Prevention and Management of Acute Limb Ischemia when Using Temporary Mechanical Circulatory Support Devices

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KEYWORDS

• Acute limb ischemia • Cardiogenic shock • Distal perfusion catheter • Femoral artery • Temporary mechanical circulatory support • Percutaneous coronary intervention

KEY POINTS

- Acute limb ischemia is an important complication of all temporary mechanical circulatory support devices.
- Device-related acute limb ischemia is principally caused by obstruction of antegrade flow to the distal limb due to a large caliber cannula or vascular sheath.
- Device-related acute limb ischemia occurs more frequently in women, in patients with peripheral artery disease, during acute myocardial infarction–related cardiogenic shock, and with veno-arterial extracorporeal membrane oxygenation use.
- Several limb perfusion strategies may be used to prevent and treat device-related acute limb ischemia.

INTRODUCTION

Temporary mechanical circulatory support (t-MCS) devices are increasingly integral in cardiovascular medicine, providing hemodynamic support for patients at high risk of hemodynamic collapse during cardiovascular procedures and in patients with cardiogenic shock (CS) due to acute myocardial infarction (AMI-CS) or heart failure (HF-CS). In recent years, there have been important advances in device miniaturization, operator proficiency, and safety of large-bore vascular access, and several t-MCS devices are now widely available for percutaneous insertion into the vasculature. t-MCS devices are no longer exclusively deployed by cardiac surgeons and interventional cardiologists, and other clinicians, including intensivists, emergency physicians, and heart failure cardiologists, have become facile with t-MCS device insertion.

With increasing device use, however, there is a growing recognition of the many potential complications of t-MCS. Acute limb ischemia (ALI) is a well-established complication of all percutaneous transfemoral t-MCS devices resulting from the abrupt reduction of blood flow into the limb, which if left unresolved may jeopardize the viability of the limb and ultimately necessitate amputation.[1] Clinical studies have demonstrated that ALI independently increases overall

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Abbreviations	
ALI	acute limb ischemia
AMI-CS	acute myocardial infarction–related cardiogenic shock
CFA	common femoral artery
CS	cardiogenic shock
DPC	distal perfusion catheter
ECPR	extracorporeal cardiopulmonary resuscitation
Fr	French
HF-CS	heart failure–related cardiogenic shock
IABP	intra-aortic balloon pump
PAD	peripheral artery disease
PCI	percutaneous coronary intervention
SCAI	Society of Cardiovascular Angiography and Intervention
SFA	superficial femoral artery
t-MCS	temporary mechanical circulatory support
VA-ECMO	venoarterial extracorporeal membrane oxygenation

in-hospital mortality when it develops in patients with CS and unsurprisingly leads to greater morbidity, hospital length of stay, and hospitalization costs in patients who survive this complication.[2–4] Thus, it is critical to understand the risk of ALI in patients planned for t-MCS support and to quickly identify and treat ALI when it occurs. As clinical experience with t-MCS has grown, there is an expanding understanding of strategies to help avoid and manage device-related ALI. We review the mechanisms, risk factors, and incidence of ALI due to t-MCS and discuss prevention and management of ALI when using t-MCS.

ANATOMIC CONSIDERATIONS AND VASCULAR ACCESS FOR MECHANICAL CIRCULATORY SUPPORT DEVICES

The typical diameter of the healthy common femoral artery (CFA) in adults ranges from 5 to 8 mm, which is equivalent to a vascular sheath size of 15 to 24 French (Fr).[5–7] There is slight tapering of the CFA as it bifurcates into the superficial femoral artery (SFA) and profunda femoris artery such that the average diameter of the SFA is 1 to 2 mm smaller than the diameter of the CFA. The caliber of the femoral arteries is affected by several factors, including patient body surface area and sex.[8,9] On average, women have smaller femoral arteries compared to men after adjusting for height, weight, and atherosclerotic disease.[8,10] Atherosclerosis can further contribute to arterial stenosis and a reduction in the luminal cross-sectional area.[6] Additionally, the caliber of the femoral arteries is dynamic and may be reduced by compensatory vasoconstriction in patients with CS or by the administration of vasopressors as part of supportive care in shock states.[11,12]

Several percutaneously deployed t-MCS devices are currently available for left ventricular (LV) hemodynamic support, including the intra-aortic balloon pump (IABP), the Impella CP transvalvular flow pump (Abiomed Inc, Danvers, MA/Johnson and Johnson MedTech, New Brunswick, NJ), peripheral venoarterial extracorporeal membrane oxygenation (VA-ECMO) cannulation, and the TandemHeart transeptal cannula (LivaNova, London, UK) for left atrial-to-femoral extracorporeal bypass (Table 1). While operating through distinct mechanisms to provide hemodynamic support, each device requires large-bore arterial access, most commonly via the CFA. The IABP and Impella CP are deployed via in situ vascular sheaths that provide stable arterial access (sheath-less IABP deployment is possible but is infrequently performed in current clinical practice). IABP sheath size ranges between 7.5 and 8.5 Fr depending on the manufacturer and balloon volume. The Impella CP is inserted through a 14-Fr peel-away introducer sheath that is removed after device placement, leaving a graduated 9-to-15-Fr repositioning sheath that allows for advancement or retraction of the device. Alternatively, the IABP and Impella CP may be inserted percutaneously into the axillary artery. The TandemHeart and VA-ECMO platforms establish extracorporeal blood flow by draining blood from the body using an inflow or drainage cannula placed in the common femoral vein and returning to the body via an outflow or return cannula placed in the CFA. Arterial outflow cannula sizes range from 15 to 25 Fr. Peripheral VA-ECMO cannulation is most commonly performed via percutaneous access of the femoral vessels. Alternatively, hybrid peripheral VA-ECMO configurations may be used by inserting the inflow cannula in the jugular vein percutaneously and the outflow cannula in the subclavian artery via surgical cutdown.

Table 1
Temporary mechanical circulatory support device characteristics

Device	IABP	Impella CP	VA-ECMO
Access Site	Femoral Axillary (not designed for this orientation)	Femoral Axillary	Femoral (percutaneous implantation or surgical cutdown) Subclavian (surgical cutdown)
Vascular Sheath or Cannula Size (Fr)	7.5–8.5 (introducer sheath typically used but not required)	Peel-away introducer sheath: 14 Repositioning sheath: graduated 9–15	15–25 (for adults)
Incidence of Lower Limb ALI	Observational data: ~2.5%-10% Randomized trials: <5%	Observational data: ~8%-15% when used for CS; <5% when used for high-risk PCI Randomized trials: ~5% when used for CS	Observational data: ~10%-20% Randomized trials: ~10%-13% when used for CS; incidence not well defined when used for ECPR

ACUTE LIMB ISCHEMIA DURING MECHANICAL CIRCULATORY SUPPORT DEVICE USE: MECHANISMS, PRESENTATION, AND RISK FACTORS

Device-related ALI is clinically distinct, differing from traditional ALI which occurs outside the context of t-MCS use and CS. Traditional ALI may arise due to several etiologies, including arterial occlusion due to in situ thrombus formation resulting from atherosclerotic plaque rupture or due to an embolus, dissection of the arterial wall, and traumatic injury. In contrast, device-related ALI primarily results from the obstruction of antegrade flow into the distal limb by the large-caliber arterial VA-ECMO cannula or vascular sheath of the IABP or Impella, but other factors often further limit distal limb blood flow.[13,14] The arterial access procedure may cause dissection or atherosclerotic plaque disruption and thrombosis, leading to an additional acute decrease in the cross-sectional luminal area. Flow limitation may also occur due to significant unruptured atherosclerotic plaques, vasoconstriction due to circulating catecholamines released during the shock state or due to the administration of vasopressors, or thrombosis secondary to coagulopathy observed during critical illness or due to activation of clotting factors by the foreign material. Finally, with VA-ECMO, the placement of the venous drainage cannula in the ipsilateral limb may lead to venous thrombosis, reducing venous flow and in turn increasing compartment pressures.

There is no standardized and universally accepted definition for ALI that develops in the setting of t-MCS use. Patients with traditional ALI present with varying symptoms depending on the duration of ischemia, classically described by the *6 Ps* of pain, pulselessness, pallor, poikilothermia, paresthesia, and paralysis. The diagnosis of ALI can be confirmed by vascular imaging with duplex ultrasound, computed tomographic angiography, or magnetic resonance angiography. In contrast, the diagnosis of device-related ALI is more challenging as patients are often unable to report new symptoms due to critical illness and as the presence of t-MCS limits nonultrasound-based imaging modalities. Distal limb hypoperfusion due to a t-MCS device may be first identified at the bedside in the cardiac catheterization laboratory or intensive care unit. The absence of a palpable pulse or Doppler signal should trigger immediate further evaluation and consideration of potential intervention. Near-infrared spectroscopy can be used to monitor tissue oxygenation in the lower extremities, with significant interlimb asymmetry raising concern for distal limb hypoperfusion.[15,16]

Although any t-MCS device requiring arterial access carries a risk of ALI, several factors highly influence the likelihood of device-related ALI arising. Device selection, cannula or sheath size, the clinical setting of device use, and several patient-specific characteristics all impact the patient's risk of developing ALI (**Table 2**). Early observational studies identified peripheral artery disease (PAD), CS, smoking history, and female sex as important risk factors for IABP-related ALI.[17–21] In a retrospective observational study of more than 7000 patients with CS

Table 2
Risk factors for acute limb ischemia during temporary mechanical circulatory support device use

Patient-specific	Women History of PAD
Clinical Context	Out-of-hospital cardiac arrest AMI-CS > HF-CS CS > high-risk PCI SCAI Stage E > SCAI Stage D > SCAI Stage C
Device-specific	VA-ECMO + IABP/Impella CP > VA-ECMO > Impella CP > IABP

between 2016 and 2023 from the Cardiogenic Shock Working Group, a large, contemporary, multicenter registry of patients with CS, ALI occurred more frequently in women, patients with a history of PAD, and patients who presented after out-of-hospital cardiac arrest.[4] ALI was more common in AMI-CS than in HF-CS (9.0% vs 3.4%) and in the more severe stages of CS (10.3% in Society of Cardiovascular Angiography and Intervention [SCAI] Stage E CS vs 4.1% in Stage D vs 1.8% in Stage C). Finally, ALI occurred more frequently with the use of larger caliber and multiple t-MCS devices: ALI developed in 3.9% of patients supported by IABP, 8.5% of patients supported by Impella, 11.5% of patients supported by VA-ECMO, and 16.6% of patients supported by VA-ECMO coupled with IABP or Impella for LV mechanical venting. These findings are consistent with other large registries that similarly identified female sex, PAD, and larger caliber t-MCS as risk factors for ALI.[2,4] Unsurprisingly, when ALI develops, there is a greater need for operative or interventional treatment including arterial bypass surgery, angioplasty, thrombectomy, endarterectomy, and amputation.[3]

ACUTE LIMB ISCHEMIA DURING MECHANICAL CIRCULATORY SUPPORT DEVICE USE: INCIDENCE IN REAL WORLD DATA AND RANDOMIZED TRIALS

Acute Limb Ischemia due to Venoarterial Extracorporeal Membrane Oxygenation

Multiple observational studies have evaluated rates of ALI with VA-ECMO. In analyses using data from large registries and in systematic reviews and meta-analyses, ALI occurs in approximately 10% to 20% of patients with VA-ECMO.[2,4,22,23] Additionally, ALI from VA-ECMO occurs more frequently during AMI-CS than during HF-CS.[4] Several randomized trials have investigated the use of VA-ECMO in patients with CS and in patients with refractory cardiac arrest (ie, for extracorporeal cardiopulmonary resuscitation [ECPR]). The Extracorporeal Life Support in Cardiogenic Shock (ECLS-SHOCK) randomized 420 patients with AMI-CS to immediate revascularization with or without peripheral VA-ECMO cannulation, finding no clinical benefit.[24] The insertion of an additional catheter for limb perfusion was strongly encouraged but not mandated in ECLS-SHOCK. Peripheral vascular complications warranting interventional or surgical therapy occurred in 11.0% of patients in the VA-ECMO arm while in only 3.8% of patients in the usual care arm (relative risk 2.86, 95% confidence interval 1.31–6.25). In the ECMO-CS (ExtraCorporeal Membrane Oxygenation in the Therapy of Cardiogenic Shock) trial, a smaller randomized trial of VA-ECMO for CS, 122 patients with rapidly deteriorating or severe CS were randomized to immediate peripheral VA-ECMO cannulation or usual care.[25] ALI occurred more frequently in the VA-ECMO arm compared with usual care (13.8% vs 5.1%, risk difference 8.7, 95% confidence interval −1.8–19.2). Comparatively, randomized trials of ECPR also examined ALI events, but arguably with less rigor. In the Early Initiation of Extracorporeal Life Support in Refractory Out-of-Hospital Cardiac Arrest Trial, 4 out of 70 patients with refractory cardiac arrest randomized to ECPR had ALI while none of the 64 patients receiving conventional cardiopulmonary resuscitation had ALI.[26] Other randomized trials of ECPR, including Advanced Reperfusion Strategies for Refractory Cardiac Arrest, Effects of Induced Moderate HYPOthermia on Mortality in Cardiogenic Shock Patients Rescued by Venoarterial ExtraCorporeal Membrane Oxygenation, and Hyperinvasive Approach in Cardiac Arrest Trial, did not specifically report ALI risk with VA-ECMO in this setting.[27–29]

Intra-aortic Balloon Pump–Related Acute Limb Ischemia

With over 5 decades of clinical experience with IABP, many reports have described the frequency of ALI complicating IABP use in patients with CS or in patients awaiting cardiac surgery. Large single-center retrospective and prospective analyses published before the year 2000 reported highly variable frequencies of IABP-related ALI ranging from approximately 3% to greater than 25%; these reports additionally described severe cases of ALI

requiring IABP explant, vascular thrombectomy, femoral–femoral bypass grafting, fasciotomy for compartment syndrome, and lower-extremity amputation.[17–21,30–35] However, the early era of IABP use differs significantly from contemporary practice: previously, cardiac surgeons were typically the operators implanting IABP, IABP implantation frequently occurred through a surgical approach that used a surgical graft anastomosed to the femoral artery, and introducer sheaths were often ≥9 Fr.[36] More contemporary observational studies of IABP in the setting of CS or the perioperative setting have demonstrated variable but generally lower rates of IABP-related ALI ranging from approximately 2.5% to 10%.[37–40] Additionally, systematic reviews and meta-analyses have demonstrated a lower risk of ALI with IABP compared to with Impella.[41,42]

Randomized trials evaluating the IABP across various clinical settings have reported vascular safety outcomes, consistently demonstrating that IABP-related ALI occurs relatively infrequently. The Intraaortic Balloon Pump in Cardiogenic Shock II trial, which randomized 600 patients presenting with AMI-CS to care with or without IABP, demonstrated no difference in the rate of ALI requiring intervention between the 2 treatment arms (4.3% in the IABP group vs 3.4% in the no IABP group).[43] The Counterpulsation to Reduce Infarct Size Pre-PCI Acute Myocardial Infarction trial randomized 337 patients with anterior ST-segment myocardial infarction but without CS to IABP or no IABP before PCI and found no events of major ALI requiring operative intervention or distal embolization in either treatment arm.[44] In the Balloon Pump–Assisted Coronary Intervention Study, 301 patients with severe LV dysfunction and extensive coronary artery disease were randomized to elective insertion of IABP before PCI versus PCI alone. The composite safety outcome of access site complications occurred in 3.3% of patients in the IABP group but in none in the usual care arm, but notably, the BCIS-1 trial did not specifically report the rates of ALI requiring surgical or percutaneous intervention.[45] Most recently, in the Altshock-2 (Study on Early Intra-aortic Balloon Pump Placement in Acute Decompensated Heart Failure Complicated by Cardiogenic Shock) trial, which randomized 101 patients with SCAI stage B, C, or D HF-CS to early insertion of IABP versus care with vasoactive agents only, ALI occurred in 2 of 53 patients supported by IABP and in none of the 48 patients randomized to usual care.[46] Thus, the incidence of ALI in randomized trials of IABP is less than 5%, which is comparatively lower than that observed in more contemporary real-world observational datasets.

Acute Limb Ischemia due to the Impella Devices

Clinical experience with the transfemoral Impella devices now spans approximately 20 years. Observational studies have reported variable but noteworthy rates in ALI associated with the currently available Impella CP device or the discontinued Impella 2.5 device, which was the first iteration of Impella for percutaneous LV support with a slightly smaller pump motor and introducer sheath compared to those of the Impella CP. While some observational studies have reported a <5% rate of Impella-related ALI in patients with CS,[47,48] the rate of Impella-related ALI was approximately 10% to 13% in several analyses of a moderate size, which primarily included patients with AMI-CS but also those with HF-CS and postcardiotomy shock.[49–51] In contrast, observational studies have suggested the risk of Impella-related ALI during percutaneous coronary intervention (PCI) to be less than 5%.[50,52] Predictably, the risk of ALI is influenced by the clinical context and duration of device therapy. When used for hemodynamic support during CS, device support typically extends for several days compared to high-risk PCI, where the device instead remains in place often for the duration of the procedure only.

Early randomized trials of percutaneous Impella in CS were small and reported few cases of device-related ALI or major vascular complications.[53,54] Most recently, the landmark DanGer Shock (Danish-German Cardiogenic Shock) trial randomized 360 patients with ST-segment elevation myocardial infarction and CS and found that treatment with Impella CP compared to standard of care alone without Impella CP reduced mortality at 6 months but led to more adverse events, including ALI.[55] In the 179 patients randomized to Impella CP support, ALI occurred in 5.6% compared to 1.1% in the standard of care arm (relative risk 5.15, 95% confidence interval 1.11–23.84). Impella use during high-risk PCI was explored in the A Prospective, Multi-center, Randomized Controlled Trial of the IMPELLA RECOVER LP 2.5 System vs Intra Aortic Balloon Pump in Patients Undergoing Non Emergent High Risk PCI (PROTECT II) trial, which randomized patients undergoing high-risk PCI to IABP or Impella 2.5.[56] Notably, PROTECT II did not specifically report rates of ALI, but there were no differences in the need of vascular operations between the treatment arms. Collectively, these observational and randomized data

indicate that ALI is a clinically significant complication of percutaneous transfemoral access for Impella use and that Impella-related ALI occurs more frequently in the setting of CS.

BEST PRACTICES FOR PREVENTION ACUTE LIMB ISCHEMIA DURING MECHANICAL CIRCULATORY SUPPORT DEVICE USE

A review of the patient's medical history and focused physical examination of the lower extremities should be conducted before proceeding with insertion of any transfemoral t-MCS device. A history of traditional atherosclerotic disease risk factors (especially diabetes mellitus and tobacco use), amputation, ulcerative wounds, percutaneous or surgical lower extremity revascularization, or abnormal noninvasive vascular studies identifies patients with potential or established PAD, may guide vascular access site selection, and may occasionally impact device choice. Indeed, the major randomized trials of t-MCS devices have all excluded patients with severe obstructive PAD precluding safe percutaneous device or cannula insertion. Physical examination should note the general appearance, color, warmth, function of the lower extremity, and the presence (or absence) and location of the posterior tibialis and dorsalis pedis pulses, either by palpation or Doppler ultrasound. Importantly, in patients with CS, clinical findings of ALI may be apparent before t-MCS insertion. In addition to a focused history and examination, several intraprocedural practices performed at the time of transfemoral t-MCS insertion likely help reduce the risk of limb ischemia and other vascular complications. Robust clinical trial data have demonstrated that ultrasound guidance for vascular access, identification of landmarks by fluoroscopy, use of the micropuncture technique, and iliofemoral angiography help to reduce the number of access attempts, time to access, and vascular complications, particularly access site bleeding.[57–62] These best practices are now recommended by multiple societal guidelines and collectively help to ensure successful and safe vascular access for the insertion of t-MCS devices (Table 3).[63–65]

PREVENTING AND MANAGING ACUTE LIMB ISCHEMIA DURING VENOARTERIAL EXTRACORPOREAL MEMBRANE OXYGENATION USE

To mitigate the risk of ALI during peripheral VA-ECMO use, the operator should select the smallest arterial return cannula acceptable for the patient's size and hemodynamic needs. Typically, a 17-Fr arterial return cannula is sufficient for most patients of average height, although a cannula measuring 19 Fr or greater may be needed in clinical scenarios when higher flows are necessary. A 15-Fr arterial return cannula may be appropriate in patients of shorter stature, particularly small women. While there may be concern that selection of a smaller arterial return cannula would provide insufficient flows, a mock circulatory loop study showed that a 15-Fr arterial return cannula could reach a target flow of greater than 3.5 L per minute and mean pressure of greater than 70 mm Hg.[66] Additionally, 2 large single-center retrospective analyses have demonstrated that while a larger cannula expectedly provides greater flow, patients on VA-ECMO with an arterial return cannula of 15 Fr or smaller had similar clinical outcomes compared to patients managed with a larger arterial return cannula.[67,68] Retrospective studies and a systematic review and meta-analysis have also shown that selection of an arterial return cannula smaller than 17 Fr reduces the risk of ALI.[68–70] Another strategy to mitigate the risk of ALI during VA-ECMO is the insertion of a distal perfusion catheter (DPC), also referred to as an antegrade perfusion catheter, into the SFA of the at-risk limb. With this approach, the extracorporeal circuit is leveraged to perfuse the at-risk limb by diverting some blood from the arterial return cannula to tubing connected to the side port of the DPC (Fig. 1). The DPC is typically inserted percutaneously in antegrade fashion into the SFA for limb perfusion but may alternatively be placed in the posterior tibial artery in retrograde fashion if SFA access is impossible or unsafe. DPC sizing is generally 5 to 7 Fr, and it is best to use a braided vascular sheath, as the braided structure facilitates insertion into tortuous vessels and helps resist kinking or collapse of the sheath. Many moderate-to-large size retrospective studies have investigated outcomes with the inclusion of a DPC during VA-ECMO use. Several studies demonstrated a reduced risk of ALI during VA-ECMO with a DPC when placed prophylactically (ie, at the time of peripheral VA-ECMO cannulation),[71–74] a finding which has been confirmed by systematic reviews and meta-analyses.[70,75] However, no randomized trial has studied the prophylactic placement of a DPC at the time of peripheral VA-ECMO cannulation, and some operators have argued for a selective approach to DPC utilization if strict protocols monitoring for limb hypoperfusion are used.[76,77] The International Society for Heart and Lung Transplantation and Heart Failure Society of

Table 3
Best practices for mitigating the risk of acute limb ischemia

Vascular Access	Fluoroscopy to identify anatomic landmarks Ultrasound and micropuncture technique for arterial entry Iliofemoral angiography to assess access location and to characterize severity of any PAD
Device Use	Explant IABP, Impella, and VA-ECMO cannulas as soon as clinically possible Insert the smallest arterial cannula appropriate for the patient's size and support needs during VA-ECMO Insert a DPC in most if not all patients on VA-ECMO
Clinical Monitoring	Identify and mark posterior tibialis and dorsalis pedis pulses before device insertion Regular pulse checks by palpation or Doppler ultrasound during device use Consider monitoring for reduced tissue oxygenation in the limbs using NIRS

Abbreviation: NIRS, near infrared spectroscopy.

America Guideline on Acute Mechanical Circulatory Support provides a class II recommendation for the consideration of DPC use, and the Extracorporeal Life Support Organization Interim Guidelines for Venoarterial Extracorporeal Membrane Oxygenation in Adult Cardiac Patients recommends the use of a DPC during VA-ECMO support.[15,78]

PREVENTING AND MANAGING ACUTE LIMB ISCHEMIA DURING INTRA-AORTIC BALLOON PUMP AND IMPELLA USE

Explant of the IABP or Impella should occur as soon as the device is no longer clinically necessary to avoid causing ALI as well as other complications. However, management of ALI due to IABP or Impella becomes challenging when the patient remains clinically dependent on device support. While VA-ECMO provides an extracorporeal circuit that delivers pressurized blood flow through a DPC to the cannulated lower extremity that may thereby reduce the risk of ALI, there exists no commercially available extracorporeal mechanical pump system to provide limb perfusion for the prevention or treatment ALI resulting from transfemoral IABP or Impella use.

Multiple case reports and one case series have described the creation of an extracorporeal circuit connected to a DPC placed in the SFA of the ischemic limb to allow for passive bypass beyond the occlusive Impella sheath. With an autotransfusion or a crossover bypass approach, a DPC is placed the SFA of the ipsilateral ischemic limb, a sheath is placed in the contralateral CFA, and the side ports of the 2 sheaths are connected via a male-to-male adaptor, establishing blood flow into the ischemic limb from the contralateral *donor* limb (Fig. 2).[79–81] These case reports demonstrate that this intervention can successfully treat and mitigate complications from Impella-related ALI. One report has described the use of the radial artery as an alternative donor vessel for bypass of an ischemic limb.[82] This strategy provides a temporary, percutaneous

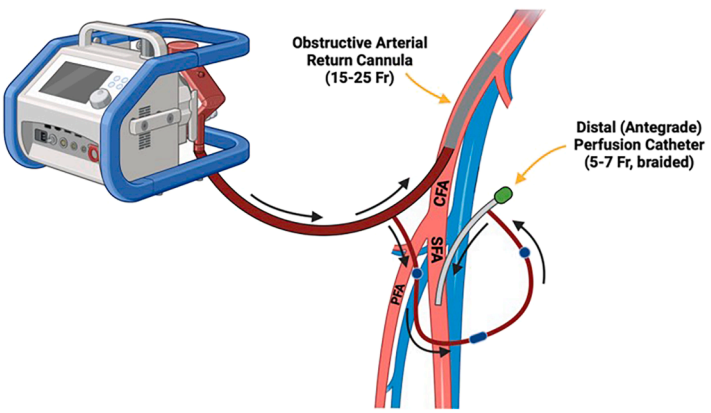

Fig. 1. DPC for VA-ECMO pressurized blood flow from the VA-ECMO circuit can be diverted from the arterial return cannula to tubing connected to a DPC (*black arrows* indicate direction of blood flow). (*Created in* BioRender. Natov, P. (2025) https://BioRender.com/y8tglp9.)

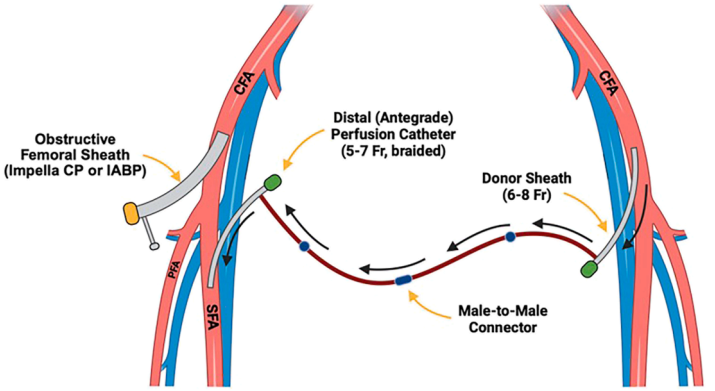

Fig. 2. Contralateral passive bypass. The contralateral common femoral artery may be used as a donor vessel to provide blood flow to the ischemic limb in a strategy known as contralateral passive bypass, crossover bypass, or autotransfusion. A donor sheath is placed in the common femoral artery in the limb contralateral to the ischemic limb. The donor sheath is connected to a DPC placed in the SFA in the ischemic limb (*black arrows* indicate direction of blood flow). With this strategy, blood flow is dependent on the native systemic arterial pressure and cardiac output. (*Created in* BioRender. Natov, P. (2025) https://BioRender.com/r57odo4.)

solution to Impella-related ALI and is analogous to surgical femoral–femoral bypass, which uses a surgical graft to connect the contralateral CFA to the distal CFA or SFA of the ischemic limb and which has been described in multiple reports during early clinical use of IABP for management of IABP-related ALI.[83,84] A percutaneous crossover bypass strategy has also been used for treatment of IABP-related ALI.[85] Additional reports have described the prophylactic use of a crossover bypass strategy to prevent ALI from Impella use in patients deemed to be at high risk for ALI due to small caliber arteries and significant PAD.[86,87] Alternatively, the DPC may be connected to the side port of the occlusive repositioning sheath via a male-to-male adaptor, creating an ipsilateral bypass circuit to establish flow in the SFA (Fig. 3).[88] However, no clinical trials have investigated outcomes of a contralateral or ipsilateral bypass strategy to treat Impella-related ALI or its efficacy as a prophylactic measure. Additionally, these extracorporeal circuits are dependent on native cardiac output and systemic arterial pressure, which may be significantly compromised in the context of CS, and there is very limited understanding about the degree of increase in blood pressure and flow in the ischemic limb resulting from this nonsurgical bypass intervention. As such, the decision to create an extracorporeal bypass circuit is currently made on a case-by-case basis and based on operator experience. Finally, as amputation is a rare but reported complication of severe ALI complicated Impella use,[89] vascular surgery consultation is advised for any case of very severe Impella- or IABP-related ALI in which there is a potential need for vascular intervention or amputation.

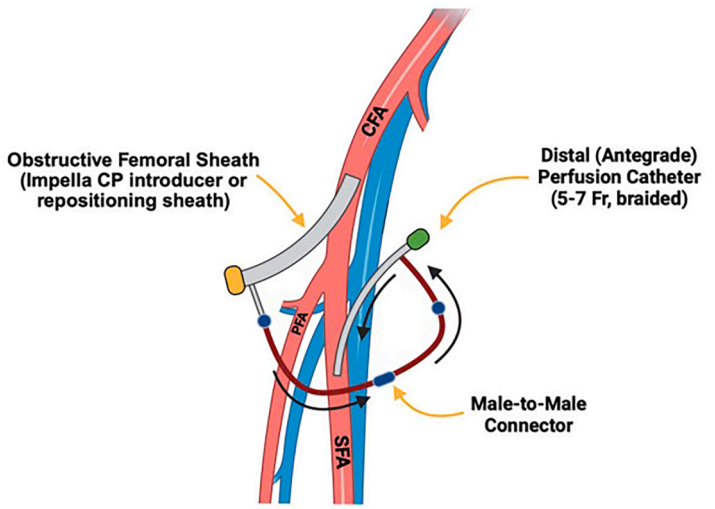

Fig. 3. Ipsilateral passive bypass blood flow into the obstructive femoral sheath may be diverted to a DPC in the ipsilateral SFA (*black arrows* indicate direction of blood flow). (*Created in* BioRender. Natov, P. (2025) https://BioRender.com/iw5kep6.)

ALTERNATIVE ACCESS: AXILLARY ARTERY

Compared to the femoral arteries, the axillary artery is on average slightly smaller in caliber, with a diameter measuring approximately 5 to 7 mm, but is less frequently affected by severe atherosclerotic disease and calcification.[90] While surgical cutdown is needed for insertion of the arterial return cannula into the subclavian or axillary artery to create a VA-ECMO circuit, percutaneous access of the axillary artery is feasible and safe for IABP or Impella CP insertion.[91–94] While axillary access is an accepted alternative for Impella CP insertion, no current IABP model is specifically designed to be deployed in this orientation. In a prospective multicenter observational study of 102 patients with an axillary Impella (primarily Impella CP), only 1 patient suffered upper-extremity ALI requiring intervention.[95] In a larger retrospective observational study of 167 patients supported by an axillary Impella, a similarly low rate of upper-extremity ALI was observed, occurring in less than 1% of patients, while approximately 5% of patients with transfemoral Impella had ALI.[96] As such, the axillary artery has emerged as a practical and safe alternative to the CFA for large-bore arterial access when a transfemoral approach is unsafe or impossible due to prior surgical intervention or severe iliofemoral or aortoiliac PAD or tortuosity.[97] This approach is advantageous as it permits patient ambulation. The best practices for CFA access, including ultrasound, micropuncture technique, and angiography, are also recommended for axillary access.[97] In rare cases of upper-extremity hypoperfusion due to a large-bore sheath, a DPC may be inserted into the brachial artery or radial artery and connected to the side port of the occlusive sheath for ipsilateral passive bypass.[88]

SUMMARY

ALI is a serious complication associated with all t-MCS devices, threatening limb viability and serving as an independent predictor of mortality in patients with CS. The risk of device-related ALI is influenced by several patient-specific, clinical, and device characteristics. A range of best practices and limb perfusion strategies can be used to prevent and manage t-MCS device related ALI.

CLINICS CARE POINTS

- Perform a Risk Assessment: Prior to device insertion, clinicians should perform a focused history and physical examination to identify high-risk patients, including women, patients with peripheral artery disease, and patients in severe cardiogenic shock.
- Utilize Best Practices for Safe Vascular Access: Employ ultrasound guidance, fluoroscopy for landmark identification, the micropuncture technique, and iliofemoral angiography to reduce access-related vascular complications.
- Optimize Cannula Sizing for VA-ECMO: Select the smallest arterial return cannula (ideally <17-Fr) that meets the patient's hemodynamic needs to reduce the risk of distal flow obstruction.
- Implement Prophylactic Distal Perfusion: When using VA-ECMO, placement of a DPC should be strongly considered at the time of cannulation to divert blood flow to the distal limb and prevent ischemia.
- Monitor Tissue Oxygenation: In addition to regular pulse and Doppler checks, consider using near-infrared spectroscopy to monitor tissue oxygen saturation, as significant inter-limb asymmetry can be an early indicator of hypoperfusion, particularly for patients supported by VA-ECMO.
- Consider Alternative Access: The axillary artery is a viable alternative to femoral access in some clinical scenarios, particularly in patients with severe iliofemoral PAD or tortuosity, and carries a lower risk of ALI while allowing for patient ambulation.

DISCLOSURE

N.K. Kapur is an employee of Johnson & Johnson MedTech: Heart Recovery.

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