a decisive role in the selection of the appropriate percutaneous Ventricle Assist Device.
- The prevalence of vascular complications remains high and is associated with higher in-hospital costs and higher mortality.
- The implementation of strategies for device selection, implantation procedure and complication management is essential to optimize the outcomes.
- Early pre- procedural recognition of severe PAD and anatomical abnormalities is crucial in determining the most appropriate vascular access. Imaging modalities such as ultrasound, angiography, and if possible, CT or MR angiography are useful to avoid complications and should be implemented.
- Consider alternative accesses (trans-axillar, trans-subclavian or trans-caval) for patients with severe PAD where trans-femoral access is classified as high risk.
- Consider surgical access.
- Involve cardiac/vascular surgeons into decision-making in complex cases.
- It is recommended to combine ultrasound and fluoroscopy to guide the trans-femoral procedures.
- Perform micropuncture technique under angiography before sheath upsizing.
- Ensure limb perfusion and the absence of vascular complications with angiography at the end of the procedure.
- Define standard operating procedures for an appropriate ICU management.
- Consider the use of closure systems to minimize the bleeding risk after device explantation.

Executive summary

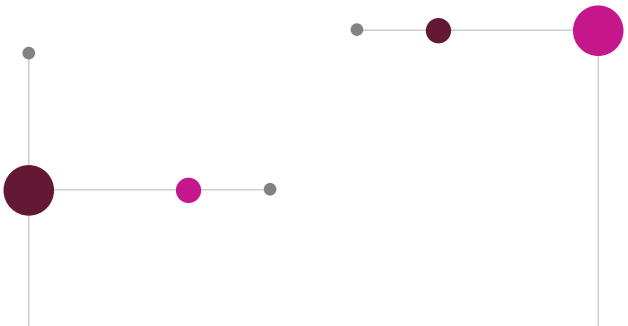
The use of pVADs has increased over the last years, with a wide spectrum of applications ranging from high-risk PCI to severe cardiogenic shock. These devices provide support to the left, the right or both ventricles over a limited amount of time (days to weeks), with the aim of hemodynamic stabilization, early catecholamine weaning and, to some extent, ventricular decompression or unloading.

However, pVADs are bulky devices and may require large bore vascular access, eventually resulting in vascular complications that are associated with higher in-hospital costs and potentially higher mortality. Major factors determining vascular complication rates are related to the center/operator experience, type of pVADs, as well as to the site of vascular access.

The implementation of SOPs for device selection, implantation procedure and complication management is critical to reduce the risk of vascular complications. In line with this, a successful pre-implantation strategy includes an extensive physical and imaging-based examination of peripheral vasculature to estimate the procedural risk.

Alternative accesses (trans-axillar, trans-subclavian or trans-caval) should be considered for patients with severe PAD, where trans-femoral access is classified as high risk. The use of closure systems after device explantation owns an added value in reducing bleeding risk.

In this chapter, we will discuss most common vascular site access for LV and RV support, describing the most important features related to different anatomical sites, while listing potential complications and strategies to reduce their risk.



1 - VASCULAR ACCESS FOR IMPLANTATION OF IABP AND OF COMMON PVADS FOR LV SUPPORT

1.1 - IABP

An IABP has 7.5 Fr size and is delivered over a guidewire either through an 8-9 Fr sheath or without a sheath. The trans-femoral approach is the most widespread, while in cases of severe PAD, small femoral arteries or thoracic and abdominal aortic aneurysms, as well as type B aortic dissections, the device can also be inserted through an axillary or subclavian artery ***(Figure 3 shows an axillary graft)***. Combination of fluoroscopy and ultrasound is recommended for the insertion.

1.2 - Impella® axial pumps

The most common vascular access for Impella® 2.5 and CP is percutaneously trans-femoral, whereas for Impella® 5.0 and the axillary access is necessary. For Impella® 5.0, additionally access via the arteria femoralis is possible. For both pumps the surgical approach with 10 mm vascular graft anastomosed to the artery is required.

While the trans-femoral access for the use of Impella® 2.5 or CP is routinely performed in the cath-lab, the axillary and femoral access of the Impella® 5.0 / 5.5 requires a surgical cut-down approach with an end-to-side 10 mm vascular graft anastomosis to the artery. This surgical axillary access for Impella® 5.0 / 5.5 is preferred for better mobilization of the patient, especially for the PROPELLA concept in inflammatory cardiomyopathy.

Using the femoral artery access for the Impella® 2.5 or CP, the device is delivered through a peel-away sheath introducer, which at the end of insertion is removed. The Impella® 2.5 or Impella® CP are fixated over a 9 Fr or 10 Fr conical sheath (so called repositioning sheath), respectively. A stepwise approach is recommended in order to avoid vascular site complications. ***Figure 1 and Figure 2*** show a fluoroscopic as well as sonographic-guided implantation of an Impella® axial pump in the clinical routine at our institution.

Table 1 - Major characteristics of vascular access for the most common LV and RV pVADs

	LV Assist Devices							
Devices	**IABP**	**Impella 2.5**	**Impella CP**	**Impella 5.0**	**Impella 5.5**	**iVAC 2L/ VAC 3L**	**Tandem Heart**	
Canula size	-	-	-	-	-	17 Fr / 21 Fr	Inflow 21 Fr Outflow 17 Fr	
Necessary sheath size	8 Fr (or 7 Fr for sheathless)	13 Fr	14 Fr	23 Fr	23 Fr	18 Fr / 23 Fr	-	
Pump size	-	12 Fr	14 Fr	21 Fr	18 Fr	-	-	
Canula geometry	Straight	Curved with pigtail			Curved	Straight	Inflow angled Outflow straight	
Insertion method	Percutaneous			Cut down via graft		Percutaneous		
Guidewire size	0.025"	0.018"	0.018"	0.025"	0.025"	0.035"	0.025"	
Access vessel diameter	≥5mm	≥6mm	≥6mm	≥7mm	≥7mm	≥6-7mm	≥6mm	

	LV and RV Assist Device	RV Assist Devices	
	Peripheral VA- ECLS	**Impella RP**	**RV Tandem Heart: RA-PA ECLS**
	Inflow 21-25 Fr Outflow 15-19 Fr	-	Inflow 21-25 Fr Outflow 17-21 Fr Alternativ: Protekt Duo dual-lumen cannula 29 Fr or 31 Fr
	-	23 Fr	-
	-	21 Fr	-
	Straight	Curved, pigtail	Straight
	-	Percutaneous	-
	0.035"	0.025"	0.035"
	≥6mm	≥6mm	-

Figure 1 - Imaging-guided implantation of Impella® axial pumps (1)

A - Ultrasound-guided femoral puncture. **B -** Ultrasound visualization of femoral artery bifurcation. **C -** Ultrasound-guided puncture of the femoral artery anterior wall (red arrow indicating the tip of the needle). **D -** Angiographic confirmation of proper 6 Fr sheath position (blue circle for the target area of puncture) before sheath upsizing. SFA superficial femoral artery, DFA deep femoral artery, CFV common femoral vein, CFA common femoral artery.

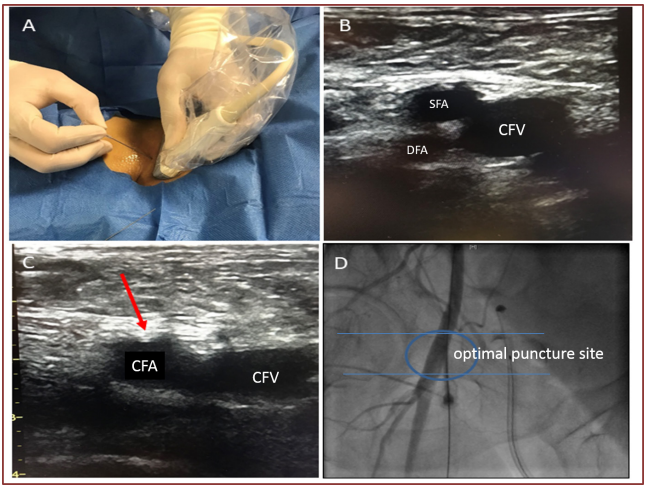
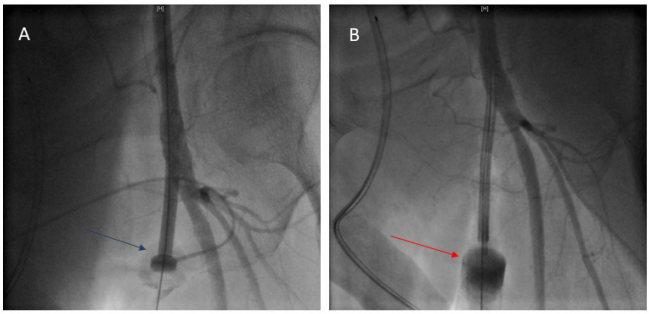


Figure 2 - Imaging-guided implantation of Impella axial pumps (2)

A - Angiographic visualization after upsizing with a 14 Fr. Impella® peel-away sheath (blue arrow). **B -** Contrast-dye application via 10 Fr repositioning sheath´s side port (red arrow represents the Tuohy-adapter). **A and B** show efficient antegrade limb perfusion after an Impella® sheath insertion.



1.3 - Peripheral VA-ECLS

The inflow venous cannula (variably sized between 21 Fr (max. 5 l/min blood flow) and 25 Fr (up to 8 l/min blood flow)) is inserted into the right atrium via a femoral or via an internal jugular vein. The outflow cannula (return cannula, sized between 15 Fr (maximal 4.0 l/min blood flow) and 19 Fr (up to 8 l/min blood flow)) is placed into the femoral artery. An axillary access is only possibly via a surgical approach (open cut-down with direct insertion or through and end-to-side anastomosed vascular graft). The latter approach offers a lower risk of limb ischemia as well as a safer cerebral oxygenation (avoids Harlequin syndrome) and allows an early mobilization of patients. However, the axillary approach is more time-consuming and is difficult to install during CPR and is recommended if femoral access is not possible or prolonged support is scheduled. As an alternative, central cannulation after median (partial) sternotomy may be considered.

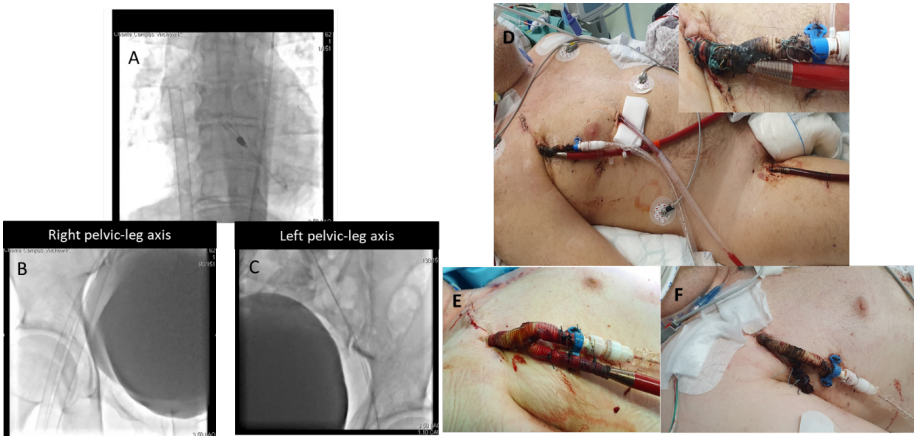
The femoral artery is the most commonly used vascular site, as the anatomical landmarks are easier to be identified ***(Figure 1)***. It is therefore suitable for quick implantation in hemodynamically unstable patients. Depending on the individual patient and local experience, implantation of the outflow cannula can be performed using the "Seldinger" technique under ultrasound and fluoroscopic guidance or in combination of an open cut-down and "Seldinger" or with graft anastomosed end-to-side graft to the artery. In case of percutaneous or direct puncture of the femoral artery, the perfusion of the lower limb is compromised due to partial or in some cases, total occlusion of the femoral artery. The adequate perfusion of the lower limb may be maintained with a 6-8 Fr cannula, inserted distal of the outflow cannula.

Combination of Impella® and VA-ECLS (concept of ECMELLA) provides unloading of the RV and reduces blood flow through lungs and oxygenation, while Impella® unloads the LV, avoiding lung oedema and facilitating LV recovery. Usually, ECLS and Impella® CP are inserted through left and right femoral arteries ***(Figure 2 A-C)***. If there is a need for a central a.v.-ECLS, the surgically applied axillary graft, which acts as an access for Impella® 5.0 / 5.5, can also be used to insert the arterial cannula of an ECLS without surgical thoracotomy. The so-called modification ECMELLA 2.0 "single arterial access" has first been described by E. Potapov (Annals of Thoracic Surgery, 2020) ***(Figure 2 D-E)***. In this modification, the axillary artery is prepared, and a vascular 10 mm graft is connected as described above for implantation of Impella® 5.0 / 5.5. The arterial cannula (15-19 Fr) of ECLS is directly inserted into the vascular graft ***(Figure 2 D, E)*** or into a side branch, anastomosed before surgery on the back table. The venous cannula (21-25 Fr) of ECLS is inserted into the femoral ***(Figure 2 D)*** or jugular vein via the "Seldinger technique". De-escalation of Impella® is possible after

stabilization of the respiratory and RV function and circulatory stabilization of the patient, while stepwise reduction of the ECLS blood flow. The arterial cannula may be removed bedside from the vascular graft, which is tunneled outside of the body and the venous cannula removed and the puncture manually compressed, as usual.

Figure 3 - Ecmella concept

A to C - Classical ECMELLA concept: Implanted Impella® CP via left **(C)** and VA-ECLS via right femoral arteria and right femoral vein **(B)** with positioned venous inflow cannula in the right atrium **(A)** and located Impella® CP in the left ventricle **(A). D to F -** ECMELLA 2.0 "single arterial access": Via a 10 mm graft inserted Impella® 5.0 and also an arterial outflow 17 Fr cannula of a VA-ECLS. In **D** also positioned a femoral located venous inflow 23 Fr cannula of the VA-ECLS. **F -** After circulatory stabilization, the VA-ECLS outflow cannula has been removed and the side branch access of the graft has been ligated. An Impella® 5.0 is still in place for further LV unloading.



1.4 - Percutaneous continuous centrifugal LVAD TandemHeart®

The cannulation system is in this case comparable to what has been described above for VA-ECLS. A 21 Fr inflow cannula is inserted via the right femoral vein, and then advanced into the left atrium via a trans-septal puncture. The outflow cannula is usually 15-19 Fr inserted into the common femoral artery.

1.5 - PulseCath iVAC 2L®

The PulseCath iVAC 2L® requires a 18 Fr sheath, which is inserted in the femoral artery. The catheter can then be advanced with the distal tip into the LV cavity under echocardiographyc or fluoroscopic guidance. For more hemodynamically support a 3L system is also already existing.

1.6 - PulseCath iVAC 3L®

The iVAC 3L is a sheathless 21 Fr cannula, which is inserted with surgical cut-down via vascular graft to the artery using a standard end-to-side anastomosis (similar procedure/access as for the Impella® 5.0/5.5 ***(See 1.2)***. The catheter can then be advanced with the distal tip into the LV cavity under echocardiographyc or fluoroscopic guidance.

2 - VASCULAR ACCESS FOR IMPLANTATION OF PRVAD'S FOR RV SUPPORT

2.1 - Impella® RP

Through a 23 Fr venous peel-away sheath, a 21 Fr Impella® RP mounted onto an 11 Fr catheter is placed from the right atrium into the pulmonary artery via the right femoral vein. The peel away sheath is replaced with a staged 11 Fr repositioning sheath.

2.2 - PROTEKDuo™

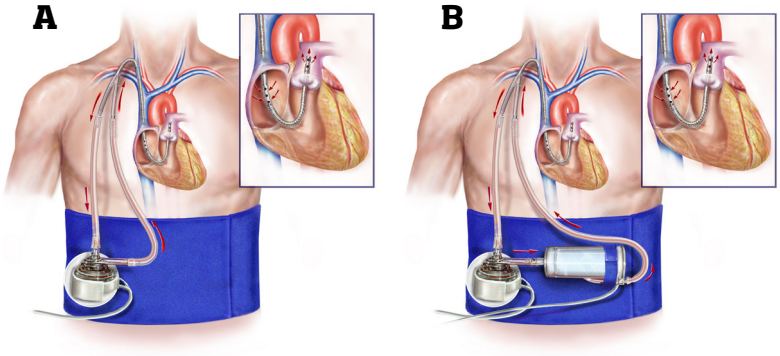
A single 29 or 31 Fr dual-lumen cannula, which is inserted in the right jugular vein. The cannula can then be advanced with the distal outflow tip across the pulmonary valve into the main PA. The blood is drained at the RA in the second lumen of the cannula ***(Figure 4a)***.

2.3 - RA-PA ECLS

A 21-25 Fr inflow cannula is inserted via a femoral vein in the RA, and a 17-21 Fr outflow cannula is inserted into the main PA via another femoral vein or via the right internal jugular vein under fluoroscopic guidance. Additionally, an oxygenator may be placed to support lung function (oxyRVAD). The abovementioned dual lumen cannula with 29 Fr (max 4.5 l/min) or 31 Fr (max 5.0 l/min) (PROTEKDuo™) can be placed into the pulmonary artery (distal lumen, outflow) via the right internal jugular vein under fluoroscopic control. The proximal opening (inflow) of this cannula remains in the RA. Additionally, an oxygenator may be placed to support lung function (oxyRVAD-Dual) also named as TandemLung™. For mobilization, this total system can be fixed at the patient with a vest ***(Figure 4b)***.

Figure 4 - PROTEKDuo dual-lumen cannulation

Schematic representation of the **A -** PROTEKDuo dual-lumen cannula, which is inserted through the right jugular vein and advanced into the pulmonary artery for right ventricular unloading. **B -** Additionally, an oxygenator may be inserted to support lung function (RA-PA ECLS).



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3 - ACCESS SITES

3.1 - Most commonly used vascular access sites

VADs are bulky devices mostly requiring a vascular access of a size above 10 Fr. Access site complications may hamper patient outcome. The most common used access sites are the femoral artery and the axillary artery. ***Table 2*** summarizes major advantages and disadvantages of both approaches. In summary, as the anatomical landmarks are easier to be identified, the femoral artery is the most commonly used access. However, the axillary approach allows an early mobilization of the patient and offers a lower risk of limb ischemia as well as access site infection.

Table 2 - Major advantages and disadvantages of the femoral and axillary approach

+ rare, ++ often, +++ very often.

	Femoral	Axillary
Patient mobilisation	-	++
Access site infection	++	+
Limb ischemia	+++	+
Requiring surgical approach	+/-	+++
Access site bleeding	+	+++
Time for implantation	+	+++

3.2 - Alternative vascular access sites

3.2.1 - Trans-caval access

The trans-caval access is an alternative access for patients with severe femoral-iliac arterial vascular disease or patients with small sized vessels. After access via a femoral vein into the IVC follow a cross over into the abdominal aorta. The technique is based on the high compliance of the ilio-femoral veins, on the proximity of the IVC and abdominal aorta, and on the fact that any bleeding from the artery can decompress directly into the adjacent low-pressure vein. For the closure of the aorto-caval, communication cardiac occluders can be used.

3.2.2 - Mechanical circulatory support delivery using intravascular lithotripsy

In patients with severe calcified femoral-iliac arterial disease, a pre-procedural intravascular lithotripsy may facilitate a safely trans-femoral access and delivery of MCS devices. As only one series of a few cases has been published, this strategy should be further evaluated.

In summary, depending on individual anatomical features, patients' characteristics and local expertise, tailored approaches for pVAD implantation are available. In ***Table 3***, main technical considerations of both percutaneous as well as surgical approaches are listed.

Table 3 - Technical considerations for percutaneous vs. surgical VAD implantation

Technical considerations for peripheral VAD implantation		
Technique	**Percutaneous**	**Surgical**
Pre procedure	• Perform pre procedure CT angiography if feasible. • Perform artery duplex / ultrasound in order to evaluate the vessel anatomy, the diameter and grad of calcification of the vessel. • Assess the bleeding risk and ischemic risk. • Indentify possible coagulations disorders.	• Perform pre procedure CT angiography if feasible. • Perform artery duplex / ultrasound in order to evaluate the vessel anatomy, the diameter and grad of calcification of the vessel. • Assess the bleeding risk and ischemic risk. • Indentify possible coagulations disorders.
Intraprocedural	• Locate the anatomical landmarks through physical examination, fluoroscopy and ultrasound. • Locate the "optimal zone" for puncture. • Perform ultrasound guided puncture in order to confirm a single puncture through the anterior wall. • Access angle < 45°. • Use micropuncture technique. • Advance the wire under fluoroscopic guidance avoiding inappropriate engagement. • Perform ipsilateral angiography (30°) through micropuncture sheath. • Before sheath upsizing perform angiography and if possible preclose before upsizing. • In case of total occlusion distal from the inserted sheath: to have a reperfusion strategy.	• Locate the anatomical landmarks through physical examination, fluoroscopy and ultrasound. • Locate the "optimal zone" for puncture. • Direct punction, outlet of canulas through skin outside of incision if appropriate and if longer support is anticipated. • Distal limp perfusion should be <u>always</u> inserted. • If appropriate, use special cannula with distal limb perfusion lumen. • If appropriate, use grafts with a diameter from 8 – 10 mm in attached end to side surgical technic to avoid peripheral / limb ischemia.
Closure management	• Implement a closure strategy (suture or not suture-based techniques) depending on local expertise and anatomical conditions. • If puncture was traumatic implement "dry closure" technique with simultaneous angiography. • Perform a post-closure angiography from a second access site in case of suspected bleeding. • Optimization of coagulation. • Control hypertension.	• Implement a closure strategy (suture or not suture-based techniques) depending on expertise. • Close the wound. • Surgical removal is obligate. • Consider patch repair after cannula removal in severe calcified arteries.

4 - VASCULAR ACCESS SITE COMPLICATIONS

Vascular complications are linked to increased morbidity and mortality in patients undergoing VADs implantation. Identification of risk factors for prediction of vascular complications is a critical issue of the percutaneous circulatory support.

The main risk factors for vascular site complications after MCS implantation are summarized in ***Table 4*** and include age, severe peripheral artery disease, diabetes mellitus, hypertension, and factors related with the implantation procedure.

Table 4 - Main risk factors for vascular site complications after MCS implantation

Risk factors for vascular complications	
Clinical characteristics	**Procedural factors**
Older age	Large bore arterial sheath
Female sex	Puncture at a non-compressible location (to high or below bifurcation)
Severe PAD	Puncture without ultrasound guidance
Smoking	Post-procedural hypertension
Diabetes mellitus	Uncorrected coagulopathy or severe thrombocytopenia
Hypertension	Intravenous glycoprotein IIb/IIIa receptor antagonists

In addition, the nature of and the rate of vascular site complications varies depending on the type of device. ***Table 5*** summarizes the rate of most common vascular site complications according to the implanted type of mechanical circulatory device.

Table 5 - Most common vascular site complications according to the type of mechanical + rare, ++ often, +++ very often.

Devices	IABP	VA-ECLS	Impella®	Tandem Heart
Access site bleeding or vascular injury requiring surgery	+	++	+	++
Limb ischemia	+	+++	++	+++
Access site infection	+	++		++